



Application General

Product Name: High DHA Kids Capsules
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 17/05/2019 08:51:49 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$820.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

S47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made Report:

Formulation

Dosage Form: Capsule, soft
Routes of Administration:
... Oral
Container Type:
Container Volume:
Container Closure:
Container Condition:

Maximum Single Dose:
Maximum Daily Dose: 2
Minimum Weight of Divided Dosage Form s47
(tablets, capsules, metered dose sprays etc.):

Ingredients

- ... Active - concentrated fish Omega-3 triglycerides
- ... Equivalent - docosahexaenoic acid
- ... Equivalent - eicosapentaenoic acid
- ... Active - potassium iodide
- ... Equivalent - potassium
- ... Equivalent - iodine
- ... Active - mixed (low-alpha type) tocopherols concentrate
- ... s47
- ... Excipient - purified water
- ... Excipient - Orange Oil
- ... Equivalent - Oxedrine
- ... Excipient - Rice bran oil
- ... Excipient - maltodextrin
- ... Excipient - vegetable oil
- ... Excipient - glycerol
- ... Excipient - Gelatin
- ... Excipient - Stevia rebaudiana

Manufacturers

s47

Indications

- Permitted Indications:
- ... Maintain/support nervous system function
 - ... Maintain/support healthy growth and development
 - ... Maintain/support brain health
 - ... Maintain/support brain/central nervous system development

-  ... Maintain/support general health and wellbeing
-  ... Helps maintain/support healthy eye development
-  ... Helps maintain/support eye retina health
-  ... Maintain/support cognitive function/mental function
-  ... Maintain/support brain function
-  ... Maintain/support nervous system health

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
-  ... Derived from seafood.

Indication Requirements:

-  ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
-  ... Product presentation must not imply or refer to neurological conditions or developmental delays.
-  ... Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:	110450_69187
Last Editor:	110450_69187



Application General

Product Name: Calcium + Vitamin D3 & K2 Kids Capsules
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 16/05/2019 11:02:01 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$820.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Pass with conditions: When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). (Ingredient(s) concerned: 'titanium dioxide')

Permitted for excipient use as a colour in oral medicines and as a colour in topical medicines for dermal application. (Ingredient(s) concerned: 'titanium dioxide')

Changes Made Report:

Formulation

Dosage Form: Capsule, soft

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

6

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

s47

Ingredients

 ... Active - menaquinone 7

 ... Active - colexcalciferol s47

 ... Active - calcium phosphate

 ... Equivalent - calcium

 ... s47

 ... s47

 ... Excipient - Stevia rebaudiana

 ... Excipient - maltodextrin

 ... Excipient - purified water

 ... Excipient - titanium dioxide

 ... Excipient - Rice bran oil

 ... Excipient - Gelatin

- ... Excipient - medium chain triglycerides
- ... Excipient - glycerol

Manufacturers

s47

Indications

Permitted Indications:

- ... Maintain/support muscle function
- ... Maintain/support healthy growth and development
- ... Aids/assists healthy bone development/growth/building
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- ... Maintain/support bone health
- ... Maintain/support immune system health
- ... Help maintain/support bone mineralisation
- ... Maintain/support teeth mineralisation
- ... Maintain/support bone strength
- ... Maintain/support healthy teeth
- ... Maintain/support teeth strength
- ... Maintain/support general health and wellbeing
- ... Maintain/support healthy immune system function
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
- ... Maintain/support healthy neuromuscular system/function

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a
- ... Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
- ... Product presentation must not imply or refer to serious immunological diseases.
- ... Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:	110450_69187
Last Editor:	110450_69187



Application General

Product Name: Fibre & Prebiotic Kids Liquid
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Contact Person: s22
Contact Telephone:
Contact Email: s22 @evolutionhealth.com.au

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 17/05/2019 03:26:38 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$820.00

Description of changes:
9D(1) correction: No

Validation Report:

Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Changes Made Report:**Formulation****Dosage Form:** Oral Liquid**Routes of Administration:**☐ ... Oral**Container Type:****Container Volume:****Container Closure:****Container Condition:****Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):****Ingredients**☐ ... Active - fructooligosaccharides☐ ... Active - inulin☐ ... s47☐ ... Excipient - purified water☐ ... Excipient - potassium sorbate☐ ... Excipient - malic acid☐ ... Excipient - xanthan gum**Manufacturers**

s47

Indications**Permitted Indications:**☐ ... Maintain/support bowel regularity☐ ... Maintain/support bowel regularity by increasing stool bulk**Standard Indications:****Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**☐ ... (If the medicine contains one sorbate) Contains [insert name of sorbate] OR (if medicine contains two or more sorbates) Contains sorbates [or words to that effect].**Indication Requirements:**☐ ... Label statement for stimulant laxatives: Prolonged use may cause serious bowel problems.☐ ... Label statement: Do not use when abdominal pain, nausea or vomiting are present or if you develop diarrhoea. If you are pregnant or breastfeeding - seek the advice of a healthcare professional before☐ ... Label statement: Drink plenty of water (or words to that effect).☐ ... Product presentation must not refer to or imply weight loss.**Supporting Documents**

Electronic Documents

TRIM Reference:
TRIM Details:

Audit Trail

Created By:	110450_69187
Last Editor:	110450_69187



Application General

Product Name: Multivitamin + Iron Kids Powder
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 23/05/2019 09:52:45 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$820.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose.

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'folic acid')

Ingredient Restriction Rule - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'ferrous fumarate')

Pass with conditions - In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). (Ingredient(s) concerned: 'Iron')

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statement on the medicine label if supplied after 1 April 2019: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'Iron')

Pass with conditions - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statement on the medicine label: -(IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect) (Ingredient(s) concerned: 'Iron')

When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Riboflavin sodium phosphate')

Changes Made Report:

Formulation

Dosage Form: Powder

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

s47

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

-  ... Active - pyridoxine hydrochloride s47
-  ... Active - magnesium phosphate tribasic
-  ... Equivalent - magnesium
-  ... Active - Malpighia glabra
-  ... Active - Biotin
-  ... Active - ferrous fumarate
-  ... Equivalent - iron
-  ... Active - potassium iodide
-  ... Equivalent - iodine
-  ... Active - nicotinamide s47
-  ... Active - zinc citrate dihydrate
-  ... Equivalent - zinc
-  ... Active - menaquinone 7
-  ... Active - Beta vulgaris
-  ... Active - riboflavin sodium phosphate
-  ... Equivalent - riboflavin
-  ... Active - lysine hydrochloride
-  ... Equivalent - lysine

- ... Active - colecalciferol s47
- ... Active - folic acid
- ... Active - calcium phosphate
- ... Equivalent - calcium
- ... Active - thiamine nitrate s47
- ... Active - retinol palmitate
- ... Equivalent - vitamin A
- ... Active - calcium ascorbate dihydrate
- ... Equivalent - ascorbic acid
- ... Active - calcium pantothenate
- ... Equivalent - pantothenic acid
- ... Active - cyanocobalamin
- ... s47
- ...
- ...
- ...
- ...
- ...
- ...
- ... Excipient - polydextrose
- ... Excipient - maltodextrin
- ... Excipient - sucrose
- ... Excipient - dextrin
- ... Excipient - butylated hydroxytoluene
- ... Excipient - thaumatin
- ... Excipient - malic acid
- ... Excipient - maize starch
- ... Excipient - colloidal anhydrous silica
- ... Excipient - microcrystalline cellulose
- ... Excipient - citric acid

Manufacturers

s47

Indications

Permitted Indications:

- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- ... Antioxidant/Reduce free radicals formed in the body
- ... Maintain/support general health and wellbeing
- ... Maintain/support energy levels
- ... Aid/assist/helps in the maintenance of blood levels of oxygen
- ... Aid/assist/helps oxygen transport to body tissues
- ... Helps maintain/support transport of oxygen in the body
- ... Aid/assist healthy red blood cell production
- ... Maintain/support blood health
- ... Relieve weariness/tiredness/fatigue/feeling of weakness
- ... Maintain/support healthy growth and development
- ... Maintain/support bone health
- ... Maintain/support bone strength
- ... Aids/assists healthy bone development/growth/building
- ... Maintain/support teeth strength
- ... Maintain/support cognitive function/mental function
- ... Maintain/support healthy immune system function

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.
-  ... Not for the treatment of iron deficiency conditions (or words to that effect).

Indication Requirements:

-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
-  ... Product presentation must not imply or refer to heart disease.
-  ... Product presentation must not imply or refer to imply chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
-  ... Product presentation must not imply or refer to serious cardiovascular conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:	110450_69187
Last Editor:	110450_69187



Application General

Product Name: Pentavite Vitamin D Kids Liquid
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 17/05/2019 06:11:37 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$820.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

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Changes Made Report:**Formulation**

Dosage Form: Liquids
Routes of Administration:
 ... Oral
Container Type:
Container Volume:
Container Closure:
Container Condition:

s47

**Minimum Weight of Divided Dosage Form
 (tablets, capsules, metered dose sprays etc.):**

Ingredients

 ... Active - colecalciferol
 ... Equivalent - colecalciferol
 ... Excipient - olive oil
 ... Excipient - butylated hydroxytoluene
 ... Excipient - Maize Oil

Manufacturers

s47

Indications**Permitted Indications:**

 ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
 ... Maintain/support healthy immune system function
 ... Maintain/support muscle function
 ... Aids/assists healthy bone development/growth/building in healthy infants
 ... Aids/assists healthy bone development/growth/building in children
 ... Maintain/support bone health
 ... Help maintain/support bone mineralisation
 ... Maintain/support bone strength
 ... Maintain/support immune system health
 ... Maintain/support healthy neuromuscular system/function
 ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
 ... Maintain/support healthy teeth
 ... Maintain/support teeth mineralisation
 ... Aids/assists teeth development
 ... Maintain/support general health and wellbeing
 ... Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

 ... Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Indication Requirements:

 ... If product is indicated for supplementation, Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a

 ... Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

 ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

 ... Product presentation must not imply or refer to serious immunological diseases.

 ... Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:

110450_69187

Last Editor:

110450_69187



Application General

Product Name: Vitamin D3 & K2 Kids Liquid
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 22/05/2019 03:34:35 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$820.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. s47

Changes Made Report:

Formulation

Dosage Form: Oral Liquid

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

s47

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

 ... Active - colecalciferol s47
 ... Active - menaquinone 7 s47
 ... s47
 ...
 ...
 ... Excipient - medium chain triglycerides

Manufacturers

s47

Indications

Permitted Indications:

 ... Maintain/support bone health
 ... Maintain/support bone strength
 ... Help maintain/support bone mineralisation
 ... Maintain/support healthy teeth
 ... Maintain/support teeth strength
 ... Aids/assists healthy bone development/growth/building
 ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
 ... Maintain/support muscle function
 ... Maintain/support healthy immune system function
 ... Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate
 ... Maintain/support teeth mineralisation
 ... Aids/assists teeth development
 ... Maintain/support muscle health
 ... Maintain/support healthy neuromuscular system/function
 ... Maintain/support immune system health
 ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
 ... Maintain/support general health and wellbeing

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

 ... Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a
-  ... Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
-  ... Product presentation must not imply or refer to serious immunological diseases.
-  ... Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:	110450_69187
Last Editor:	110450_69187



Application General

Product Name: Multivitamin + Iron Kids Powder
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 30/05/2019 09:13:04 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$820.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose.

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Riboflavin sodium phosphate')

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'folic acid')

Ingredient Restriction Rule - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'ferrous fumarate')

Pass with conditions - In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). (Ingredient(s) concerned: 'Iron')

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statement on the medicine label if supplied after 1 April 2019: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'Iron')

Pass with conditions - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statement on the medicine label: -(IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect) (Ingredient(s) concerned: 'Iron')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made Report:

Formulation

Dosage Form: Powder, oral

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

s47

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

-  ... Active - ferrous fumarate
-  ... Equivalent - iron
-  ... Active - folic acid
-  ... Active - cyanocobalamin
-  ... Active - magnesium phosphate tribasic
-  ... Equivalent - magnesium
-  ... Active - Beta vulgaris
-  ... Active - thiamine nitrate s47
-  ... Active - calcium pantothenate
-  ... Equivalent - pantothenic acid
-  ... Active - calcium phosphate
-  ... Equivalent - calcium
-  ... Active - lysine hydrochloride
-  ... Equivalent - lysine
-  ... Active - zinc citrate dihydrate
-  ... Equivalent - zinc
-  ... Active - calcium ascorbate dihydrate
-  ... Equivalent - ascorbic acid

- ... Active - riboflavin sodium phosphate
- ... Equivalent - riboflavin
- ... Active - Biotin
- ... Active - colecalfiferol s47
- ... Active - pyridoxine hydrochloride s47
- ... Active - Malpighia glabra
- ... Active - nicotinamide s47
- ... Active - retinol palmitate
- ... Equivalent - vitamin A
- ... Active - menaquinone 7
- s47
- ...
- ...
- ...
- ...
- ...
- ...
- ...
- ... Excipient - maize starch
- ... Excipient - butylated hydroxytoluene
- ... Excipient - colloidal anhydrous silica
- ... Excipient - malic acid
- ... Excipient - citric acid
- ... Excipient - microcrystalline cellulose
- ... Excipient - dextrin
- ... Excipient - maltodextrin
- ... Excipient - polydextrose
- ... Excipient - sucrose
- ... Excipient - thaumatin

Manufacturers

s47

Indications

Permitted Indications:

- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- ... Antioxidant/Reduce free radicals formed in the body
- ... Maintain/support general health and wellbeing
- ... Maintain/support energy levels
- ... Aid/assist/helps in the maintenance of blood levels of oxygen
- ... Aid/assist/helps oxygen transport to body tissues
- ... Helps maintain/support transport of oxygen in the body
- ... Aid/assist healthy red blood cell production
- ... Maintain/support blood health
- ... Relieve weariness/tiredness/fatigue/feeling of weakness
- ... Maintain/support healthy growth and development
- ... Maintain/support bone health
- ... Maintain/support bone strength
- ... Aids/assists healthy bone development/growth/building
- ... Maintain/support teeth strength
- ... Maintain/support cognitive function/mental function
- ... Maintain/support healthy immune system function

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
- ... If symptoms persist consult your healthcare practitioner (or words to that effect).
- ... Not for the treatment of iron deficiency conditions (or words to that effect).

Indication Requirements:

- ... Label statement: If symptoms persist, talk to your health professional.
- ... Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
- ... Product presentation must not imply or refer to heart disease.
- ... Product presentation must not imply or refer to imply chronic fatigue syndrome.
- ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- ... Product presentation must not imply or refer to serious cardiovascular conditions.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:	110450_69187
Last Editor:	110450_69187



Application General

Product Name: Immune Support Daily Kids Powder
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Contact Person: s22
Contact Telephone:
Contact Email: s22 @evolutionhealth.com.au

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 29/05/2019 02:47:36 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$820.00

Description of changes:
9D(1) correction: No

Validation Report:

Changes Made Report:

Formulation

Dosage Form: Powder, oral
Routes of Administration:
 ... Oral
Container Type:
Container Volume:
Container Closure:
Container Condition:

s47

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

Ingredients

- ... Active - Citrus bioflavonoids extract
- ... Active - lysine hydrochloride
- ... Equivalent - lysine
- ... Active - Honey
- ... Active - Sambucus nigra
- ... Active - zinc citrate dihydrate
- ... Equivalent - zinc
- ... Active - calcium ascorbate dihydrate
- ... Equivalent - ascorbic acid
- ... Active - colecalfiferol [s47](#)
- ... Active - retinol palmitate
- ... Equivalent - vitamin A
- ... [s47](#)
- ...
- ...
- ...
- ...
- ...
- ...
- ... Excipient - sucrose
- ... Excipient - dextrin
- ... Excipient - butylated hydroxytoluene
- ... Excipient - polydextrose
- ... Excipient - maize starch
- ... Excipient - citric acid
- ... Excipient - malic acid
- ... Excipient - thaumatin
- ... Excipient - maltodextrin
- ... Excipient - colloidal anhydrous silica

Manufacturers

s47

Indications

Permitted Indications:

- ... Maintain/support general health and wellbeing
- ... Maintain/support immune system health
- ... Maintain/support healthy immune system function
- ... Antioxidant/Reduce free radicals formed in the body
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold
- ... Linked indication - Decrease/reduce excess mucous
- ... Linked indication - Decrease/reduce/relieve cough

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).
- ... If symptoms persist consult your healthcare practitioner (or words to that effect).
- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral

supplements should not replace a balanced diet.

 ... Not suitable for infants under the age of twelve months (or words to that effect).

Indication Requirements:

 ... Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice.

 ... Label statement: If symptoms persist, talk to your health professional.

 ... Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

 ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

TRIM Details:

Audit Trail

Created By:	110450_69187
Last Editor:	110450_69187



Application General

Product Name: Vitamin D Kids Softgel
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 12/06/2019 04:33:58 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$820.00
Validation Report:

Changes Made Report:

Formulation

Dosage Form: Capsule, soft
Routes of Administration:
 ... Oral
Container Type:
Container Volume:
Container Closure:
Container Condition:

Maximum Single Dose:
Maximum Daily Dose: 3
Minimum Weight of Divided Dosage Form (tablets, capsules, metered dose sprays etc.): s47

Ingredients

... Active - colecalciferol
 ... Excipient - olive oil
 ... Excipient - Sunflower Oil
 ... Excipient - purified water
 ... Excipient - glycerol
 ... Excipient - Gelatin

... Excipient - Rosmarinus officinalis
 ... Equivalent - camphor
 ... Equivalent - cineole
 ... Excipient - butylated hydroxytoluene
 ... Excipient - Maize Oil

Manufacturers

s47

Indications

Permitted Indications:

... Maintain/support (state vitamin/mineral/nutrient) levels in the body
 ... Maintain/support healthy immune system function
 ... Maintain/support muscle function
 ... Aids/assists healthy bone development/growth/building in healthy infants
 ... Aids/assists healthy bone development/growth/building in children
 ... Maintain/support bone health
 ... Help maintain/support bone mineralisation
 ... Maintain/support bone strength
 ... Maintain/support immune system health
 ... Maintain/support healthy neuromuscular system/function
 ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
 ... Maintain/support healthy teeth
 ... Maintain/support teeth mineralisation
 ... Aids/assists teeth development
 ... Maintain/support general health and wellbeing
 ... Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a
- ... Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
- ... Product presentation must not imply or refer to serious immunological diseases.
- ... Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Supporting Documents

Electronic Documents

TRIM Reference:
Audit Trail

Created By:	110450_69187
Last Editor:	110450_69187



Application General

Product Name: Vitamin A + D Kids Liquid
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 13/06/2019 01:50:51 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$820.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

Changes Made Report:

Formulation

Dosage Form: Oral Liquid

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

s47

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

Ingredients

-  ... Active - colecalciferol
-  ... Active - retinol acetate
-  ... Equivalent - vitamin A
-  ... Excipient - vegetable oil
-  ... Excipient - olive oil

- ... Excipient - butylated hydroxytoluene
- ... Excipient - Maize Oil

Manufacturers

s47

Indications

Permitted Indications:

- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
- ... Aids/assists healthy bone development/growth/building
- ... Maintain/support healthy immune system function
- ... Maintain/support muscle function
- ... Aids/assists healthy bone development/growth/building in healthy infants
- ... Aids/assists healthy bone development/growth/building in children
- ... Maintain/support bone health
- ... Help maintain/support bone mineralisation
- ... Maintain/support bone strength
- ... Maintain/support immune system health
- ... Maintain/support healthy neuromuscular system/function
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- ... Maintain/support healthy teeth
- ... Maintain/support teeth mineralisation
- ... Aids/assists teeth development
- ... Maintain/support general health and wellbeing
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate
- ... Maintain/support healthy eye function
- ... Maintain/support eye health
- ... Maintain/support healthy eyesight/vision
- ... Maintain/support skin health
- ... Maintain/support skin integrity/structure
- ... Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- ... Maintain/support body mucous membrane health

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a
- ... Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
- ... Product presentation must not imply or refer to serious immunological diseases.
- ... Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
- ... Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular

degeneration.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:	110450_69187
Last Editor:	110450_69187



Application General

Product Name: Vitamin A + D Kids Softgel
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Contact Person: s22
Contact Telephone:
Contact Email: s22 @evolutionhealth.com.au

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 21/06/2019 04:50:40 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$820.00

Description of changes:
9D(1) correction: No

Validation Report:

Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

Changes Made Report:

Formulation

Dosage Form:

Capsule, soft

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:**Maximum Single Dose:****Maximum Daily Dose:**

3

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

s47

Ingredients

-  ... Active - colecalciferol
-  ... Active - retinol acetate
-  ... Equivalent - vitamin A
-  ... Excipient - Gelatin
-  ... Excipient - Sunflower Oil
-  ... Excipient - glycerol
-  ... Excipient - Rosmarinus officinalis
-  ... Equivalent - camphor
-  ... Equivalent - cineole
-  ... Excipient - olive oil
-  ... Excipient - vegetable oil
-  ... Excipient - purified water
-  ... Excipient - butylated hydroxytoluene
-  ... Excipient - Maize Oil

Manufacturers

s47

Indications**Permitted Indications:**

-  ... Maintain/support healthy eye function
-  ... Aids/assists healthy bone development/growth/building in children
-  ... Maintain/support bone strength
-  ... Maintain/support teeth mineralisation
-  ... Maintain/support body mucous membrane health
-  ... Maintain/support skin integrity/structure
-  ... Maintain/support bone health
-  ... Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
-  ... Maintain/support general health and wellbeing
-  ... Maintain/support healthy immune system function
-  ... Maintain/support muscle function
-  ... Aids/assists healthy bone development/growth/building in healthy infants
-  ... Help maintain/support bone mineralisation
-  ... Maintain/support immune system health
-  ... Maintain/support eye health
-  ... Aids/assists teeth development
-  ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
-  ... Maintain/support healthy teeth
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
-  ... Maintain/support skin health
-  ... Aids/assists healthy bone development/growth/building
-  ... Maintain/support healthy eyesight/vision
-  ... Maintain/support healthy neuromuscular system/function
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:****Indication Requirements:**

-  ... If product is indicated for supplementation, Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a
-  ... Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
-  ... Product presentation must not imply or refer to serious immunological diseases.
-  ... Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
-  ... Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

Supporting Documents**Electronic Documents****TRIM Reference:****TRIM Details:****Audit Trail**

Created By:	110450_69187
Last Editor:	110450_69187



Application General

Product Name: Calcium + Magnesium + Vitamin D3 Kids Liquid
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 08/07/2019 01:23:53 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$840.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine

label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect). [s47](#)

Changes Made Report:

Formulation

Dosage Form: Liquids
Routes of Administration:
 ... Oral
Container Type:
Container Volume:
Container Closure:
Container Condition:

[s47](#)

**Minimum Weight of Divided Dosage Form
 (tablets, capsules, metered dose sprays etc.):**

Ingredients

 ... Active - zinc citrate dihydrate
 ... Equivalent - zinc
 ... Active - calcium citrate
 ... Equivalent - calcium
 ... Active - magnesium citrate
 ... Equivalent - magnesium
 ... Active - magnesium citrate
 ... Equivalent - magnesium
 ... Active - colecalciferol [s47](#)
 ... [s47](#)
 ...
 ...
 ...
 ... Excipient - inulin
 ... Excipient - Steviol glycosides
 ... Excipient - purified water
 ... Excipient - malic acid
 ... Excipient - xanthan gum
 ... Excipient - fructose
 ... Excipient - potassium sorbate

Manufacturers

[s47](#)

Indications

Permitted Indications:

 ... Maintain/support general health and wellbeing
 ... Maintain/support muscle function

-  ... Maintain/support muscle health
-  ... Maintain/support nervous system health
-  ... Maintain/support nervous system function
-  ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
-  ... Maintain/support bone strength
-  ... Maintain/support bone health
-  ... Maintain/support healthy teeth
-  ... Maintain/support teeth strength
-  ... Aids/assists healthy bone development/growth/building
-  ... Maintain/support energy production
-  ... Help maintain/support bone mineralisation
-  ... Maintain/support healthy growth and development
-  ... Maintain/support healthy immune system function
-  ... Maintain/support immune system health

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... (If the medicine contains one sorbate) Contains [insert name of sorbate] OR (if medicine contains two or more sorbates) Contains sorbates [or words to that effect].
-  ... (If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].
-  ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Indication Requirements:

-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
-  ... Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
-  ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:

110450_69187

Last Editor:

110450_69187



Application General

Product Name: Iron
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Contact Person: s22
Contact Telephone:
Contact Email: s22 @evolutionhealth.com.au

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 16/08/2019 09:53:37 AM
This application is to: Replace an existing listing **AUST L 318835**
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$840.00

Description of changes:
9D(1) correction: No

Validation Report:

Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

Ingredient Restriction Rule - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'ferric pyrophosphate')

Pass with conditions - In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). (Ingredient(s) concerned: 'Iron')

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statement on the medicine label if supplied after 1 April 2019: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'Iron')

Pass with conditions - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statement on the medicine label: -(IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect) (Ingredient(s) concerned: 'Iron')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Sodium chloride')

Pass with Condition - In a solid preparation containing this ingredient, the pH of a 10 g/L aqueous solution must not be more than 11.5. In a liquid or a semi-solid preparation containing this ingredient, the pH of the preparation must not exceed 11.5. (Ingredient(s) concerned: 'Sodium chloride')

Changes Made
Changes Made Report:

s47

Formulation

Dosage Form: Powder
Routes of Administration:
 ... Oral
Container Type: Sachet
Container Volume:
Container Closure:
Container Condition:

s47

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

Ingredients

-  ... Active - ferric pyrophosphate
-  ... Equivalent - iron
-  ... Excipient - maltodextrin
-  ... Excipient - sorbitol
-  ... Excipient - xylitol
-  ... Excipient - sodium chloride
-  ... Excipient - lecithin
-  ... Excipient - dextrin
-  ... Excipient - Beta vulgaris

Manufacturers

s47

Indications

Permitted Indications:

-  ... Maintain/support energy levels
-  ... Maintain/support energy production
-  ... Maintain/support general health and wellbeing
-  ... Aid/assist healthy red blood cell production
-  ... Maintain/support blood health
-  ... Helps maintain/support transport of oxygen in the body
-  ... Aid/assist/helps oxygen transport to body tissues
-  ... Helps maintain/support haemoglobin formation/synthesis
-  ... Maintain/support immune system health
-  ... Maintain/support healthy immune system function
-  ... Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
-  ... Aid/assist/helps synthesis of neurotransmitters

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Not for the treatment of iron deficiency conditions (or words to that effect).
-  ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral

supplements should not replace a balanced diet.

Indication Requirements:

-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
-  ... Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
-  ... Product presentation must not imply or refer to heart disease.
-  ... Product presentation must not imply or refer to imply chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to serious cardiovascular conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents****TRIM Reference:****TRIM Details:****Audit Trail**

Created By:	110450_69187
Last Editor:	110450_69187



Application General

Product Name: Calcium + Vitamin D3 & K2 Kids Chewables
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 10/10/2019 11:26:34 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$840.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations

only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

Changes Made Report:

Formulation

Dosage Form: Tablet, chewable

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose: 2

Maximum Daily Dose: 2

Minimum Weight of Divided Dosage Form s47
(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - colecalciferol s47

 ... Active - menaquinone 7

 ... Active - calcium citrate tetrahydrate

 ... Equivalent - calcium

 ... s47

 ...

 ...

 ... Excipient - microcrystalline cellulose

 ... Excipient - colloidal anhydrous silica

 ... Excipient - magnesium stearate

 ... Excipient - thaumatin

 ... Excipient - sorbitol

 ... Excipient - citric acid

Manufacturers

s47

Indications

Permitted Indications:

-  ... Maintain/support general health and wellbeing
-  ... Aids/assists healthy bone development/growth/building
-  ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
-  ... Maintain/support bone strength
-  ... Maintain/support teeth strength
-  ... Maintain/support muscle function
-  ... Maintain/support healthy growth and development
-  ... Help maintain/support bone mineralisation
-  ... Maintain/support immune system health

-  ... Maintain/support healthy immune system function
-  ... Maintain/support bone health
-  ... Maintain/support teeth mineralisation
-  ... Maintain/support healthy teeth
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
-  ... Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:	112837_69187
Last Editor:	112837_69187



Application General

Product Name: Activated Folate Capsule
Export Names:  ... s47
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 21/08/2020 12:55:20 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$860.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects: a) the maximum daily dose must provide 400 - 500 micrograms of folic acid; and b) the following statements must be included on the label: - (NEUR) 'Warning: Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek specific medical advice (or words to that effect)'.

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

When used in combination with folic acid, folinic acid and/or their derivatives, the medicine must not provide more than a total of 500 mcg of folic acid, folinic acid and/or their derivatives in total per maximum recommended daily dose. (Ingredient(s) concerned: 'Levomefolate calcium')

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'Levomefolic acid')

Ingredient Restriction Rule - When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects, the following statement must be included on the label: - (NEUR) 'Warning: Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek specific medical advice (or words to that effect)'. (Ingredient(s) concerned: 'Levomefolic acid')

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. (Ingredient(s) concerned: 'titanium dioxide')

Changes Made Report:

Formulation

Dosage Form:

Capsule, hard

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:
Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

1

Ingredients

- ... Active - levomefolate calcium
- ... Equivalent - levomefolic acid
- ... Excipient - magnesium stearate
- ... Excipient - purified water
- ... Excipient - titanium dioxide
- ... Excipient - Gelatin
- ... Excipient - microcrystalline cellulose
- ... Excipient - colloidal anhydrous silica

Manufacturers

s47

Indications

Permitted Indications:

- ... Maintain/support healthy pregnancy
- ... Maintain/support placenta health/growth
- ... Maintains/support healthy foetal development
- ... Maintain/support general health and wellbeing in females
- ... Maintain/support preconception health in females
- ... Aid/assist healthy red blood cell production in females
- ... Maintain/support maternal health

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

... Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Indication Requirements:

- ... If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
- ... Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
- ... Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.
- ... Product presentation must not imply or refer to infertility.
- ... Product presentation must not imply or refer to serious cardiovascular conditions.

Supporting Documents

Electronic Documents

TRIM Reference:
Audit Trail

Created By:	112840_69187
Last Editor:	112837_69187



Application General

Product Name: Pentavite pentalife preconception & pregnancy activated folate
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 04/09/2020 12:15:55 PM
This application is to: Replace an existing listing **AUST L** 342639
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$860.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects: a) the maximum daily dose must provide 400 - 500 micrograms of folic acid; and b) the following statements must be included on the label: - (NEUR) 'Warning: Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek specific medical advice (or words to that effect)'.

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. (Ingredient(s) concerned: 'titanium dioxide')

When used in combination with folic acid, folinic acid and/or their derivatives, the medicine must not provide more than a total of 500 mcg of folic acid, folinic acid and/or their derivatives in total per maximum recommended daily dose. (Ingredient(s) concerned: 'Levomefolate calcium')

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'Levomefolic acid')

Ingredient Restriction Rule - When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects, the following statement must be included on the label: - (NEUR) 'Warning: Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek specific medical advice (or words to that effect)'. (Ingredient(s) concerned: 'Levomefolic acid')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form:

Capsule, hard

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:
Maximum Daily Dose:
Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

1

Ingredients

... Active - levomefolate calcium
 ... Equivalent - levomefolic acid
 ... Excipient - purified water
 ... Excipient - colloidal anhydrous silica
 ... Excipient - titanium dioxide
 ... Excipient - magnesium stearate
 ... Excipient - Gelatin
 ... Excipient - microcrystalline cellulose

Manufacturers

s47

Indications

Permitted Indications:

... Maintain/support general health and wellbeing in females
 ... Aid/assist healthy red blood cell production in females
 ... Maintains/support healthy foetal development
 ... Maintain/support healthy pregnancy
 ... Maintain/support maternal health
 ... Maintain/support preconception health in females
 ... Maintain/support placenta health/growth

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

... Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin...

Indication Requirements:

... If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
 ... Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
 ... Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.
 ... Product presentation must not imply or refer to infertility.
 ... Product presentation must not imply or refer to serious cardiovascular conditions.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:	112838_69187
Last Editor:	112838_69187



Application General

Product Name: Multivitamin + iron liquid for kids
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 27/01/2022 12:38:57 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$870.00
Validation Report:

Changes Made Report:

Formulation

Dosage Form: Oral Liquid
Routes of Administration:
 ... Oral
Container Type:
Container Volume:
Container Closure:
Container Condition:

S47

Minimum Weight of Divided Dosage Form
 (tablets, capsules, metered dose sprays etc.):

Ingredients

... Active - mecobalamin (co-methylcobalamin)
 ... Active - retinol palmitate
 ... Equivalent - vitamin A
 ... Active - ascorbic acid
 ... Active - thiamine hydrochloride
 ... Equivalent - thiamine

-  ... Active - ferric pyrophosphate [s47](#)
-  ... Active - zinc citrate dihydrate
-  ... Equivalent - zinc
-  ... Active - riboflavin sodium phosphate
-  ... Equivalent - riboflavin
-  ... Active - nicotinamide
-  ... Active - levomefolate calcium
-  ... Equivalent - levomefolic acid
-  ... Active - calcium pantothenate
-  ... Equivalent - pantothenic acid
-  ... Active - colecalciferol [s47](#)
-  ... Active - pyridoxal 5-phosphate monohydrate
-  ... Equivalent - pyridoxine
-  ... Active - Biotin
-  ... Active - potassium iodide
-  ... Equivalent - iodine
-  ... [s47](#)
-  ...
-  ...
-  ...
-  ... Excipient - Gelatin
-  ... Excipient - cochineal
-  ... Excipient - maize starch
-  ... Excipient - purified water
-  ... Excipient - citric acid
-  ... Excipient - xanthan gum
-  ... Excipient - xylitol
-  ... Excipient - dl-alpha-tocopherol
-  ... Excipient - Stevia rebaudiana
-  ... Excipient - potassium sorbate
-  ... Excipient - sucrose
-  ... Excipient - glycerol

Manufacturers

[s47](#)

Indications

Permitted Indications:

-  ... Maintain/support energy levels
-  ... Maintain/support healthy growth and development
-  ... Maintain/support general health and wellbeing
-  ... Maintain/support healthy immune system function
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
-  ... Maintain/support healthy appetite when dietary intake is inadequate
-  ... Maintain/support bone strength
-  ... Maintain/support teeth strength
-  ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

 ... Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

Indication Requirements:

 ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

 ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

 ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

 ... Product presentation must not imply or refer to chronic fatigue syndrome.

 ... Product presentation must not imply or refer to eating disorders.

 ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:	122701_69187
Last Editor:	122701_69187



Application General

Product Name: Multivitamin + iron liquid kids
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 08/06/2023 01:24:18 PM
This application is to: Replace an existing listing **AUST L 394201**
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$893.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

Pass with Conditions - When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'Levomefolate calcium')

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'Levomefolic acid')

Restricted Ingredient Rule - Only for use as an active homeopathic ingredient or for excipient use only as

a colour in oral and topical medicines. (Ingredient(s) concerned: 'Cochineal')

Pass with conditions - The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. (Ingredient(s) concerned: 'Pyridoxine')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Riboflavin sodium phosphate', [s47](#))

Ingredient Restriction Rule - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: [s47](#))

Pass with conditions - In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). (Ingredient(s) concerned: [s47](#))

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: [s47](#))

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: [s47](#))

Changes Made

Changes Made Report:

[s47](#)

Formulation

Dosage Form:

Oral Liquid

Routes of Administration:



... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

s47

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

-  ... Active - ferric pyrophosphate s47
-  ... Active - retinol palmitate
-  ... Equivalent - vitamin A
-  ... Active - calcium pantothenate
-  ... Equivalent - pantothenic acid
-  ... Active - levomefolate calcium
-  ... Equivalent - levomefolic acid
-  ... Active - nicotinamide
-  ... Active - zinc citrate dihydrate
-  ... Equivalent - zinc
-  ... Active - potassium iodide
-  ... Equivalent - iodine
-  ... Active - colecalciferol s47
-  ... Active - Biotin
-  ... Active - mecobalamin
-  ... Active - ascorbic acid
-  ... Active - thiamine hydrochloride
-  ... Equivalent - thiamine
-  ... Active - pyridoxal 5-phosphate monohydrate
-  ... Equivalent - pyridoxine
-  ... Active - riboflavin sodium phosphate
-  ... Equivalent - riboflavin
-  ... s47
-  ...
-  ...
-  ...
-  ... Excipient - maize starch
-  ... Excipient - Stevia rebaudiana
-  ... Excipient - sucrose
-  ... Excipient - glycerol
-  ... Excipient - cochineal
-  ... Excipient - purified water
-  ... Excipient - citric acid
-  ... Excipient - xanthan gum
-  ... Excipient - Gelatin
-  ... Excipient - dl-alpha-tocopherol
-  ... Excipient - xylitol
-  ... Excipient - potassium sorbate

Manufacturers

s47

Indications

Permitted Indications:

-  ... Maintain/support energy levels
-  ... Maintain/support healthy growth and development
-  ... Maintain/support general health and wellbeing
-  ... Maintain/support teeth strength
-  ... Maintain/support bone strength
-  ... Maintain/support healthy appetite when dietary intake is inadequate
-  ... Maintain/support healthy immune system function
-  ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Contains sorbate(s).

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
-  ... Product presentation must not imply or refer to chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to eating disorders.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:	122701_69187
Last Editor:	123550_69187



Application General

Product Name: Calcium + Vitamin D3 & K2 Kids Capsules
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 05/08/2019 12:10:34 PM
This application is to: Replace an existing listing **AUST L 317704**
Payment Exemption Number:
Application Type: Grouping
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

S47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Pass with conditions: When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). (Ingredient(s) concerned: 'titanium dioxide')

Permitted for excipient use as a colour in oral medicines and as a colour in topical medicines for dermal application. (Ingredient(s) concerned: 'titanium dioxide')

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form:

Capsule, soft

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

6

Minimum Weight of Divided Dosage Form

s47

(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - colecalciferol s47

 ... Active - menaquinone 7

 ... Active - calcium phosphate

 ... Equivalent - calcium

 ... s47

 ...

 ... Excipient - purified water

 ... Excipient - titanium dioxide

 ... Excipient - glycerol

 ... Excipient - Stevia rebaudiana

 ... Excipient - Gelatin

 ... Excipient - medium chain triglycerides

... Excipient - Rice bran oil
 ... Excipient - maltodextrin

Manufacturers

s47

Indications

Permitted Indications:

... Maintain/support healthy growth and development
 ... Maintain/support general health and wellbeing
 ... Maintain/support healthy teeth
 ... Maintain/support teeth mineralisation
 ... Maintain/support teeth strength
 ... Maintain/support bone health
 ... Aids/assists healthy bone development/growth/building
 ... Maintain/support bone strength
 ... Help maintain/support bone mineralisation
 ... Maintain/support immune system health
 ... Maintain/support healthy immune system function
 ... Maintain/support muscle function
 ... Maintain/support healthy neuromuscular system/function
 ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
 ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
 ... Maintain/support muscle health

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...

Indication Requirements:

... If product is indicated for supplementation, Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a
 ... Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
 ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
 ... Product presentation must not imply or refer to serious immunological diseases.
 ... Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:	110450_69187
Last Editor:	110450_69187



Application General

Product Name: Multivitamin + Iron Kids Powder
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 05/08/2019 11:31:06 AM
This application is to: Replace an existing listing **AUST L 318085**
Payment Exemption Number:
Application Type: Grouping
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose.

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Ingredient Restriction Rule - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'ferrous fumarate')

Pass with conditions - In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). (Ingredient(s) concerned: 'Iron')

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statement on the medicine label if supplied after 1 April 2019: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'Iron')

Pass with conditions - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statement on the medicine label: -(IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect) (Ingredient(s) concerned: 'Iron')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the

medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'folic acid')

When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Riboflavin sodium phosphate')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Powder, oral

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

s47

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

-  ... Active - menaquinone 7
-  ... Active - calcium ascorbate dihydrate
-  ... Equivalent - ascorbic acid
-  ... Active - Biotin
-  ... Active - zinc citrate dihydrate
-  ... Equivalent - zinc
-  ... Active - magnesium phosphate tribasic
-  ... Equivalent - magnesium
-  ... Active - nicotinamide s47
-  ... Active - pyridoxine hydrochloride s47
-  ... Active - ferrous fumarate
-  ... Equivalent - iron
-  ... Active - colecalciferol s47
-  ... Active - retinol palmitate
-  ... Equivalent - vitamin A
-  ... Active - calcium phosphate
-  ... Equivalent - calcium

- ... Active - folic acid
- ... Active - lysine hydrochloride
- ... Equivalent - lysine
- ... Active - riboflavin sodium phosphate
- ... Equivalent - riboflavin
- ... Active - calcium pantothenate
- ... Equivalent - pantothenic acid
- ... Active - thiamine nitrate [s47](#)
- ... Active - Malpighia glabra
- ... Active - Beta vulgaris
- ... Active - cyanocobalamin
- ... [s47](#)
- ...
- ...
- ...
- ...
- ...
- ...
- ... Excipient - maltodextrin
- ... Excipient - citric acid
- ... Excipient - colloidal anhydrous silica
- ... Excipient - malic acid
- ... Excipient - polydextrose
- ... Excipient - butylated hydroxytoluene
- ... Excipient - microcrystalline cellulose
- ... Excipient - thaumatin
- ... Excipient - maize starch
- ... Excipient - dextrin
- ... Excipient - sucrose

Manufacturers

[s47](#)

Indications

Permitted Indications:

- ... Antioxidant/Reduce free radicals formed in the body
- ... Maintain/support energy levels
- ... Relieve weariness/tiredness/fatigue/feeling of weakness
- ... Maintain/support healthy growth and development
- ... Maintain/support general health and wellbeing
- ... Maintain/support teeth strength
- ... Maintain/support bone health
- ... Aids/assists healthy bone development/growth/building
- ... Maintain/support bone strength
- ... Aid/assist healthy red blood cell production
- ... Maintain/support blood health
- ... Aid/assist/helps in the maintenance of blood levels of oxygen
- ... Helps maintain/support transport of oxygen in the body
- ... Aid/assist/helps oxygen transport to body tissues
- ... Maintain/support healthy immune system function
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- ... Maintain/support cognitive function/mental function
- ... Maintain/support immune system health

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

-  ... Not for the treatment of iron deficiency conditions (or words to that effect).
-  ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...
-  ... If symptoms persist consult your healthcare practitioner

Indication Requirements:

-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
-  ... Product presentation must not imply or refer to heart disease.
-  ... Product presentation must not imply or refer to imply chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
-  ... Product presentation must not imply or refer to serious cardiovascular conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:	110450_69187
Last Editor:	110450_69187



Application General

Product Name: Calcium + Magnesium + Vitamin D3 Kids Liquid
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 05/08/2019 12:37:41 PM
This application is to: Replace an existing listing **AUST L 319887**
Payment Exemption Number:
Application Type: Grouping
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars'

(or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect). (Ingredient(s) concerned: [s47](#))

Changes Made

Changes Made Report:

[s47](#)

Formulation

Dosage Form:

Liquids

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

[s47](#)

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

-  ... Active - colecalciferol [s47](#)
-  ... Active - magnesium citrate
-  ... Equivalent - magnesium
-  ... Active - calcium citrate
-  ... Equivalent - calcium
-  ... Active - magnesium citrate
-  ... Equivalent - magnesium
-  ... Active - zinc citrate dihydrate
-  ... Equivalent - zinc
-  .. [s47](#)
-  ..
-  ..
-  ... Excipient - malic acid
-  ... Excipient - Steviol glycosides
-  ... Excipient - purified water
-  ... Excipient - fructose
-  ... Excipient - inulin
-  ... Excipient - xanthan gum
-  ... Excipient - potassium sorbate

Manufacturers

[s47](#)

Indications

Permitted Indications:

-  ... Maintain/support energy production
-  ... Maintain/support healthy growth and development

-  ... Maintain/support general health and wellbeing
-  ... Maintain/support healthy teeth
-  ... Maintain/support teeth strength
-  ... Maintain/support bone health
-  ... Aids/assists healthy bone development/growth/building
-  ... Maintain/support bone strength
-  ... Help maintain/support bone mineralisation
-  ... Maintain/support immune system health
-  ... Maintain/support healthy immune system function
-  ... Maintain/support muscle health
-  ... Maintain/support muscle function
-  ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
-  ... Maintain/support nervous system health
-  ... Maintain/support nervous system function
-  ... Maintain/support energy levels

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Contains sorbate(s).
-  ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...
-  ... Contains sugars

Indication Requirements:

-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
-  ... Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
-  ... Product presentation must not imply or refer to imply chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:

110450_69187

Last Editor:

110450_69187



Application General

Product Name: Immune Support Daily Kids Chewables
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 10/12/2019 05:09:48 PM
This application is to: Replace an existing listing **AUST L 324880**
Payment Exemption Number:
Application Type: Grouping
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s))

concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Tablet, chewable

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose: 2

Maximum Daily Dose: 2

Minimum Weight of Divided Dosage Form s47
(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - colecalciferol s47

 ... Active - Honey

 ... Active - retinol palmitate

 ... Equivalent - vitamin A

- ... Active - calcium ascorbate dihydrate
- ... Equivalent - ascorbic acid
- ... Active - Citrus bioflavonoids extract
- ... Active - Sambucus nigra
- ... Active - zinc citrate dihydrate
- ... Equivalent - zinc
- ... s47
- ...
- ...
- ...
- ...
- ...
- ... Excipient - citric acid
- ... Excipient - thaumatin
- ... Excipient - magnesium stearate
- ... Excipient - sucrose
- ... Excipient - maltodextrin
- ... Excipient - maize starch
- ... Excipient - colloidal anhydrous silica
- ... Excipient - butylated hydroxytoluene
- ... Excipient - sorbitol
- ... Excipient - dextrin

Manufacturers

s47

Indications

Permitted Indications:

- ... Antioxidant/Reduce free radicals formed in the body
- ... Helps reduce/decrease free radical damage to body cells
- ... Maintain/support healthy growth and development
- ... Maintain/support general health and wellbeing
- ... Maintain/support immune system health
- ... Maintain/support healthy immune system function
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold
- ... Linked indication - Decrease/reduce/relieve cough
- ... Linked indication - Decrease/reduce excess mucous

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... Not suitable for infants under the age of twelve months
- ... Adults only. OR Not to be used in children under two years of age
- ... If symptoms persist consult your healthcare practitioner
- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a

 ... Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

 ... Label statement: If symptoms persist, talk to your health professional.

 ... Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

 ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:	112840_69187
Last Editor:	112837_69187



Application General

Product Name: Immune Support Daily Kids Chewables
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 03/12/2019 08:57:26 AM
This application is to: Replace an existing listing **AUST L 324880**
Payment Exemption Number:
Application Type: Grouping
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s))

concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Tablet, chewable

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose: 2

Maximum Daily Dose: 2

Minimum Weight of Divided Dosage Form s47
(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - Citrus bioflavonoids extract

 ... Active - colecalciferol s47

- ... Active - calcium ascorbate dihydrate
- ... Equivalent - ascorbic acid
- ... Active - retinol palmitate
- ... Equivalent - vitamin A
- ... Active - Honey
- ... Active - zinc citrate dihydrate
- ... Equivalent - zinc
- ... Active - Sambucus nigra
- ... [s47](#)
- ...
- ...
- ...
- ...
- ...
- ... Excipient - colloidal anhydrous silica
- ... Excipient - maize starch
- ... Excipient - sorbitol
- ... Excipient - dextrin
- ... Excipient - citric acid
- ... Excipient - maltodextrin
- ... Excipient - butylated hydroxytoluene
- ... Excipient - thaumatin
- ... Excipient - magnesium stearate
- ... Excipient - sucrose

Manufacturers

[s47](#)

Indications

Permitted Indications:

- ... Antioxidant/Reduce free radicals formed in the body
- ... Helps reduce/decrease free radical damage to body cells
- ... Maintain/support healthy growth and development
- ... Maintain/support general health and wellbeing
- ... Maintain/support immune system health
- ... Maintain/support healthy immune system function
- ... Decrease/reduce/relieve symptoms of common cold
- ... Linked indication - Decrease/reduce excess mucous
- ... Linked indication - Decrease/reduce/relieve cough
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...
- ... If symptoms persist consult your healthcare practitioner
- ... Adults only. OR Not to be used in children under two years of age
- ... Not suitable for infants under the age of twelve months

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
-  ... Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:	112837_69187
Last Editor:	112837_69187



Application General

Product Name: High DHA Kids Capsules
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 17/05/2019 08:51:49 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$820.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made Report:

Formulation

Dosage Form: Capsule, soft

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose: 2

Minimum Weight of Divided Dosage Form s47
(tablets, capsules, metered dose sprays etc.):

Ingredients

-  ... Active - concentrated fish Omega-3 triglycerides
-  ... Equivalent - docosahexaenoic acid
-  ... Equivalent - eicosapentaenoic acid
-  ... Active - potassium iodide
-  ... Equivalent - potassium
-  ... Equivalent - iodine
-  ... Active - mixed (low-alpha type) tocopherols concentrate
-  ... s47
-  ... Excipient - purified water
-  ... Excipient - Orange Oil
-  ... Equivalent - Oxedrine
-  ... Excipient - Rice bran oil
-  ... Excipient - maltodextrin
-  ... Excipient - vegetable oil
-  ... Excipient - glycerol
-  ... Excipient - Gelatin
-  ... Excipient - Stevia rebaudiana

Manufacturers

s47

Indications

Permitted Indications:

-  ... Maintain/support nervous system function
-  ... Maintain/support healthy growth and development
-  ... Maintain/support brain health
-  ... Maintain/support brain/central nervous system development

-  ... Maintain/support general health and wellbeing
-  ... Helps maintain/support healthy eye development
-  ... Helps maintain/support eye retina health
-  ... Maintain/support cognitive function/mental function
-  ... Maintain/support brain function
-  ... Maintain/support nervous system health

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
-  ... Derived from seafood.

Indication Requirements:

-  ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
-  ... Product presentation must not imply or refer to neurological conditions or developmental delays.
-  ... Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:	110450_69187
Last Editor:	110450_69187



Application General

Product Name: GRAPE SEED PLUS
Export Names:  ... s47
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 09/02/2024 02:30:38 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$939.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The

recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Croscarmellose sodium')

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. [s47](#)

Changes Made Report:

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - nicotinamide

 ... Active - ascorbic acid

 ... Active - Vitis vinifera

 ... [s47](#)

 ... Excipient - magnesium stearate

 ... Excipient - purified talc

 ... Excipient - croscarmellose sodium

 ... Excipient - tricalcium phosphate

 ... Excipient - allura red AC aluminium lake

 ... Excipient - polyvinyl alcohol

 ... Excipient - microcrystalline cellulose

 ... Excipient - indigo carmine aluminium lake

 ... Excipient - titanium dioxide

 ... Excipient - triacetin

 ... Excipient - hypromellose

Manufacturers

[s47](#)

Indications

Permitted Indications:

 ... Maintain/support general health and wellbeing

 ... Antioxidant/Reduce free radicals formed in the body

 ... Maintain/support collagen formation

 ... Aid/assist/helps connective tissue production/formation

-  ... Maintain/support connective tissue health
-  ... Maintain/support immune system health
-  ... Maintain/support healthy immune system function
-  ... Maintain/support bone health
-  ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
-  ... Maintain/support healthy teeth
-  ... Maintain/support skin health
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
-  ... Maintain/support (state vitamin/mineral) within normal range
-  ... Maintain/support energy levels
-  ... Maintain/support energy production
-  ... Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
-  ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
-  ... Product presentation must not imply or refer to chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:

131143_69187

Last Editor:

122703_69187



Application General

Product Name: Milk Thistle
Export Names:  ... s47
 ...
 ...
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 14/02/2024 09:41:05 AM
This application is to: Replace an existing listing **AUST L 338098**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Croscarmellose sodium')

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. (Ingredient(s) concerned: 'titanium dioxide')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

-  ... Active - Curcuma longa
-  ... Active - inositol
-  ... Active - Silybum marianum
-  ... Excipient - hypromellose
-  ... Excipient - macrogol 400
-  ... Excipient - magnesium stearate

... Excipient - povidone
 ... Excipient - maltodextrin
 ... Excipient - crospovidone
 ... Excipient - iron oxide yellow
 ... Excipient - croscarmellose sodium
 ... Excipient - microcrystalline cellulose
 ... Excipient - hydrogenated vegetable oil
 ... Excipient - Carnauba Wax
 ... Excipient - silicon dioxide
 ... Excipient - calcium hydrogen phosphate dihydrate
 ... Excipient - titanium dioxide
 ... Excipient - vanillin
 ... Excipient - colloidal anhydrous silica

Manufacturers

s47

Indications

Permitted Indications:

... Traditionally used in Western herbal medicine to maintain/support healthy liver function
 ... Traditionally used in Western herbal medicine to maintain/support liver health

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

Indication Requirements:

... Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:
 Last Editor:

123550_69187
 123550_69187



Application General

Product Name: Women's Care & Liver Cleanse
Export Names:  s47
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 14/03/2024 09:00:15 AM
This application is to: Replace an existing listing **AUST L 417032**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. (Ingredient(s) concerned: 'titanium dioxide')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Sodium ascorbate', 'Croscarmellose sodium')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - nicotinamide

 ... Active - Silybum marianum

- ... Active - sodium ascorbate
- ... Equivalent - ascorbic acid
- ... Active - Reynoutria japonica
- ... Excipient - iron oxide red
- ... Excipient - vanillin
- ... Excipient - crospovidone
- ... Excipient - iron oxide yellow
- ... Excipient - titanium dioxide
- ... Excipient - magnesium stearate
- ... Excipient - croscarmellose sodium
- ... Excipient - calcium phosphate
- ... Excipient - microcrystalline cellulose
- ... Excipient - povidone
- ... Excipient - silicon dioxide
- ... Excipient - macrogol 400
- ... Excipient - Carnuba Wax
- ... Excipient - hypromellose
- ... Excipient - maize starch

Manufacturers

s47

Indications

Permitted Indications:

- ... Antioxidant/Reduce free radicals formed in the body
- ... Maintain/support collagen formation
- ... Maintain/support natural liver cleansing/detoxification processes
- ... Maintain/support energy levels
- ... Maintain/support energy production
- ... Maintain/support body mucous membrane health
- ... Maintain/support general health and wellbeing
- ... Maintain/support connective tissue health
- ... Aid/assist/helps connective tissue production/formation
- ... Maintain/support bone health
- ... Maintain/support healthy liver function
- ... Maintain/support liver health
- ... Maintain/support immune system health
- ... Maintain/support healthy immune system function
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
- ... Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- ... Maintain/support (state vitamin/mineral) within normal range
- ... Maintain/support nervous system health
- ... Maintain/support nervous system function
- ... Traditionally used in Chinese medicine to haemagogue/emmenagogue/promotes menstrual flow
- ... Maintain/support skin health
- ... Maintain/support wound healing

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:****Indication Requirements:**

-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Product presentation must not imply or refer to abortifacient action.
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
-  ... Product presentation must not imply or refer to chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
-  ... Product presentation must not imply or refer to drugs/alcohol.
-  ... Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
-  ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.
-  ... Product presentation must only refer to detoxification in relation to natural body processes.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:

122703_69187

Last Editor:

122703_69187



Application General

Product Name: Women's Care & Liver Cleanse
Export Names:  ... [s47](#)
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 23/05/2024 10:43:09 AM
This application is to: Replace an existing listing **AUST L 417032**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

[s47](#)

s47



AFG Quality and Regulatory Consulting Pty Ltd - MI-2018-LI-00645-1 - has conditions -No further conditions are applicable.

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. (Ingredient(s) concerned: 'titanium dioxide')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Sodium ascorbate', 'Croscarmellose sodium')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - nicotinamide

 ... Active - Silybum marianum

 ... Active - sodium ascorbate

- ... Equivalent - ascorbic acid
- ... Active - Reynoutria japonica
- ... Excipient - iron oxide red
- ... Excipient - vanillin
- ... Excipient - crospovidone
- ... Excipient - iron oxide yellow
- ... Excipient - titanium dioxide
- ... Excipient - magnesium stearate
- ... Excipient - croscarmellose sodium
- ... Excipient - calcium phosphate
- ... Excipient - microcrystalline cellulose
- ... Excipient - povidone
- ... Excipient - silicon dioxide
- ... Excipient - macrogol 400
- ... Excipient - Carnauba Wax
- ... Excipient - hypromellose
- ... Excipient - maize starch

Manufacturers

s47

Indications

Permitted Indications:

- ... Antioxidant/Reduce free radicals formed in the body
- ... Maintain/support collagen formation
- ... Maintain/support natural liver cleansing/detoxification processes
- ... Maintain/support energy levels
- ... Maintain/support energy production
- ... Maintain/support body mucous membrane health
- ... Maintain/support general health and wellbeing
- ... Maintain/support connective tissue health
- ... Aid/assist/helps connective tissue production/formation
- ... Maintain/support bone health
- ... Maintain/support healthy liver function
- ... Maintain/support liver health
- ... Maintain/support immune system health
- ... Maintain/support healthy immune system function
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
- ... Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- ... Maintain/support (state vitamin/mineral) within normal range
- ... Maintain/support nervous system health
- ... Maintain/support nervous system function
- ... Traditionally used in Chinese medicine to haemagogue/emmenagogue/promotes menstrual flow
- ... Maintain/support skin health
- ... Maintain/support wound healing

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:****Indication Requirements:**

-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Product presentation must not imply or refer to abortifacient action.
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
-  ... Product presentation must not imply or refer to chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
-  ... Product presentation must not imply or refer to drugs/alcohol.
-  ... Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
-  ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.
-  ... Product presentation must only refer to detoxification in relation to natural body processes.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:

122703_69187

Last Editor:

122703_69187



Application General

Product Name: Man Vitality Plus
Export Names:  ... s47
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 31/07/2024 10:25:10 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$983.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

For Information Only - Species listed on CITES - if exporting or importing this product please contact the Department of Sustainability, Environment, Water, Population and Communities by telephone (DSEWPaC) on 02 6274 1111, facsimile on 02 6274 1921, or email to wildlifetrade@environment.gov.au to determine whether Australia's wildlife legislation places any controls on this ingredient. Further information is available on the Department of Sustainability, Environment, Water, Population and Communities' Wildlife Trade and Conservation website: <http://www.environment.gov.au/biodiversity/trade-use/index.html> (Ingredient(s) concerned: 'Panax ginseng')

For Information Only - May be a native species - if exporting this product please contact the Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) by telephone on 02 6274 1111, facsimile on 02 6274 1921, or email to wildlifetrade@environment.gov.au to determine whether Australia's wildlife legislation places any controls on this ingredient. Further information is available on the DSEWPaC's Wildlife Trade and Conservation website: <http://www.environment.gov.au/biodiversity/trade-use/index.html> (Ingredient(s) concerned: 'Tribulus terrestris')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Croscarmellose sodium')

Changes Made Report:

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

3

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

-  ... Active - zinc citrate dihydrate
-  ... Equivalent - zinc
-  ... Active - Turnera diffusa
-  ... Equivalent - beta-arbutin
-  ... Active - Panax ginseng
-  ... Active - Tribulus terrestris
-  ... [s47](#)
-  ... Excipient - crospovidone
-  ... Excipient - croscarmellose sodium
-  ... Excipient - maltodextrin
-  ... Excipient - microcrystalline cellulose
-  ... Excipient - povidone
-  ... Excipient - tricalcium phosphate
-  ... Excipient - silicon dioxide
-  ... Excipient - magnesium stearate

Manufacturers

[s47](#)

Indications

Permitted Indications:

-  ... Traditionally used in Western herbal medicine to body tonic
-  ... Traditionally used in Western herbal medicine to enhance/promote/increase urine output
-  ... Traditionally used in Western herbal medicine to maintain/support urinary tract health
-  ... Traditionally used in Western herbal medicine to aphrodisiac/enhance/improve/promote healthy libido

-  ... Traditionally used in Western herbal medicine to maintain/support healthy libido
-  ... Traditionally used in Western herbal medicine to maintain/support healthy sexual function
-  ... Traditionally used in Chinese medicine to relieve weariness/tiredness/fatigue/feeling of weakness
-  ... Maintain/support physical endurance/capacity/stamina
-  ... Maintain/support healthy immune system function
-  ... Maintain/support cognitive function/mental function
-  ... Maintain/support mental concentration/focus/clarity
-  ... Maintain/support general health and wellbeing
-  ... Traditionally used in Chinese medicine to maintain/support vitality
-  ... Traditionally used in Chinese medicine to enhance/promote energy levels
-  ... Traditionally used in Chinese medicine to engender fluid
-  ... Antioxidant/Reduce free radicals formed in the body
-  ... Maintain/support immune system health
-  ... Maintain/support reproductive system health in males
-  ... Maintain/support testosterone level
-  ... Maintain/support healthy reproductive hormones
-  ... Maintain/support preconception health in healthy males
-  ... Maintain/support sperm production in healthy males
-  ... Maintain/support sperm health in healthy males
-  ... Traditionally used in Chinese medicine to decrease/reduce/relieve headache symptoms

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

Indication Requirements:

-  ... If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
-  ... If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.
-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Product presentation must not imply or refer to chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to hormone imbalances.
-  ... Product presentation must not imply or refer to infertility.
-  ... Product presentation must not imply or refer to kidney disease.
-  ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Last Editor:

122703_69187



Application General

Product Name: By-Health Xin Luo Su Tablets
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 19/11/2024 07:59:29 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$983.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Croscarmellose sodium')

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. (Ingredient(s) concerned: 'titanium dioxide')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. s47

s47

The ingredient 'lactose' must be derived from bovine milk in order to be eligible for self-assessment and must comply with the European Pharmacopoeial monograph for the minimisation of TSE risk (Ingredient(s) concerned: 'lactose')

Changes Made Report:

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

1

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

 ... Active - Lycopersicon esculentum s47

 ... s47

 ... Excipient - microcrystalline cellulose

 ... Excipient - titanium dioxide

 ... Excipient - triacetin

 ... Excipient - lactose

 ... Excipient - brilliant scarlet 4R aluminium lake

 ... Excipient - purified talc

 ... Excipient - allura red AC aluminium lake

 ... Excipient - croscarmellose sodium

 ... Excipient - magnesium stearate

 ... Excipient - hypromellose

... Excipient - polyvinyl alcohol
... Excipient - silicon dioxide
... Excipient - indigo carmine aluminium lake

Manufacturers

s47



Indications

Permitted Indications:

... Maintain/support blood health
... Maintain/support healthy blood circulation

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

... Contains lactose (or words to that effect).

Indication Requirements:

... Product presentation must not imply or refer to serious cardiovascular conditions.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:

122703_69187

Last Editor:

122703_69187



Application General

Product Name: By-Health Xin Luo Su Tablets
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 19/11/2024 07:59:29 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$983.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Croscarmellose sodium')

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. (Ingredient(s) concerned: 'titanium dioxide')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. s47

s47

The ingredient 'lactose' must be derived from bovine milk in order to be eligible for self-assessment and must comply with the European Pharmacopoeial monograph for the minimisation of TSE risk (Ingredient(s) concerned: 'lactose')

Changes Made Report:

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

1

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

... Active - Lycopersicon esculentum s47

... s47

... Excipient - microcrystalline cellulose

... Excipient - titanium dioxide

... Excipient - triacetin

... Excipient - lactose

... Excipient - brilliant scarlet 4R aluminium lake

... Excipient - purified talc

... Excipient - allura red AC aluminium lake

... Excipient - croscarmellose sodium

... Excipient - magnesium stearate

... Excipient - hypromellose

... Excipient - polyvinyl alcohol
... Excipient - silicon dioxide
... Excipient - indigo carmine aluminium lake

Manufacturers

s47



Indications

Permitted Indications:

... Maintain/support blood health
... Maintain/support healthy blood circulation

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

... Contains lactose (or words to that effect).

Indication Requirements:

... Product presentation must not imply or refer to serious cardiovascular conditions.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:

122703_69187

Last Editor:

122703_69187



Application General

Product Name: Liver Cleanse & Metabolism
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 22/01/2025 04:25:23 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$983.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Pass with Condition - When for oral use AND the extract ratio is equal to or more than 25:1 AND the

equivalent dry weight per dosage unit is equal to or more than 2g, the medicine requires the following warning statement on the medicine label: - (GINGER) 'Individuals taking anticoagulants should seek medical advice before taking this medicine.' AND 'Individuals at risk of bleeding problems should seek advice from their healthcare practitioner prior to taking this medicine' (Ingredient(s) concerned: 'Zingiber officinale')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Pass with conditions - The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. (Ingredient(s) concerned: 'Pyridoxine')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Croscarmellose sodium')

Changes Made Report:

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose: 2

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - riboflavin
 ... Active - Laminaria japonica
 ... Equivalent - iodine
 ... Active - pyridoxine hydrochloride
 ... Equivalent - pyridoxine
 ... Active - Zingiber officinale
 ... Active - d-alpha-tocopheryl acetate
 ... Equivalent - d-alpha-tocopherol
 ... Equivalent - d-alpha-tocopheryl acetate
 ... Active - Silybum marianum
 ... [s47](#)
 ... Excipient - maltodextrin
 ... Excipient - microcrystalline cellulose
 ... Excipient - Acacia

-  ... Excipient - crospovidone
-  ... Excipient - magnesium stearate
-  ... Excipient - povidone
-  ... Excipient - silicon dioxide
-  ... Excipient - croscarmellose sodium
-  ... Excipient - dl-alpha-tocopherol

Manufacturers

s47

Indications

Permitted Indications:

-  ... Maintain/support natural liver cleansing/detoxification processes
-  ... Maintain/support liver health
-  ... Maintain/support healthy liver function
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal spasm
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite
-  ... Traditionally used in Western herbal medicine to digestive tonic/improve digestive weakness
-  ... Traditionally used in Western herbal medicine to relieve digestive discomfort
-  ... Maintain/support energy production
-  ... Maintain/support energy levels
-  ... Maintain/support general health and wellbeing
-  ... Maintain/support eye health
-  ... Maintain/support healthy eye function
-  ... Maintain/support healthy immune system function
-  ... Maintain/support skin health
-  ... Maintain/support healthy body tissues
-  ... Maintain/support red blood cell health
-  ... Helps maintain/support haemoglobin formation/synthesis
-  ... Aid/assist nail growth
-  ... Maintain/support (state vitamin/mineral) within normal range
-  ... Maintain/support (state vitamin/mineral) within normal range
-  ... Aid/assist/helps connective tissue production/formation
-  ... Helps convert (state food) into energy
-  ... Aid/assist/helps glucose/sugar/carbohydrate metabolism
-  ... Antioxidant/Reduce free radicals formed in the body
-  ... Maintain/support healthy immune system function

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

Indication Requirements:

-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Product presentation must not imply or refer to chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
-  ... Product presentation must not imply or refer to drugs/alcohol.
-  ... Product presentation must not imply or refer to eating disorders.
-  ... Product presentation must not imply or refer to gastro oesophageal reflux disease.
-  ... Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
-  ... Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
-  ... Product presentation must not imply or refer to serious cardiovascular conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.
-  ... Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
-  ... Product presentation must only refer to detoxification in relation to natural body processes.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:	122703_69187
Last Editor:	133089_69187



Application General

Product Name: Pentavite pentalife preconception & pregnancy activated folate
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 29/09/2022 11:52:27 AM
This application is to: Replace an existing listing **AUST L** 343478
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Restricted word found: Pregnant/Pregnancy - Medicines that are targeted to pregnant women through the name and/or presentation of the medicine should only use permitted indications that specifically refer to pregnancy. The use of general permitted indications in medicines targeted to pregnant women is not permitted, as the TGA eBS Code Tables do not include a population qualifier for 'pregnancy' or 'pregnant women'. The use of a general permitted indication for a sub-population for which there is no population qualifier may change the meaning and intent of the indication, such that it is no longer a permitted indication. Please refer to the following guidance on the appropriate use of permitted indications for listed medicines that are targeted to pregnancy or pregnant women:
<https://www.tga.gov.au/faqs-issues-raised-industry-relation-permitted-indications>.

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. (Ingredient(s) concerned: 'titanium dioxide')

Pass with Conditions - When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'Levomefolate calcium')

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'Levomefolic acid')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form:

Capsule, hard

Routes of Administration:



... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:
Maximum Daily Dose:
Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

1

Ingredients

... Active - levomefolate calcium
 ... Equivalent - levomefolic acid
 ... Excipient - titanium dioxide
 ... Excipient - microcrystalline cellulose
 ... Excipient - Gelatin
 ... Excipient - colloidal anhydrous silica
 ... Excipient - purified water
 ... Excipient - magnesium stearate

Manufacturers

s47

Indications

Permitted Indications:

... Maintain/support general health and wellbeing in females
 ... Aid/assist healthy red blood cell production in females
 ... Maintains/support healthy foetal development
 ... Maintain/support healthy pregnancy
 ... Maintain/support maternal health
 ... Maintain/support preconception health in females
 ... Maintain/support placenta health/growth

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

... Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin...

Indication Requirements:

... If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
 ... Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
 ... Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.
 ... Product presentation must not imply or refer to infertility.
 ... Product presentation must not imply or refer to serious cardiovascular conditions.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:	123550_69187
Last Editor:	123550_69187



Application General

Product Name: HighFlex Glucosamine Hydrochloride 1500 Plus Calcium
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 07/02/2025 11:28:55 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$983.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations

only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

Pass with conditions - When derived from crustacea/crustacean products, the medicine requires the following warning statement on the medicine label: - (SHELL) 'Contains crustacea' OR 'Contains crustacean products' (Ingredient(s) concerned: 'glucosamine hydrochloride')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Croscarmellose sodium', 'Starch sodium octenyl succinate')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made Report:

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

2

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

 ... Active - colecalciferol
 ... Active - glucosamine hydrochloride
 ... Active - menaquinone 7
 ... Active - calcium carbonate
 ... Equivalent - calcium
 ... **s47**
 ... Excipient - medium chain triglycerides
 ... Excipient - glyceryl monostearate
 ... Excipient - croscarmellose sodium
 ... Excipient - maize starch
 ... Excipient - sucrose
 ... Excipient - magnesium stearate
 ... Excipient - spray-dried glucose syrup
 ... Excipient - maltodextrin
 ... Excipient - dl-alpha-tocopherol
 ... Excipient - silicon dioxide
 ... Excipient - Acacia

... Excipient - povidone
 ... Excipient - starch sodium octenyl succinate
 ... Excipient - microcrystalline cellulose

Manufacturers

s47

Indications

Permitted Indications:

... Maintain/support collagen formation
 ... Maintain/support joint health
 ... Maintain/support joint mobility/flexibility
 ... Helps maintain/supports healthy joint cartilage growth/development/production
 ... Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
 ... Maintain/support muscle function
 ... Maintain/support general health and wellbeing
 ... Maintain/support (state vitamin/mineral) within normal range
 ... Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
 ... Maintain/support healthy immune system function
 ... Maintain/support immune system health
 ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
 ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
 ... Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
 ... Decrease/reduce/relieve mild joint pain/soreness

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

Indication Requirements:

... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
 ... Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.
 ... Label statement: If symptoms persist, talk to your health professional.
 ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
 ... Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.
 ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
 ... Product presentation must not imply or refer to serious immunological diseases.
 ... Product presentation must only refer to mild joint symptoms.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:	122703_69187
Last Editor:	133089_69187



Application General

Product Name: Liver protect
Export Names:  ... [s47](#)
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 12/03/2025 11:58:17 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$983.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

[s47](#)

s47

Pass with Condition - When for oral use AND the extract ratio is equal to or more than 25:1 AND the equivalent dry weight per dosage unit is equal to or more than 2g, the medicine requires the following warning statement on the medicine label: - (GINGER) 'Individuals taking anticoagulants should seek medical advice before taking this medicine.' AND 'Individuals at risk of bleeding problems should seek advice from their healthcare practitioner prior to taking this medicine' (Ingredient(s) concerned: 'Zingiber officinale')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made Report:

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - Silybum marianum

 ... Active - Zingiber officinale

 ... Active - inositol

 ... Active - choline bitartrate

 ... Equivalent - choline

 ... s47

 ... Excipient - maltodextrin

 ... Excipient - silicon dioxide

 ... Excipient - crospovidone

 ... Excipient - copovidone

 ... Excipient - microcrystalline cellulose

 ... Excipient - magnesium stearate

Manufacturers

s47

s47

Indications**Permitted Indications:**

- ... Maintain/support natural liver cleansing/detoxification processes
- ... Maintain/support liver health
- ... Maintain/support healthy liver function
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal spasm
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite
- ... Traditionally used in Western herbal medicine to digestive tonic/improve digestive weakness
- ... Traditionally used in Western herbal medicine to relieve digestive discomfort
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:****Indication Requirements:**

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Label statement: If symptoms persist, talk to your health professional.
- ... Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
- ... Product presentation must not imply or refer to drugs/alcohol.
- ... Product presentation must not imply or refer to eating disorders.
- ... Product presentation must not imply or refer to gastro oesophageal reflux disease.
- ... Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
- ... Product presentation must only refer to detoxification in relation to natural body processes.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:
Last Editor:

122703_69187
122703_69187



Application General

Product Name: Liver Cleanse & Metabolism
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 18/03/2025 11:42:18 AM
This application is to: Replace an existing listing **AUST L 477466**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

Pass with Condition - When for oral use AND the extract ratio is equal to or more than 25:1 AND the equivalent dry weight per dosage unit is equal to or more than 2g, the medicine requires the following warning statement on the medicine label: - (GINGER) 'Individuals taking anticoagulants should seek medical advice before taking this medicine.' AND 'Individuals at risk of bleeding problems should seek advice from their healthcare practitioner prior to taking this medicine' (Ingredient(s) concerned: 'Zingiber officinale')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Pass with conditions - The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. (Ingredient(s) concerned: 'Pyridoxine')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Croscarmellose sodium')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

2

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

-  ... Active - Silybum marianum
-  ... Active - Zingiber officinale
-  ... Active - riboflavin
-  ... Active - pyridoxine hydrochloride
-  ... Equivalent - pyridoxine
-  ... Active - d-alpha-tocopheryl acetate

- ... Equivalent - d-alpha-tocopheryl acetate
- ... Equivalent - d-alpha-tocopherol
- ... Active - Laminaria japonica
- ... Equivalent - iodine
- ... [s47](#)
- ... Excipient - silicon dioxide
- ... Excipient - maltodextrin
- ... Excipient - Acacia
- ... Excipient - croscarmellose sodium
- ... Excipient - crospovidone
- ... Excipient - microcrystalline cellulose
- ... Excipient - magnesium stearate
- ... Excipient - dl-alpha-tocopherol
- ... Excipient - povidone

Manufacturers

[s47](#)

Indications

Permitted Indications:

- ... Antioxidant/Reduce free radicals formed in the body
- ... Maintain/support natural liver cleansing/detoxification processes
- ... Maintain/support energy levels
- ... Helps convert (state food) into energy
- ... Maintain/support energy production
- ... Maintain/support healthy eye function
- ... Maintain/support eye health
- ... Maintain/support general health and wellbeing
- ... Aid/assist nail growth
- ... Aid/assist/helps connective tissue production/formation
- ... Maintain/support healthy body tissues
- ... Maintain/support red blood cell health
- ... Helps maintain/support haemoglobin formation/synthesis
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal spasm
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- ... Traditionally used in Western herbal medicine to relieve digestive discomfort
- ... Traditionally used in Western herbal medicine to digestive tonic/improve digestive weakness
- ... Maintain/support healthy liver function
- ... Maintain/support liver health
- ... Maintain/support healthy immune system function
- ... Maintain/support healthy immune system function
- ... Aid/assist/helps glucose/sugar/carbohydrate metabolism
- ... Maintain/support (state vitamin/mineral) within normal range
- ... Maintain/support (state vitamin/mineral) within normal range
- ... Maintain/support skin health

Standard Indications:

Specific Indications:**Warnings and Indication Requirements****Coded Warnings:****Indication Requirements:**

-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Product presentation must not imply or refer to chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
-  ... Product presentation must not imply or refer to drugs/alcohol.
-  ... Product presentation must not imply or refer to eating disorders.
-  ... Product presentation must not imply or refer to gastro oesophageal reflux disease.
-  ... Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
-  ... Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
-  ... Product presentation must not imply or refer to serious cardiovascular conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.
-  ... Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
-  ... Product presentation must only refer to detoxification in relation to natural body processes.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:	122703_69187
Last Editor:	122703_69187



Application General

Product Name: Daily Multivitamin
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 16/04/2025 11:41:37 AM
This application is to: Replace an existing listing **AUST L 364115**
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$983.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose.

The Coded Warning (POTAS1) is required where the total potassium content of the maximum recommended daily dose of the medicine is greater than 39 mg (1mmol) elemental potassium. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Potassium iodide')

Pass with conditions - The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. (Ingredient(s) concerned: 'Pyridoxine')

The Coded Warning (SODIUM) is required where the total sodium content of the maximum recommended daily dose of the medicine is greater than 120 mg of elemental sodium. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: [s47](#))

The Coded Warning (SUGOLS) is required where total sugar alcohol content of the medicine exceeds 2 g per maximum recommended daily dose. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Mannitol')

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'folic acid')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A

can cause birth defects.” NOTE: Position this warning at the beginning of the directions for use. - (VITA3) “The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.” (Ingredient(s) concerned: 'vitamin a')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Pastille

Routes of Administration:

... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

1

Minimum Weight of Divided Dosage Form (tablets, capsules, metered dose sprays etc.):

s47

Ingredients

... Active - dl-alpha-tocopheryl acetate

... Active - ascorbic acid

... Active - zinc sulfate monohydrate

... Equivalent - zinc

... Active - potassium iodide

... Equivalent - iodine

... Active - cyanocobalamin

... Active - pyridoxine hydrochloride

... Equivalent - pyridoxine

... Active - colexcalciferol s47

... Active - Biotin

... Active - menaquinone 7

... Active - nicotinamide

... Active - folic acid

... Active - retinol palmitate

... Equivalent - vitamin A

s47

...

...

...

... Excipient - sodium ascorbate

... Excipient - Coconut Oil

... Excipient - purified water

... Excipient - silicon dioxide

... Excipient - maize starch

... Excipient - dl-alpha-tocopherol

... Excipient - citric acid

... Excipient - mannitol

... Excipient - liquid glucose

-  ... Excipient - Gelatin
-  ... Excipient - glucose
-  ... Excipient - Acacia
-  ... Excipient - Carnauba Wax
-  ... Excipient - sucrose
-  ... Excipient - tricalcium phosphate
-  ... Excipient - modified food starch
-  ... Excipient - medium chain triglycerides

Manufacturers

s47

Indications

Permitted Indications:

-  ... Antioxidant/Reduce free radicals formed in the body
-  ... Maintain/support energy production in children
-  ... Maintain/support healthy growth and development in children
-  ... Maintain/support general health and wellbeing in children
-  ... Maintain/support healthy teeth
-  ... Maintain/support teeth mineralisation in children
-  ... Maintain/support teeth strength in children
-  ... Maintain/support bone health in children
-  ... Aids/assists healthy bone development/growth/building in children
-  ... Maintain/support bone strength in children
-  ... Help maintain/support bone mineralisation in children
-  ... Maintain/support immune system health in children
-  ... Maintain/support healthy immune system function in children
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
-  ... Maintain/support cognitive function/mental function in children

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...
-  ... Contains sugars

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

-  ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:	122703_69187
Last Editor:	122703_69187



Application General

Product Name: Liver protect
Export Names:  ... [s47](#)
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 04/06/2025 03:28:54 PM
This application is to: Replace an existing listing [AUST L 482812](#)
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

[s47](#)

s47

Pass with Condition - When for oral use AND the extract ratio is equal to or more than 25:1 AND the equivalent dry weight per dosage unit is equal to or more than 2g, the medicine requires the following warning statement on the medicine label: - (GINGER) 'Individuals taking anticoagulants should seek medical advice before taking this medicine.' AND 'Individuals at risk of bleeding problems should seek advice from their healthcare practitioner prior to taking this medicine' (Ingredient(s) concerned: 'Zingiber officinale')

The Coded Warning (GLUTEN) is required where gluten (including in ingredients derived from gluten-containing grains) is present in a medicine in a concentration of 20 parts per million or more. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Maltodextrin')

Ingredient Restriction Rule - Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made

Changes Made Report:

s47

Formulation**Dosage Form:** Tablet, film coated**Routes of Administration:** ... Oral**Container Type:****Container Volume:****Container Closure:****Container Condition:****Maximum Single Dose:****Maximum Daily Dose:****Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):****Ingredients** ... Active - Silybum marianum ... Active - inositol ... Active - choline bitartrate ... Equivalent - choline ... Active - Zingiber officinale ... [s47](#) ... Excipient - maltodextrin ... Excipient - microcrystalline cellulose ... Excipient - copovidone ... Excipient - magnesium stearate ... Excipient - silicon dioxide ... Excipient - crospovidone**Manufacturers**[s47](#)**Indications****Permitted Indications:** ... Maintain/support natural liver cleansing/detoxification processes ... Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite ... Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain) ... Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative ... Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal spasm ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia ... Traditionally used in Western herbal medicine to relieve digestive discomfort ... Traditionally used in Western herbal medicine to digestive tonic/improve digestive weakness ... Maintain/support healthy liver function ... Maintain/support liver health

 ... Maintain/support (state vitamin/mineral/nutrient) levels in the body

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
-  ... Product presentation must not imply or refer to drugs/alcohol.
-  ... Product presentation must not imply or refer to eating disorders.
-  ... Product presentation must not imply or refer to gastro oesophageal reflux disease.
-  ... Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
-  ... Product presentation must only refer to detoxification in relation to natural body processes.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:	122703_69187
Last Editor:	122703_69187



Application General

Product Name: GRAPE SEED
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 29/09/2022 11:56:40 AM
This application is to: Replace an existing listing **AUST L 328611**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

Pass with Conditions - When caffeine is a standalone ingredient for internal use or oral application, the following warning statement is required on the medicine label: (ADULT) 'Adults only' (or words to that effect). When caffeine is a component and the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statement are required on the label: (ADULT) 'Adults only' (or words to that effect). (Ingredient(s) concerned: 'Caffeine')

Ingredient Restriction Rule: When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%. (Ingredient(s) concerned: 'Caffeine')

Ingredient Restriction Rule - When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label: - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.' - (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.' (Ingredient(s) concerned: 'Caffeine')

Changes Made

Changes Made Report:
s47

Formulation

Dosage Form: Capsule, hard

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

2

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

s47

Ingredients

 ... Active - Camellia sinensis

 ... Equivalent - caffeine

 ... Active - ascorbic acid

 ... Active - Vitis vinifera

 ... s47

 ... Excipient - magnesium stearate

 ... Excipient - silicon dioxide

 ... Excipient - microcrystalline cellulose

Manufacturerss47
**Indications****Permitted Indications:**

- ... Antioxidant/Reduce free radicals formed in the body
- ... Helps reduce/decrease free radical damage to body cells
- ... Maintain/support collagen formation
- ... Maintain/support general health and wellbeing
- ... Maintain/support skin health

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

- ... Adults only.
- ... Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.
- ... Contains caffeine [state quantity per dosage unit or per mL or per gram of product]
- ... Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin...

Indication Requirements:**Supporting Documents****Electronic Documents****TRIM Reference:****Audit Trail**

Created By:

123550_69187

Last Editor:

123550_69187



Application General

Product Name: HIGHFLEX GLUCOSAMINE HYDROCHLORIDE 1800 ADVANCED
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 26/06/2025 10:22:08 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$983.00
Validation Report:

Changes Made Report:

Formulation

Dosage Form: Tablet, film coated
Routes of Administration:
 ... Oral
Container Type:
Container Volume:
Container Closure:
Container Condition:

Maximum Single Dose:
Maximum Daily Dose: 3
Minimum Weight of Divided Dosage Form (tablets, capsules, metered dose sprays etc.):

Ingredients

... Active - calcium carbonate
 ... Equivalent - calcium
 ... Active - colecalciferol
 ... Active - menaquinone 7
 ... Active - glucosamine hydrochloride
 ... Active - sodium chondroitin sulfate

- ... Active - Secale cereale
- ... Active - Devil's Claw Tuber Dry
- ... Active - Boswellia serrata
- ... Equivalent - boswellic acid
- ... [s47](#)
- ... Excipient - magnesium stearate
- ... Excipient - starch sodium octenyl succinate
- ... Excipient - monobasic calcium phosphate
- ... Excipient - dl-alpha-tocopherol
- ... Excipient - Acacia
- ... Excipient - medium chain triglycerides
- ... Excipient - maltodextrin
- ... Excipient - povidone
- ... Excipient - copovidone
- ... Excipient - glyceryl monostearate
- ... Excipient - crospovidone
- ... Excipient - maize starch
- ... Excipient - silicon dioxide
- ... Excipient - microcrystalline cellulose
- ... Excipient - spray-dried glucose syrup
- ... Excipient - sucrose

Manufacturers

[s47](#)

Indications

Permitted Indications:

- ... Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
- ... Maintain/support collagen formation
- ... Maintain/support general health and wellbeing
- ... Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
- ... Helps maintain/supports healthy joint cartilage growth/development/production
- ... Maintain/support joint health
- ... Maintain/support joint mobility/flexibility
- ... Decrease/reduce/relieve mild joint pain/soreness
- ... Maintain/support healthy immune system function
- ... Maintain/support immune system health
- ... Maintain/support muscle function
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
- ... Maintain/support (state vitamin/mineral) within normal range

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Adults only.
-  ... Not recommended for use by pregnant and lactating women (or words to that effect).

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.
-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
-  ... Product presentation must not imply or refer to serious immunological diseases.
-  ... Product presentation must only refer to mild joint symptoms.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:	122703_69187
Last Editor:	122703_69187



Application General

Product Name: Liver Cleanse & Health
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 21/07/2025 04:53:45 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$1014.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

Pass with Condition - When for oral use AND the extract ratio is equal to or more than 25:1 AND the equivalent dry weight per dosage unit is equal to or more than 2g, the medicine requires the following warning statement on the medicine label: - (GINGER) 'Individuals taking anticoagulants should seek medical advice before taking this medicine.' AND 'Individuals at risk of bleeding problems should seek advice from their healthcare practitioner prior to taking this medicine' (Ingredient(s) concerned: 'Zingiber officinale')

The Coded Warning (GLUTEN) is required where gluten (including in ingredients derived from gluten-containing grains) is present in a medicine in a concentration of 20 parts per million or more. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Maltodextrin')

Ingredient Restriction Rule - Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made Report:

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

Ingredients

-  ... Active - Silybum marianum
-  ... Active - inositol
-  ... Active - Zingiber officinale
-  ... [s47](#)
-  ... Excipient - magnesium stearate
-  ... Excipient - maltodextrin
-  ... Excipient - crospovidone
-  ... Excipient - microcrystalline cellulose
-  ... Excipient - copovidone
-  ... Excipient - silicon dioxide

Manufacturers

[s47](#)


Indications**Permitted Indications:**

-  ... Maintain/support natural liver cleansing/detoxification processes
-  ... Maintain/support liver health
-  ... Maintain/support healthy liver function
-  ... Maintain/support general health and wellbeing
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal spasm
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite
-  ... Traditionally used in Western herbal medicine to digestive tonic/improve digestive weakness
-  ... Traditionally used in Western herbal medicine to relieve digestive discomfort

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:****Indication Requirements:**

-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
-  ... Product presentation must not imply or refer to drugs/alcohol.
-  ... Product presentation must not imply or refer to eating disorders.
-  ... Product presentation must not imply or refer to gastro oesophageal reflux disease.
-  ... Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

 ... Product presentation must only refer to detoxification in relation to natural body processes.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:	122703_69187
Last Editor:	122703_69187



Application General

Product Name: Liver Cleanse & Metabolism
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 08/08/2025 09:25:40 AM
This application is to: Replace an existing listing **AUST L 477466**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

Pass with Condition - When for oral use AND the extract ratio is equal to or more than 25:1 AND the equivalent dry weight per dosage unit is equal to or more than 2g, the medicine requires the following warning statement on the medicine label: - (GINGER) 'Individuals taking anticoagulants should seek medical advice before taking this medicine.' AND 'Individuals at risk of bleeding problems should seek advice from their healthcare practitioner prior to taking this medicine' (Ingredient(s) concerned: 'Zingiber officinale')

The Coded Warning (GLUTEN) is required where gluten (including in ingredients derived from gluten-containing grains) is present in a medicine in a concentration of 20 parts per million or more. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Maltodextrin')

Ingredient Restriction Rule - Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats. (Ingredient(s) concerned: 'Maltodextrin')

Pass with conditions - The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. (Ingredient(s) concerned: 'Pyridoxine')

The Coded Warning (SODIUM) is required where the total sodium content of the maximum recommended daily dose of the medicine is greater than 120 mg of elemental sodium. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Croscarmellose sodium')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form:

Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:
Container Volume:
Container Closure:
Container Condition:

Maximum Single Dose:
Maximum Daily Dose:
Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

2

Ingredients

-  ... Active - Silybum marianum
-  ... Active - Zingiber officinale
-  ... Active - riboflavin
-  ... Active - pyridoxine hydrochloride
-  ... Equivalent - pyridoxine
-  ... Active - d-alpha-tocopheryl acetate
-  ... Equivalent - d-alpha-tocopheryl acetate
-  ... Equivalent - d-alpha-tocopherol
-  ... Active - Laminaria japonica
-  ... Equivalent - iodine
-  ... [s47](#)
-  ... Excipient - silicon dioxide
-  ... Excipient - maltodextrin
-  ... Excipient - Acacia
-  ... Excipient - croscarmellose sodium
-  ... Excipient - crospovidone
-  ... Excipient - microcrystalline cellulose
-  ... Excipient - magnesium stearate
-  ... Excipient - dl-alpha-tocopherol
-  ... Excipient - povidone

Manufacturers

[s47](#)

Indications

Permitted Indications:

-  ... Antioxidant/Reduce free radicals formed in the body
-  ... Maintain/support natural liver cleansing/detoxification processes
-  ... Maintain/support energy levels
-  ... Helps convert (state food) into energy
-  ... Maintain/support energy production
-  ... Maintain/support healthy eye function
-  ... Maintain/support eye health
-  ... Maintain/support general health and wellbeing
-  ... Aid/assist nail growth
-  ... Aid/assist/helps connective tissue production/formation
-  ... Maintain/support healthy body tissues

-  ... Maintain/support red blood cell health
-  ... Helps maintain/support haemoglobin formation/synthesis
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal spasm
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
-  ... Traditionally used in Western herbal medicine to relieve digestive discomfort
-  ... Traditionally used in Western herbal medicine to digestive tonic/improve digestive weakness
-  ... Maintain/support healthy liver function
-  ... Maintain/support liver health
-  ... Maintain/support healthy immune system function
-  ... Maintain/support healthy immune system function
-  ... Aid/assist/helps glucose/sugar/carbohydrate metabolism
-  ... Maintain/support (state vitamin/mineral) within normal range
-  ... Maintain/support (state vitamin/mineral) within normal range
-  ... Maintain/support skin health

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

Indication Requirements:

-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Product presentation must not imply or refer to chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
-  ... Product presentation must not imply or refer to drugs/alcohol.
-  ... Product presentation must not imply or refer to eating disorders.
-  ... Product presentation must not imply or refer to gastro oesophageal reflux disease.
-  ... Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
-  ... Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
-  ... Product presentation must not imply or refer to serious cardiovascular conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.
-  ... Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
-  ... Product presentation must only refer to detoxification in relation to natural body processes.

Supporting Documents

Electronic Documents

TRIM Reference:
Audit Trail

Created By:	122703_69187
Last Editor:	122703_69187



Application General

Product Name: HIGHFLEX GLUCOSAMINE HYDROCHLORIDE 1800 ADVANCED
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 21/08/2025 03:19:13 PM
This application is to: Replace an existing listing **AUST L 500045**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

The Coded Warning (SHELL) Contains crustacea OR Contains crustacean products is required when the medicine contains ingredients derived from crustacea or crustacean products. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'glucosamine hydrochloride')

The Coded Warning (GLUTEN) is required where gluten (including in ingredients derived from gluten-containing grains) is present in a medicine in a concentration of 20 parts per million or more. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Maltodextrin')

Ingredient Restriction Rule - Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats. (Ingredient(s) concerned: 'Maltodextrin')

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

The Coded Warning (SODIUM) is required where the total sodium content of the maximum recommended daily dose of the medicine is greater than 120 mg of elemental sodium. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Starch sodium octenyl succinate', 'Sodium chondroitin sulfate')

The Coded Warning (SUGARS) is required where the presence of sugars may have a significant glycaemic effect and the total sugar content (including lactose) exceeds 100 mg per recommended daily dose of the medicine. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Sucrose')

Pass with conditions: When used as an active ingredient, the maximum daily dose must not provide more than 1,200 mg of sodium chondroitin sulfate and the following statements must be included on the medicine label: - (ADULT) 'Adults only' (or words to that effect); - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect) (Ingredient(s) concerned: 'Sodium chondroitin sulfate')

Changes Made
Changes Made Report:

s47

s47

Formulation**Dosage Form:** Tablet, film coated**Routes of Administration:** ... Oral**Container Type:****Container Volume:****Container Closure:****Container Condition:****Maximum Single Dose:****Maximum Daily Dose:**

3

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):****Ingredients**

-  ... Active - glucosamine hydrochloride
-  ... Active - calcium carbonate
-  ... Equivalent - calcium
-  ... Active - colecalciferol
-  ... Active - menaquinone 7
-  ... Active - sodium chondroitin sulfate
-  ... Active - Devil's Claw Tuber Dry
-  ... Active - Boswellia serrata
-  ... Equivalent - boswellic acid
-  ... Active - Secale cereale
-  ... [s47](#)
-  ... Excipient - maltodextrin
-  ... Excipient - povidone
-  ... Excipient - medium chain triglycerides
-  ... Excipient - Acacia
-  ... Excipient - silicon dioxide
-  ... Excipient - glyceryl monostearate
-  ... Excipient - starch sodium octenyl succinate
-  ... Excipient - spray-dried glucose syrup
-  ... Excipient - microcrystalline cellulose
-  ... Excipient - crospovidone
-  ... Excipient - magnesium stearate
-  ... Excipient - sucrose
-  ... Excipient - maize starch
-  ... Excipient - copovidone
-  ... Excipient - monobasic calcium phosphate
-  ... Excipient - dl-alpha-tocopherol

Manufacturers

s47

S47

Indications**Permitted Indications:**

- ... Maintain/support collagen formation
- ... Maintain/support general health and wellbeing
- ... Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
- ... Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
- ... Helps maintain/supports healthy joint cartilage growth/development/production
- ... Maintain/support joint health
- ... Maintain/support joint mobility/flexibility
- ... Decrease/reduce/relieve mild joint pain/soreness
- ... Maintain/support immune system health
- ... Maintain/support healthy immune system function
- ... Maintain/support muscle function
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
- ... Maintain/support (state vitamin/mineral) within normal range

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

- ... Adults only.
- ... Not recommended for use by pregnant and lactating women

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.
- ... Label statement: If symptoms persist, talk to your health professional.
- ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
- ... Product presentation must not imply or refer to serious immunological diseases.
- ... Product presentation must only refer to mild joint symptoms.

Supporting Documents**Electronic Documents****TRIM Reference:**

Audit Trail

Created By:	122703_69187
Last Editor:	122703_69187



Application General

Product Name: Milk Thistle
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 29/09/2022 12:03:45 PM
This application is to: Replace an existing listing **AUST L 338098**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Croscarmellose sodium')

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. (Ingredient(s) concerned: 'titanium dioxide')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form:

Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

Minimum Weight of Divided Dosage Form

(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - Curcuma longa

 ... Active - inositol

 ... Active - Silybum marianum

 ... Excipient - hypromellose

 ... Excipient - macrogol 400

 ... Excipient - magnesium stearate

 ... Excipient - povidone

 ... Excipient - maltodextrin

... Excipient - crospovidone
... Excipient - iron oxide yellow
... Excipient - croscarmellose sodium
... Excipient - microcrystalline cellulose
... Excipient - hydrogenated vegetable oil
... Excipient - Carnauba Wax
... Excipient - silicon dioxide
... Excipient - calcium hydrogen phosphate dihydrate
... Excipient - titanium dioxide
... Excipient - vanillin
... Excipient - colloidal anhydrous silica

Manufacturers

s47



Indications

Permitted Indications:

... Traditionally used in Western herbal medicine to maintain/support healthy liver function
... Traditionally used in Western herbal medicine to maintain/support liver health

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

Indication Requirements:

... Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:
Last Editor:

123550_69187
123550_69187



Application General

Product Name: Multivitamin liquid for infants
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 27/01/2022 12:12:29 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$870.00
Validation Report:

Changes Made Report:

Formulation

Dosage Form: Oral Liquid
Routes of Administration:
 ... Oral
Container Type:
Container Volume:
Container Closure:
Container Condition:

s47

Minimum Weight of Divided Dosage Form (tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - colecalciferol s47
 ... Active - retinol palmitate
 ... Equivalent - vitamin A
 ... Active - calcium ascorbate dihydrate
 ... Equivalent - ascorbic acid
 ... Active - riboflavin sodium phosphate
 ... Equivalent - riboflavin
 ... Active - nicotinamide
 ... Active - thiamine hydrochloride
 ... Equivalent - thiamine
 ... Active - pyridoxine hydrochloride

... Equivalent - pyridoxine

s47

... Excipient - Stevia rebaudiana

... Excipient - xylitol

... Excipient - potassium sorbate

... Excipient - citric acid

... Excipient - glycerol

... Excipient - dl-alpha-tocopherol

... Excipient - sucrose

... Excipient - purified water

... Excipient - maize starch

... Excipient - Gelatin

Manufacturers

s47

Indications

Permitted Indications:

- ... Maintain/support general health and wellbeing
- ... Maintain/support healthy growth and development
- ... Maintain/support immune system health
- ... Maintain/support healthy immune system function
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
- ... Maintain/support bone strength
- ... Maintain/support teeth strength
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- ... Maintain/support healthy teeth
- ... Maintain/support bone health

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert t approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:
Last Editor:

122701_69187
122701_69187

Created:
Last Edited:



Application General

Product Name: GRAPE SEED
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 11/02/2022 02:33:40 PM
This application is to: Replace an existing listing **AUST L 328611**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Pass with Conditions - When caffeine is a standalone ingredient for internal use or oral application, the following warning statement is required on the medicine label: (ADULT) 'Adults only' (or words to that effect). When caffeine is a component and the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statement are required on the label: (ADULT) 'Adults only' (or words to that effect). (Ingredient(s) concerned: 'Caffeine')

Ingredient Restriction Rule - When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label: - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.' - (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.' (Ingredient(s) concerned: 'Caffeine')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Capsule, hard

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

2

Minimum Weight of Divided Dosage Form

s47

(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - Camellia sinensis

 ... Equivalent - caffeine

 ... Active - ascorbic acid

 ... Active - Vitis vinifera

 ... s47

 ... Excipient - magnesium stearate

 ... Excipient - silicon dioxide

 ... Excipient - microcrystalline cellulose

Manufacturers

s47

Indications

Permitted Indications:

 ... Antioxidant/Reduce free radicals formed in the body

 ... Helps reduce/decrease free radical damage to body cells

 ... Maintain/support collagen formation

 ... Maintain/support general health and wellbeing

 ... Maintain/support skin health

Standard Indications :

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Adults only.
-  ... Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.
-  ... Contains caffeine [state quantity per dosage unit or per mL or per gram of product]
-  ... Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin...

Indication Requirements :

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:
Last Editor:

123550_69187
123550_69187

Created:
Last Edited:



Application General

Product Name: Milk Thistle
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 11/02/2022 02:38:38 PM
This application is to: Replace an existing listing **AUST L 338098**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Croscarmellose sodium')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. (Ingredient(s) concerned: 'titanium dioxide')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Tablet, film coated

Routes of Administration :

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition :

Maximum Single Dose:

Maximum Daily Dose:

Minimum Weight of Divided Dosage Form

(tablets, capsules, metered dose sprays etc.):

Ingredients

-  ... Active - Curcuma longa
-  ... Active - inositol
-  ... Active - Silybum marianum
-  ... Excipient - hydrogenated vegetable oil
-  ... Excipient - calcium hydrogen phosphate dihydrate
-  ... Excipient - microcrystalline cellulose
-  ... Excipient - magnesium stearate
-  ... Excipient - silicon dioxide
-  ... Excipient - crospovidone
-  ... Excipient - croscarmellose sodium
-  ... Excipient - povidone
-  ... Excipient - maltodextrin
-  ... Excipient - colloidal anhydrous silica
-  ... Excipient - hypromellose
-  ... Excipient - macrogol 400
-  ... Excipient - vanillin
-  ... Excipient - Carnauba Wax
-  ... Excipient - iron oxide yellow
-  ... Excipient - titanium dioxide

Manufacturers

s47

s47

Indications**Permitted Indications:**

- ... Traditionally used in Western herbal medicine to maintain/support healthy liver function
- ... Traditionally used in Western herbal medicine to maintain/support liver health

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:****Indication Requirements:**

- ... Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:
Last Editor:

123550_69187
123550_69187

Created:
Last Edited:



Application General

Product Name: Iron
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 11/02/2022 02:41:41 PM
This application is to: Replace an existing listing **AUST L 318835**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Ingredient Restriction Rule - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'ferric pyrophosphate')

Pass with conditions - In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). (Ingredient(s) concerned: 'Iron')

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'Iron')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Sodium chloride')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Powder

Routes of Administration:

 ... Oral

Container Type: Sachet

Container Volume:

Container Closure:

Container Condition:

s47

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - ferric pyrophosphate

 ... Equivalent - iron

 ... Excipient - lecithin

 ... Excipient - dextrin

 ... Excipient - sodium chloride

 ... Excipient - beetroot

 ... Excipient - maltodextrin

 ... Excipient - sorbitol

 ... Excipient - xylitol

Manufacturers

s47

s47

Indications**Permitted Indications:**

- ... Maintain/support energy levels
- ... Maintain/support energy production
- ... Maintain/support general health and wellbeing
- ... Aid/assist healthy red blood cell production
- ... Maintain/support blood health
- ... Helps maintain/support transport of oxygen in the body
- ... Aid/assist/helps oxygen transport to body tissues
- ... Helps maintain/support haemoglobin formation/synthesis
- ... Maintain/support immune system health
- ... Maintain/support healthy immune system function
- ... Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- ... Aid/assist/helps synthesis of neurotransmitters

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

- ... Not for the treatment of iron deficiency conditions (or words to that effect).

Indication Requirements:

- ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake dietary calories and increased physical activity.
- ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Product presentation must not imply or refer to chronic fatigue syndrome.
- ... Product presentation must not imply or refer to heart disease.
- ... Product presentation must not imply or refer to serious cardiovascular conditions.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:
Last Editor:

123550_69187
123550_69187

Created:
Last Edited:



Application General

Product Name: Multivitamin + Iron Kids Chewables
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 11/02/2022 02:48:34 PM
This application is to: Replace an existing listing **AUST L 324881**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose.

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Riboflavin sodium phosphate')

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'folic acid')

Ingredient Restriction Rule - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'ferrous fumarate')

Restricted Ingredient Rule - Divided preparations are listable without pack size restrictions when the quantity of iron from all ingredients in the product (excluding up to 10 mg of iron oxide when used as an excipient) is 5 mg or less per dosage unit and the recommended Maximum Daily Dose contains 24 mg or less of iron. (Ingredient(s) concerned: 'Iron')

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'Iron')

Pass with Conditions - The requirements specified in paragraphs (a) to (b) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) When used in a medicine: (i) with an oral route of administration; (ii)

not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). (b) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age. (Ingredient(s) concerned: 'magnesium phosphate tribasic')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Tablet, chewable

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose: 2

Maximum Daily Dose: 2

Minimum Weight of Divided Dosage Form s47

(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - retinol palmitate
 ... Equivalent - vitamin A
 ... Active - calcium ascorbate dihydrate
 ... Equivalent - ascorbic acid
 ... Equivalent - calcium
 ... Active - calcium pantothenate
 ... Equivalent - pantothenic acid
 ... Equivalent - calcium
 ... Active - calcium phosphate
 ... Equivalent - calcium
 ... Active - colesteciferol s47
 ... Active - menaquinone 7
 ... Active - thiamine nitrate s47
 ... Active - nicotinamide s47
 ... Active - pyridoxine hydrochloride s47
 ... Active - riboflavin sodium phosphate
 ... Equivalent - riboflavin
 ... Active - Biotin
 ... Active - folic acid
 ... Active - lysine hydrochloride
 ... Equivalent - lysine
 ... Active - cyanocobalamin
 ... Active - ferrous fumarate
 ... Equivalent - iron
 ... Active - magnesium phosphate tribasic
 ... Equivalent - magnesium
 ... Active - zinc citrate dihydrate
 ... Equivalent - zinc
 ... Active - potassium iodide
 ... Equivalent - iodine

...	s47
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...	
...	Excipient - sorbitol
...	Excipient - magnesium stearate
...	Excipient - thaumatin
...	Excipient - citric acid
...	Excipient - colloidal anhydrous silica
...	Excipient - microcrystalline cellulose
...	Excipient - maize starch
...	Excipient - sucrose
...	Excipient - butylated hydroxytoluene
...	Excipient - dextrin

Manufacturers

s47

Indications

Permitted Indications:

- ... Antioxidant/Reduce free radicals formed in the body
- ... Helps reduce/decrease free radical damage to body cells
- ... Maintain/support energy levels
- ... Maintain/support energy production
- ... Relieve weariness/tiredness/fatigue/feeling of weakness
- ... Maintain/support healthy growth and development
- ... Maintain/support general health and wellbeing
- ... Maintain/support teeth strength
- ... Maintain/support bone health
- ... Aids/assists healthy bone development/growth/building
- ... Maintain/support bone strength
- ... Aid/assist healthy red blood cell production
- ... Maintain/support blood health
- ... Aid/assist/helps in the maintenance of blood levels of oxygen
- ... Helps maintain/support transport of oxygen in the body
- ... Maintain/support immune system health
- ... Maintain/support healthy immune system function
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- ... Maintain/support cognitive function/mental function

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... If symptoms persist consult your healthcare practitioner
- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...

Indication Requirements:

- ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake dietary calories and increased physical activity.
- ... Label statement: If symptoms persist, talk to your health professional.

... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

... Product presentation must not imply or refer to chronic fatigue syndrome.

... Product presentation must not imply or refer to heart disease.

... Product presentation must not imply or refer to mental illnesses, disorders or conditions.

... Product presentation must not imply or refer to serious cardiovascular conditions.

... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:
Last Editor:

123550_69187
123550_69187

Created:
Last Edited:



Application General

Product Name: Calcium + Vitamin D3 & K2 Kids Chewables
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 11/02/2022 02:52:11 PM
This application is to: Replace an existing listing **AUST L 327134**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in

children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Tablet, chewable

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose: 3

Maximum Daily Dose: 3

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.): s47

Ingredients

 ... Active - menaquinone 7

 ... Active - calcium citrate tetrahydrate

 ... Equivalent - calcium

 ... Active - colexcalciferol s47

 ... s47

 ...

 ...

 ... Excipient - sorbitol

 ... Excipient - thaumatin

 ... Excipient - citric acid

 ... Excipient - microcrystalline cellulose

 ... Excipient - colloidal anhydrous silica

 ... Excipient - magnesium stearate

Manufacturers

s47

Indications

Permitted Indications:

 ... Maintain/support healthy growth and development

 ... Maintain/support general health and wellbeing

 ... Maintain/support healthy teeth

 ... Maintain/support teeth mineralisation

 ... Maintain/support teeth strength

 ... Maintain/support bone health

 ... Aids/assists healthy bone development/growth/building

 ... Maintain/support bone strength

 ... Help maintain/support bone mineralisation

 ... Maintain/support immune system health

 ... Maintain/support healthy immune system function

 ... Maintain/support muscle function

 ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

 ... Maintain/support (state vitamin/mineral/nutrient) levels in the body

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

 ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...

Indication Requirements:

 ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

 ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

 ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

 ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:
Last Editor:

123550_69187
123550_69187

Created:
Last Edited:



Application General

Product Name: Pentavite pentalife preconception & pregnancy activated folate
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 11/02/2022 02:56:36 PM
This application is to: Replace an existing listing **AUST L 343478**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Restricted word found: Pregnant/Pregnancy - Medicines that are targeted to pregnant women through the name and/or presentation of the medicine should only use permitted indications that specifically refer to pregnancy. The use of general permitted indications in medicines targeted to pregnant women is not permitted, as the TGA eBS Code Tables do not include a population qualifier for 'pregnancy' or 'pregnant women'. The use of a general permitted indication for a sub-population for which there is no population qualifier may change the meaning and intent of the indication, such that it is no longer a permitted indication. Please refer to the following guidance on the appropriate use of permitted indications for listed medicines that are targeted to pregnancy or pregnant women: <https://www.tga.gov.au/faqs-issues-raised-industry-relation-permitted-indications>.

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. (Ingredient(s) concerned: 'titanium dioxide')

Pass with Conditions - When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'Levomefolate calcium')

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'Levomefolic acid')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Capsule, hard

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

1

Minimum Weight of Divided Dosage Form

(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - levomefolate calcium

 ... Equivalent - levomefolic acid

 ... Excipient - purified water

 ... Excipient - colloidal anhydrous silica

 ... Excipient - titanium dioxide

 ... Excipient - magnesium stearate

... Excipient - Gelatin
 ... Excipient - microcrystalline cellulose

Manufacturers

s47

Indications

Permitted Indications:

... Maintain/support general health and wellbeing in females
 ... Aid/assist healthy red blood cell production in females
 ... Maintains/support healthy foetal development
 ... Maintain/support healthy pregnancy
 ... Maintain/support maternal health
 ... Maintain/support preconception health in females
 ... Maintain/support placenta health/growth

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

... Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin...

Indication Requirements:

... If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly your first trimester.
 ... Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
 ... Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.
 ... Product presentation must not imply or refer to infertility.
 ... Product presentation must not imply or refer to serious cardiovascular conditions.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:
 Last Editor:

123550_69187
 123550_69187

Created:
 Last Edited:



Application General

Product Name: Man Vitality
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 22/02/2022 11:46:12 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$870.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

For Information Only - Species listed on CITES - if exporting or importing this product please contact the Department of Sustainability, Environment, Water, Population and Communities by telephone (DSEWPaC) on 02 6274 1111, facsimile on 02 6274 1921, or email to wildlifetrade@environment.gov.au to determine whether Australia's wildlife legislation places any controls on this ingredient. Further information is available on the Department of Sustainability, Environment, Water, Population and Communities' Wildlife Trade and Conservation website: <http://www.environment.gov.au/biodiversity/trade-use/index.html> (Ingredient(s) concerned: 'Panax quinquefolius')

For Information Only - May be a native species - if exporting this product please contact the Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) by telephone on 02 6274 1111, facsimile on 02 6274 1921, or email to wildlifetrade@environment.gov.au to determine whether Australia's wildlife legislation places any controls on this ingredient. Further information is available on the DSEWPaC's Wildlife Trade and Conservation website: <http://www.environment.gov.au/biodiversity/trade-use/index.html> (Ingredient(s) concerned: 'Tribulus terrestris')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Sodium starch glycollate')

Changes Made Report:

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose: 3

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

 ... Active - zinc citrate dihydrate

 ... Equivalent - zinc

 ... Active - Epimedium sagittatum

 ... Active - Panax quinquefolius

 ... Active - Tribulus terrestris

 ... [s47](#)

 ... Excipient - magnesium stearate

 ... Excipient - povidone

 ... Excipient - microcrystalline cellulose

 ... Excipient - sodium starch glycollate

 ... Excipient - isomalt

Manufacturers

[s47](#)

s47

Indications**Permitted Indications:**

- ... Maintain/support testosterone level
- ... Maintain/support reproductive system health

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:****Indication Requirements:**

- ... Product presentation must not imply or refer to infertility.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:
Last Editor:

122703_69187
123550_69187

Created:
Last Edited:



Application General

Product Name: Immune Support Daily Kids Chewables
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 17/02/2022 03:33:36 PM
This application is to: Replace an existing listing **AUST L 324880**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

When the route of administration is oral, the medicine requires the following warning statement is required on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). (Ingredient(s) concerned: 'honey')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Tablet, chewable

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose: 2

Maximum Daily Dose: 2

Minimum Weight of Divided Dosage Form s47

(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - colecalciferol s47

 ... Active - Honey

 ... Active - retinol palmitate

 ... Equivalent - vitamin A

 ... Active - calcium ascorbate dihydrate

 ... Equivalent - ascorbic acid

 ... Active - Citrus bioflavonoids extract

 ... Active - Sambucus nigra

... Active - zinc citrate dihydrate

... Equivalent - zinc

s47

... Excipient - citric acid

... Excipient - thaumatin

... Excipient - magnesium stearate

... Excipient - sucrose

... Excipient - maltodextrin

... Excipient - maize starch

... Excipient - colloidal anhydrous silica

... Excipient - butylated hydroxytoluene

... Excipient - sorbitol

... Excipient - dextrin

Manufacturers

s47

Indications

Permitted Indications:

- ... Antioxidant/Reduce free radicals formed in the body
- ... Helps reduce/decrease free radical damage to body cells
- ... Maintain/support healthy growth and development
- ... Maintain/support general health and wellbeing
- ... Maintain/support immune system health
- ... Maintain/support healthy immune system function
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold
- ... Linked indication - Decrease/reduce excess mucous
- ... Linked indication - Decrease/reduce/relieve cough

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...
- ... Not suitable for infants under the age of twelve months
- ... Adults only. OR Not to be used in children under two years of age
- ... If symptoms persist consult your healthcare practitioner

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or word that effect).
- ... Label statement: If symptoms persist, talk to your health professional.
- ... Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:
Last Editor:

123550_69187
123550_69187

Created:
Last Edited:



Application General

Product Name: Daily Multivitamin
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 21/02/2022 11:25:03 AM
This application is to: Replace an existing listing **AUST L 364115**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose.

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect). [s47](#)

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). [s47](#)

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'folic acid')

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

Changes Made**Changes Made Report:**

s47

Formulation**Dosage Form:** Pastille**Routes of Administration:** ... Oral**Container Type:****Container Volume:****Container Closure:****Container Condition:****Maximum Single Dose:****Maximum Daily Dose:**

1

Minimum Weight of Divided Dosage Form

s47

(tablets, capsules, metered dose sprays etc.):**Ingredients**

 ... Active - ascorbic acid
 ... Active - nicotinamide
 ... Active - zinc sulfate monohydrate
 ... Equivalent - zinc
 ... Active - cyanocobalamin
 ... Active - colexcalciferol s47
 ... Active - pyridoxine hydrochloride
 ... Equivalent - pyridoxine
 ... Active - potassium iodide
 ... Equivalent - iodine
 ... Active - dl-alpha-tocopheryl acetate
 ... Active - folic acid
 ... Active - menaquinone 7
 ... Active - Biotin
 ... Active - retinol palmitate
 ... Equivalent - vitamin A
 ... s47
 ...
 ...
 ...
 ... Excipient - medium chain triglycerides
 ... Excipient - Gelatin
 ... Excipient - Carnauba Wax
 ... Excipient - silicon dioxide
 ... Excipient - modified food starch
 ... Excipient - citric acid
 ... Excipient - dl-alpha-tocopherol
 ... Excipient - maize starch
 ... Excipient - glucose
 ... Excipient - liquid glucose
 ... Excipient - mannitol
 ... Excipient - purified water
 ... Excipient - sucrose
 ... Excipient - Acacia
 ... Excipient - tricalcium phosphate

Manufacturers

s47

s47

Indications**Permitted Indications:**

- ... Antioxidant/Reduce free radicals formed in the body
- ... Maintain/support energy production in children
- ... Maintain/support healthy growth and development in children
- ... Maintain/support general health and wellbeing in children
- ... Maintain/support healthy teeth
- ... Maintain/support teeth mineralisation in children
- ... Maintain/support teeth strength in children
- ... Maintain/support bone health in children
- ... Aids/assists healthy bone development/growth/building in children
- ... Maintain/support bone strength in children
- ... Help maintain/support bone mineralisation in children
- ... Maintain/support immune system health in children
- ... Maintain/support healthy immune system function in children
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
- ... Maintain/support cognitive function/mental function in children

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...
- ... Contains sugars

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake dietary calories and increased physical activity.
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
- ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:
Last Editor:

119976_69187
119976_69187

Created:
Last Edited:



Application General

Product Name: Daily Immune Support
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 21/02/2022 11:36:05 AM
This application is to: Replace an existing listing **AUST L 364120**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect). [s47](#)

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

When the route of administration is oral, the medicine requires the following warning statement is required on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). (Ingredient(s) concerned: 'honey')

Changes Made

Changes Made Report:

[s47](#)

Formulation

Dosage Form: Pastille

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

4

Minimum Weight of Divided Dosage Form

[s47](#)

(tablets, capsules, metered dose sprays etc.):

Ingredients

-  ... Active - Sambucus nigra
-  ... Active - zinc sulfate monohydrate
-  ... Equivalent - zinc
-  ... Active - ascorbic acid
-  ... Active - Honey
-  ... [s47](#)
-  ...
-  ... Excipient - citric acid
-  ... Excipient - silicon dioxide
-  ... Excipient - sucrose
-  ... Excipient - medium chain triglycerides
-  ... Excipient - Carnauba Wax
-  ... Excipient - glucose
-  ... Excipient - Gelatin
-  ... Excipient - maltodextrin
-  ... Excipient - liquid glucose

Manufacturers

[s47](#)

s47

Indications**Permitted Indications:**

- ... Antioxidant/Reduce free radicals formed in the body in children
- ... Maintain/support healthy growth and development
- ... Maintain/support general health and wellbeing in children
- ... Helps enhance/promote connective tissue health in children
- ... Maintain/support immune system health in children
- ... Maintain/support healthy immune system function in children
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold in children
- ... Linked indication - Decrease/reduce/relieve cough
- ... Maintain/support skin health in children
- ... Maintain/support wound healing in children

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

- ... Not suitable for infants under the age of twelve months
- ... Contains sugars
- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...

Indication Requirements:

- ... Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or word that effect).
- ... Label statement: If symptoms persist, talk to your health professional.
- ... Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:
Last Editor:

119976_69187
119976_69187

Created:
Last Edited:



Application General

Product Name: Daily Calcium + Vit D3
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 21/02/2022 11:53:01 AM
This application is to: Replace an existing listing **AUST L 364119**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect). [s47](#)

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). [s47](#)

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made

Changes Made Report:

[s47](#)

Formulation

Dosage Form: Pastille

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

4

Minimum Weight of Divided Dosage Form

[s47](#)

(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - colecalciferol [s47](#)

 ... Active - calcium phosphate

 ... Equivalent - calcium

 ... [s47](#)

 ...

 ...

 ...

 ... Excipient - maltodextrin

 ... Excipient - sucrose

 ... Excipient - Gelatin

 ... Excipient - citric acid

 ... Excipient - medium chain triglycerides

 ... Excipient - Carnauba Wax

 ... Excipient - liquid glucose

Manufacturers

s47

Indications

Permitted Indications:

- ... Maintain/support healthy growth and development in children
- ... Maintain/support general health and wellbeing in children
- ... Aids/assists teeth development in children
- ... Maintain/support healthy teeth in children
- ... Maintain/support teeth mineralisation in children
- ... Maintain/support teeth strength in children
- ... Maintain/support bone health in children
- ... Aids/assists healthy bone development/growth/building in children
- ... Maintain/support bone strength in children
- ... Help maintain/support bone mineralisation in children
- ... Maintain/support muscle health in children
- ... Maintain/support muscle function in children
- ... Maintain/support healthy neuromuscular system/function in children
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body in children

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... Contains sugars
- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
- ... Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:
Last Editor:

119976_69187
119976_69187

Created:
Last Edited:



Application General

Product Name: Immune Support Daily Kids Chewables
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 31/03/2022 12:55:43 PM
This application is to: Replace an existing listing **AUST L 324880**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

When the route of administration is oral, the medicine requires the following warning statement is required on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). (Ingredient(s) concerned: 'honey')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Tablet, chewable

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

2

Maximum Daily Dose:

2

Minimum Weight of Divided Dosage Form

s47

(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - retinol palmitate

 ... Equivalent - vitamin A

 ... Active - calcium ascorbate dihydrate

 ... Equivalent - ascorbic acid

- ... Active - zinc citrate dihydrate
- ... Equivalent - zinc
- ... Active - Citrus bioflavonoids extract
- ... Active - Honey
- ... Active - Sambucus nigra
- ... Active - coledalciferol s47
- ... s47
- ...
- ...
- ...
- ...
- ...
- ... Excipient - butylated hydroxytoluene
- ... Excipient - citric acid
- ... Excipient - sucrose
- ... Excipient - thaumatin
- ... Excipient - colloidal anhydrous silica
- ... Excipient - maize starch
- ... Excipient - dextrin
- ... Excipient - sorbitol
- ... Excipient - maltodextrin
- ... Excipient - magnesium stearate

Manufacturers

s47

Indications

Permitted Indications:

- ... Antioxidant/Reduce free radicals formed in the body
- ... Helps reduce/decrease free radical damage to body cells
- ... Maintain/support healthy growth and development
- ... Maintain/support general health and wellbeing
- ... Maintain/support immune system health
- ... Maintain/support healthy immune system function
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold
 - ... Linked indication - Decrease/reduce excess mucous
 - ... Linked indication - Decrease/reduce/relieve cough

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...
- ... If symptoms persist consult your healthcare practitioner
- ... Adults only. OR Not to be used in children under two years of age
- ... Not suitable for infants under the age of twelve months

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or word that effect).

-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:	123550_69187	Created:
Last Editor:	123550_69187	Last Edited:



Application General

Product Name: Multivitamin + Iron Kids Chewables
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 31/03/2022 01:02:07 PM
This application is to: Replace an existing listing **AUST L 324881**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

S47

When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose.

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Riboflavin sodium phosphate')

Ingredient Restriction Rule - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'ferrous fumarate')

Restricted Ingredient Rule - Divided preparations are listable without pack size restrictions when the quantity of iron from all ingredients in the product (excluding up to 10 mg of iron oxide when used as an excipient) is 5 mg or less per dosage unit and the recommended Maximum Daily Dose contains 24 mg or less of iron. (Ingredient(s) concerned: 'Iron')

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'Iron')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

Pass with Conditions - When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or

more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age. (Ingredient(s) concerned: 'magnesium phosphate tribasic')

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'folic acid')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Tablet, chewable

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose: 2

Maximum Daily Dose: 2

Minimum Weight of Divided Dosage Form s47
(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - menaquinone 7
 ... Active - pyridoxine hydrochloride s47
 ... Active - zinc citrate dihydrate
 ... Equivalent - zinc
 ... Active - thiamine nitrate s47
 ... Active - cyanocobalamin
 ... Active - colexcalciferol s47
 ... Active - lysine hydrochloride
 ... Equivalent - lysine
 ... Active - calcium pantothenate
 ... Equivalent - calcium
 ... Equivalent - pantothenic acid
 ... Active - riboflavin sodium phosphate
 ... Equivalent - riboflavin
 ... Active - Biotin
 ... Active - ferrous fumarate
 ... Equivalent - iron
 ... Active - retinol palmitate
 ... Equivalent - vitamin A
 ... Active - magnesium phosphate tribasic
 ... Equivalent - magnesium
 ... Active - nicotinamide s47
 ... Active - potassium iodide
 ... Equivalent - iodine
 ... Active - folic acid
 ... Active - calcium ascorbate dihydrate
 ... Equivalent - ascorbic acid
 ... Equivalent - calcium

- ... Active - calcium phosphate
- ... Equivalent - calcium
- ... s47
- ...
- ...
- ...
- ...
- ...
- ...
- ... Excipient - butylated hydroxytoluene
- ... Excipient - maize starch
- ... Excipient - sucrose
- ... Excipient - microcrystalline cellulose
- ... Excipient - sorbitol
- ... Excipient - dextrin
- ... Excipient - citric acid
- ... Excipient - thaumatin
- ... Excipient - magnesium stearate
- ... Excipient - colloidal anhydrous silica

Manufacturers

s47

Indications

Permitted Indications:

- ... Antioxidant/Reduce free radicals formed in the body
- ... Helps reduce/decrease free radical damage to body cells
- ... Maintain/support energy levels
- ... Maintain/support energy production
- ... Relieve weariness/tiredness/fatigue/feeling of weakness
- ... Maintain/support healthy growth and development
- ... Maintain/support general health and wellbeing
- ... Maintain/support teeth strength
- ... Maintain/support bone health
- ... Aids/assists healthy bone development/growth/building
- ... Maintain/support bone strength
- ... Aid/assist healthy red blood cell production
- ... Maintain/support blood health
- ... Aid/assist/helps in the maintenance of blood levels of oxygen
- ... Helps maintain/support transport of oxygen in the body
- ... Maintain/support immune system health
- ... Maintain/support healthy immune system function
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- ... Maintain/support cognitive function/mental function

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... If symptoms persist consult your healthcare practitioner
- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...

Indication Requirements:

-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake dietary calories and increased physical activity.
-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
-  ... Product presentation must not imply or refer to chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to heart disease.
-  ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
-  ... Product presentation must not imply or refer to serious cardiovascular conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:

123550_69187

Created:

Last Editor:

123550_69187

Last Edited:



Application General

Product Name: Calcium + Vitamin D3 & K2 Kids Chewables
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 31/03/2022 01:06:10 PM
This application is to: Replace an existing listing **AUST L 327134**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Tablet, chewable

Routes of Administration:

... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose: 3

Maximum Daily Dose: 3

Minimum Weight of Divided Dosage Form s47
(tablets, capsules, metered dose sprays etc.):

Ingredients

... Active - calcium citrate tetrahydrate

... Equivalent - calcium

... Active - menaquinone 7

... Active - colexaliferol s47

s47

... Excipient - citric acid

... Excipient - magnesium stearate

... Excipient - sorbitol

... Excipient - colloidal anhydrous silica

... Excipient - thaumatin

... Excipient - microcrystalline cellulose

Manufacturers

s47

Indications

Permitted Indications:

... Maintain/support healthy growth and development

... Maintain/support general health and wellbeing

... Maintain/support healthy teeth

... Maintain/support teeth mineralisation

... Maintain/support teeth strength

... Maintain/support bone health

... Aids/assists healthy bone development/growth/building

... Maintain/support bone strength

... Help maintain/support bone mineralisation

... Maintain/support immune system health

... Maintain/support healthy immune system function

-  ... Maintain/support muscle function
-  ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:
Last Editor:

123550_69187
123550_69187

Created:
Last Edited:



Application General

Product Name: Milk Thistle
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 13/04/2022 05:06:43 PM
This application is to: Replace an existing listing **AUST L 338098**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. (Ingredient(s) concerned: 'titanium dioxide')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Croscarmellose sodium')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

Minimum Weight of Divided Dosage Form

(tablets, capsules, metered dose sprays etc.):

Ingredients

-  ... Active - Curcuma longa
-  ... Active - inositol
-  ... Active - Silybum marianum
-  ... Excipient - silicon dioxide
-  ... Excipient - hydrogenated vegetable oil
-  ... Excipient - calcium hydrogen phosphate dihydrate
-  ... Excipient - hypromellose
-  ... Excipient - macrogol 400
-  ... Excipient - iron oxide yellow
-  ... Excipient - Carnauba Wax
-  ... Excipient - povidone
-  ... Excipient - titanium dioxide
-  ... Excipient - croscarmellose sodium
-  ... Excipient - vanillin
-  ... Excipient - crospovidone
-  ... Excipient - microcrystalline cellulose
-  ... Excipient - maltodextrin

... Excipient - magnesium stearate
 ... Excipient - colloidal anhydrous silica

Manufacturers

s47

Indications

Permitted Indications:

... Traditionally used in Western herbal medicine to maintain/support healthy liver function
 ... Traditionally used in Western herbal medicine to maintain/support liver health

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

Indication Requirements:

... Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:
 Last Editor:

119976_69187
 119976_69187

Created:
 Last Edited:



Application General

Product Name: Multivitamin + Iron Liquid for Kids
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory 74-86 Garden Road Clayton VIC 3168
Correspondence Address :
Version: 1

Contact Person:
Contact Telephone:
Contact Email:

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 17/08/2022 05:20:48 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$893.00

Description of changes:
9D(1) correction: No

Validation Report:

Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). s47

Pass with conditions - The requirements specified in paragraphs (a) to (b) below apply to a medicine that contains the ingredient that is: - listed in the Register before 1 March 2022; and - released for supply before 1 March 2023. (a) The maximum recommended daily dose must provide no more than 200 mg of pyridoxine. (b) If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].' The requirements specified in paragraphs (c) to (d) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2022; or - released for supply on or after 1 March 2023. (c) The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. (d) If the maximum recommended daily dose of the medicine provides more than 10 mg of pyridoxine, the following warning statement is required on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].' (Ingredient(s) concerned: 'Pyridoxine')

Ingredient Restriction Rule - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). s47

Pass with conditions - In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).

s47

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). s47

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. s47

Ingredient Restriction Rule - When the quantity of sugar alcohols per maximum recommended daily dose is more than 2 grams, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea (or words to that effect).' (Ingredient(s) concerned: 'Sorbitol solution (70 per cent) (non-crystallising)')

Changes Made Report:

Formulation

Dosage Form: Oral Liquid

Routes of Administration :

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

s47

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

-  ... Active - nicotinamide
-  ... Active - ferric pyrophosphate s47
-  ... Active - thiamine hydrochloride
-  ... Equivalent - thiamine
-  ... Active - pyridoxine hydrochloride
-  ... Equivalent - pyridoxine
-  ... Active - riboflavin sodium phosphate
-  ... Equivalent - riboflavin
-  ... Active - ascorbic acid
-  ... Active - colexcalciferol s47
-  ... s47
-  ...
-  ...
-  ...
-  ... Excipient - potassium sorbate
-  ... Excipient - xanthan gum
-  ... Excipient - purified water
-  ... Excipient - polysorbate 80
-  ... Excipient - sorbitol solution (70 per cent) (non-crystallising)
-  ... Equivalent - sorbitol
-  ... Excipient - saccharin sodium

Manufacturers

s22

Indications

Permitted Indications:

-  ... Maintain/support immune system health
-  ... Maintain/support general health and wellbeing
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
-  ... Maintain/support energy levels
-  ... Maintain/support healthy immune system function
-  ... Maintain/support healthy growth and development

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Contains saccharin sodium (or words to that effect).

 ... Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert t approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

Indication Requirements:

 ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

 ... Product presentation must not imply or refer to chronic fatigue syndrome.

 ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents****TRIM Reference:****TRIM Details:****Audit Trail**

Created By:
Last Editor:

122701_69187
122701_69187

Created:
Last Edited:



Application General

Product Name: Multivitamin liquid for infants
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 11/08/2022 01:51:45 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$893.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal

use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.
(Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Riboflavin sodium phosphate')

Pass with conditions - The requirements specified in paragraphs (a) to (b) below apply to a medicine that contains the ingredient that is: - listed in the Register before 1 March 2022; and - released for supply before 1 March 2023. (a) The maximum recommended daily dose must provide no more than 200 mg of pyridoxine. (b) If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].' The requirements specified in paragraphs (c) to (d) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2022; or - released for supply on or after 1 March 2023. (c) The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. (d) If the maximum recommended daily dose of the medicine provides more than 10 mg of pyridoxine, the following warning statement is required on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].' (Ingredient(s) concerned: 'Pyridoxine')

Changes Made Report:

Formulation

Dosage Form:

Oral Liquid

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition :

s47

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):****Ingredients**

-  ... Active - nicotinamide
-  ... Active - retinol palmitate
-  ... Equivalent - vitamin A
-  ... Active - calcium ascorbate dihydrate
-  ... Equivalent - ascorbic acid
-  ... Active - pyridoxine hydrochloride
-  ... Equivalent - pyridoxine
-  ... Active - colexaliferol s47
-  ... Active - riboflavin sodium phosphate
-  ... Equivalent - riboflavin
-  ... Active - thiamine hydrochloride
-  ... Equivalent - thiamine
-  ... s47
-  ...
-  ...
-  ...
-  ... Excipient - Gelatin
-  ... Excipient - maize starch
-  ... Excipient - glycerol
-  ... Excipient - purified water
-  ... Excipient - citric acid
-  ... Excipient - xylitol
-  ... Excipient - Stevia rebaudiana
-  ... Excipient - sucrose
-  ... Excipient - dl-alpha-tocopherol
-  ... Excipient - potassium sorbate

Manufacturers

s47

Indications**Permitted Indications:**

-  ... Maintain/support general health and wellbeing
-  ... Maintain/support healthy growth and development
-  ... Maintain/support immune system health
-  ... Maintain/support healthy immune system function
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
-  ... Maintain/support bone strength
-  ... Maintain/support teeth strength
-  ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
-  ... Maintain/support healthy teeth
-  ... Maintain/support bone health

Standard Indications:**Specific Indications:****Warnings and Indication Requirements**

Coded Warnings:

 ... Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert t approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

Indication Requirements:

 ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

 ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

 ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

 ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:
Last Editor:

122701_69187
122701_69187

Created:
Last Edited:



Application General

Product Name: Multivitamin + iron liquid kids
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 17/08/2022 03:45:24 PM
This application is to: Replace an existing listing **AUST L 383491**
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$893.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal

use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

Pass with Conditions - When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'Levomefolate calcium')

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'Levomefolic acid')

Restricted Ingredient Rule - Only for use as an active homeopathic ingredient or for excipient use only as a colour in oral and topical medicines. (Ingredient(s) concerned: 'Cochineal')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). [s47](#)

Ingredient Restriction Rule - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). [s47](#)

Pass with conditions - In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). [s47](#)

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). [s47](#)

Pass with conditions - The requirements specified in paragraphs (a) to (b) below apply to a medicine that contains the ingredient that is: - listed in the Register before 1 March 2022; and - released for

supply before 1 March 2023. (a) The maximum recommended daily dose must provide no more than 200 mg of pyridoxine. (b) If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].' The requirements specified in paragraphs (c) to (d) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2022; or - released for supply on or after 1 March 2023. (c) The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. (d) If the maximum recommended daily dose of the medicine provides more than 10 mg of pyridoxine, the following warning statement is required on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].' (Ingredient(s) concerned: 'Pyridoxine')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form:

Oral Liquid

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

s47

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

-  ... Active - retinol palmitate
-  ... Equivalent - vitamin A
-  ... Active - calcium pantothenate
-  ... Equivalent - pantothenic acid
-  ... Active - levomefolate calcium
-  ... Equivalent - levomefolic acid
-  ... Active - nicotinamide
-  ... Active - zinc citrate dihydrate
-  ... Equivalent - zinc
-  ... Active - potassium iodide
-  ... Equivalent - iodine
-  ... Active - ferric pyrophosphate s47
-  ... Active - colecalciferol s47
-  ... Active - Biotin
-  ... Active - mecobalamin (co-methylcobalamin)

- ... Active - ascorbic acid
- ... Active - thiamine hydrochloride
- ... Equivalent - thiamine
- ... Active - pyridoxal 5-phosphate monohydrate
- ... Equivalent - pyridoxine
- ... Active - riboflavin sodium phosphate
- ... Equivalent - riboflavin
- ... [S47](#)
- ...
- ...
- ... Excipient - maize starch
- ... Excipient - Stevia rebaudiana
- ... Excipient - sucrose
- ... Excipient - glycerol
- ... Excipient - cochineal
- ... Excipient - purified water
- ... Excipient - citric acid
- ... Excipient - xanthan gum
- ... Excipient - Gelatin
- ... Excipient - dl-alpha-tocopherol
- ... Excipient - xylitol
- ... Excipient - potassium sorbate

Manufacturers

[S47](#)

Indications

Permitted Indications:

- ... Maintain/support energy levels
- ... Maintain/support healthy growth and development
- ... Maintain/support general health and wellbeing
- ... Maintain/support teeth strength
- ... Maintain/support bone strength
- ... Maintain/support healthy appetite when dietary intake is inadequate
- ... Maintain/support healthy immune system function
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... Contains sorbate(s).

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to

osteoporosis specified in column 2 of Table 2 of this instrument are also used.



... Product presentation must not imply or refer to chronic fatigue syndrome.

... Product presentation must not imply or refer to eating disorders.

... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:

122701_69187

Created:

Last Editor:

122701_69187

Last Edited:



Application General

Product Name: Man Vitality
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory 74-86 Garden Road Clayton VIC 3168
Correspondence Address:
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 31/08/2022 09:18:37 AM
This application is to: Replace an existing listing **AUST L 384791**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

S47

s47

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Sodium starch glycollate')

For Information Only - Species listed on CITES - if exporting or importing this product please contact the Department of Sustainability, Environment, Water, Population and Communities by telephone (DSEWPac) on 02 6274 1111, facsimile on 02 6274 1921, or email to wildlifetrade@environment.gov.au to determine whether Australia's wildlife legislation places any controls on this ingredient. Further information is available on the Department of Sustainability, Environment, Water, Population and Communities' Wildlife Trade and Conservation website: <http://www.environment.gov.au/biodiversity/trade-use/index.html> (Ingredient(s) concerned: 'Panax quinquefolius')

For Information Only - May be a native species - if exporting this product please contact the Department of Sustainability, Environment, Water, Population and Communities (DSEWPac) by telephone on 02 6274 1111, facsimile on 02 6274 1921, or email to wildlifetrade@environment.gov.au to determine whether Australia's wildlife legislation places any controls on this ingredient. Further information is available on the DSEWPac's Wildlife Trade and Conservation website: <http://www.environment.gov.au/biodiversity/trade-use/index.html> (Ingredient(s) concerned: 'Tribulus terrestris')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

3

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

 ... Active - Epimedium sagittatum

 ... Active - zinc citrate dihydrate

 ... Equivalent - zinc

 ... Active - Panax quinquefolius

 ... Active - Tribulus terrestris

 ... s47

 ... Excipient - povidone

 ... Excipient - isomalt

 ... Excipient - microcrystalline cellulose

 ... Excipient - sodium starch glycollate

 ... Excipient - magnesium stearate

Manufacturers

S47



Indications

Permitted Indications:

- ... Maintain/support reproductive system health
- ... Maintain/support testosterone level

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

Indication Requirements:

- ... Product presentation must not imply or refer to infertility.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:
Last Editor:

122703_69187
123550_69187

Created:
Last Edited:



Application General

Product Name: Daily Immune Support
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 14/09/2022 02:22:03 PM
This application is to: Replace an existing listing **AUST L 364120**
Payment Exemption Number:
Application Type: Grouping
Application Status: Completed
Submission Cost: \$893.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

S47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect). (Ingredient(s) concerned: 'Sucrose', 'liquid glucose', 'glucose', 'honey', [s47](#))

When the route of administration is oral, the medicine requires the following warning statement is required on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). (Ingredient(s) concerned: 'honey')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made

Changes Made Report:

[s47](#)

Formulation

Dosage Form: Pastille

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

4

Minimum Weight of Divided Dosage Form

[s47](#)

(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - zinc sulfate monohydrate

 ... Equivalent - zinc

 ... Active - ascorbic acid

 ... Active - Sambucus nigra

 ... Active - Honey

 ... [s47](#)

 ...

 ... Excipient - medium chain triglycerides

 ... Excipient - Carnauba Wax

 ... Excipient - sucrose

 ... Excipient - liquid glucose

 ... Excipient - glucose

 ... Excipient - Gelatin

 ... Excipient - silicon dioxide

 ... Excipient - maltodextrin

 ... Excipient - citric acid

Manufacturers

s47

Indications**Permitted Indications:**

- ... Antioxidant/Reduce free radicals formed in the body in children
- ... Maintain/support general health and wellbeing in children
- ... Maintain/support immune system health in children
- ... Maintain/support healthy immune system function in children
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold in children
- ... Linked indication - Decrease/reduce/relieve cough
- ... Maintain/support skin health in children
- ... Maintain/support wound healing in children
- ... Maintain/support connective tissue health in children
- ... Maintain/support healthy growth and development in children

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...
- ... Not suitable for infants under the age of twelve months
- ... Contains sugars

Indication Requirements:

- ... Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or word that effect).
- ... Label statement: If symptoms persist, talk to your health professional.
- ... Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:
Last Editor:

122701_69187
123550_69187

Created:
Last Edited:



Application General

Product Name: Milk Thistle
Export Names: 
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 16/09/2022 01:32:21 PM
This application is to: Replace an existing listing **AUST L 338098**
Payment Exemption Number:
Application Type: Grouping
Application Status: Completed
Submission Cost: \$893.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47



s47

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Croscarmellose sodium')

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. (Ingredient(s) concerned: 'titanium dioxide')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

Minimum Weight of Divided Dosage Form

(tablets, capsules, metered dose sprays etc.):

Ingredients

-  ... Active - Curcuma longa
-  ... Active - inositol
-  ... Active - Silybum marianum
-  ... Excipient - hypromellose
-  ... Excipient - macrogol 400
-  ... Excipient - magnesium stearate
-  ... Excipient - povidone
-  ... Excipient - maltodextrin
-  ... Excipient - crospovidone
-  ... Excipient - iron oxide yellow
-  ... Excipient - croscarmellose sodium
-  ... Excipient - microcrystalline cellulose
-  ... Excipient - hydrogenated vegetable oil
-  ... Excipient - Carnauba Wax

... Excipient - silicon dioxide
 ... Excipient - calcium hydrogen phosphate dihydrate
 ... Excipient - titanium dioxide
 ... Excipient - vanillin
 ... Excipient - colloidal anhydrous silica

Manufacturers

S47

Indications

Permitted Indications:

... Traditionally used in Western herbal medicine to maintain/support healthy liver function
 ... Traditionally used in Western herbal medicine to maintain/support liver health

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

Indication Requirements:

... Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:
 Last Editor:

123550_69187
 123550_69187

Created:
 Last Edited:



Application General

Product Name: Multivitamin + Iron Kids Chewables
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory 74-86 Garden Road Clayton VIC 3168
Correspondence Address:
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock ? No

Validation Results

Valid from: 29/09/2022 11:34:52 AM
This application is to: Replace an existing listing **AUST L 324881**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

S47

When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose.

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'folic acid')

Pass with Conditions - When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age. (Ingredient(s) concerned: 'magnesium phosphate tribasic')

Ingredient Restrictio Rule - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'ferrous fumarate')

Restricted Ingredient Rule - Divided preparations are listable without pack size restrictions when the quantity of iron from all ingredients in the product (excluding up to 10 mg of iron oxide when used as an excipient) is 5 mg or less per dosage unit and the recommended Maximum Daily Dose contains 24 mg or less of iron. (Ingredient(s) concerned: 'Iron')

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'Iron')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents

for men.” (Ingredient(s) concerned: 'vitamin a')

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Riboflavin sodium phosphate')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Tablet, chewable

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose: 2

Maximum Daily Dose: 2

Minimum Weight of Divided Dosage Form s47
(tablets, capsules, metered dose sprays etc.):

Ingredients

-  ... Active - folic acid
-  ... Active - magnesium phosphate tribasic
-  ... Equivalent - magnesium
-  ... Active - nicotinamide s47
-  ... Active - ferrous fumarate
-  ... Equivalent - iron
-  ... Active - Biotin
-  ... Active - retinol palmitate
-  ... Equivalent - vitamin A
-  ... Active - calcium phosphate
-  ... Equivalent - calcium
-  ... Active - colecalciferol s47
-  ... Active - lysine hydrochloride
-  ... Equivalent - lysine
-  ... Active - cyanocobalamin
-  ... Active - calcium ascorbate dihydrate
-  ... Equivalent - ascorbic acid
-  ... Equivalent - calcium
-  ... Active - calcium pantothenate
-  ... Equivalent - calcium
-  ... Equivalent - pantothenic acid
-  ... Active - thiamine nitrate s47
-  ... Active - zinc citrate dihydrate
-  ... Equivalent - zinc
-  ... Active - pyridoxine hydrochloride s47
-  ... Active - potassium iodide

- ... Equivalent - iodine
- ... Active - menaquinone 7
- ... Active - riboflavin sodium phosphate
- ... Equivalent - riboflavin
- ... s47
- ...
- ...
- ...
- ...
- ...
- ...
- ...
- ... Excipient - dextrin
- ... Excipient - microcrystalline cellulose
- ... Excipient - citric acid
- ... Excipient - maize starch
- ... Excipient - colloidal anhydrous silica
- ... Excipient - sucrose
- ... Excipient - magnesium stearate
- ... Excipient - butylated hydroxytoluene
- ... Excipient - sorbitol
- ... Excipient - thaumatin

Manufacturers

s47

Indications

Permitted Indications:

- ... Antioxidant/Reduce free radicals formed in the body
- ... Helps reduce/decrease free radical damage to body cells
- ... Maintain/support energy levels
- ... Maintain/support energy production
- ... Relieve weariness/tiredness/fatigue/feeling of weakness
- ... Maintain/support healthy growth and development
- ... Maintain/support general health and wellbeing
- ... Maintain/support teeth strength
- ... Maintain/support bone health
- ... Aids/assists healthy bone development/growth/building
- ... Maintain/support bone strength
- ... Aid/assist healthy red blood cell production
- ... Maintain/support blood health
- ... Aid/assist/helps in the maintenance of blood levels of oxygen
- ... Helps maintain/support transport of oxygen in the body
- ... Maintain/support immune system health
- ... Maintain/support healthy immune system function
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- ... Maintain/support cognitive function/mental function

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... If symptoms persist consult your healthcare practitioner
- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...

Indication Requirements:

-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake dietary calories and increased physical activity.
-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
-  ... Product presentation must not imply or refer to chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to heart disease.
-  ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
-  ... Product presentation must not imply or refer to serious cardiovascular conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:
Last Editor:

123550_69187
123550_69187

Created:
Last Edited:



Application General

Product Name: Liver Cleanse
Export Names:  ... s47
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 11/04/2023 04:26:09 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$893.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Croscarmellose sodium')

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. (Ingredient(s) concerned: 'titanium dioxide')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made Report:

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

Ingredients

-  ... Active - d-alpha-tocopheryl acid succinate
-  ... Equivalent - d-alpha-tocopherol
-  ... Active - lycopene
-  ... Active - Silybum marianum
-  ... Equivalent - silymarin
-  ... Active - Curcuma longa
-  ... Excipient - croscarmellose sodium
-  ... Excipient - microcrystalline cellulose
-  ... Excipient - magnesium stearate
-  ... Excipient - silicon dioxide
-  ... Excipient - crospovidone
-  ... Excipient - hypromellose
-  ... Excipient - maltodextrin
-  ... Excipient - macrogol 400
-  ... Excipient - maize starch

-  ... Excipient - vanillin
-  ... Excipient - iron oxide yellow
-  ... Excipient - inositol
-  ... Excipient - dl-alpha-tocopherol
-  ... Excipient - Carnauba Wax
-  ... Excipient - povidone
-  ... Excipient - modified food starch
-  ... Excipient - titanium dioxide
-  ... Excipient - calcium hydrogen phosphate dihydrate

Manufacturers

s47

Indications

Permitted Indications:

-  ... Antioxidant/Reduce free radicals formed in the body
-  ... Maintain/support natural liver cleansing/detoxification processes
-  ... Maintain/support liver health
-  ... Maintain/support healthy liver function
-  ... Maintain/support general health and wellbeing
-  ... Helps maintain/support bile secretion/flow
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
-  ... Traditionally used in Western herbal medicine to maintain/support healthy digestion
-  ... Traditionally used in Western herbal medicine to relieve digestive discomfort
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention
-  ... Maintain/support healthy immune system function when dietary intake is inadequate
-  ... Maintain/support immune system health when dietary intake is inadequate
-  ... Maintain/support wound healing when dietary intake is inadequate
-  ... Maintain/support general health and wellbeing when dietary intake is inadequate
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body when dietary intake is inadequate
-  ... Maintain/support (state vitamin/mineral) within normal range when dietary intake is inadequate

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

-  ... Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
-  ... Product presentation must not imply or refer to drugs/alcohol.
-  ... Product presentation must not imply or refer to gastro oesophageal reflux disease.
-  ... Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
-  ... Product presentation must not imply or refer to serious immunological diseases.
-  ... Product presentation must only refer to detoxification in relation to natural body processes.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:	122701_69187
Last Editor:	122701_69187



Application General

Product Name: Immune Support Daily Kids Chewables
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 02/06/2023 12:21:28 PM
This application is to: Replace an existing listing **AUST L 324880**
Payment Exemption Number:
Application Type: Grouping
Application Status: Completed
Submission Cost: \$893.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

When the route of administration is oral, the medicine requires the following warning statement is required on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). (Ingredient(s) concerned: 'honey')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form:

Tablet, chewable

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:
Container Condition:

Maximum Single Dose: 2
Maximum Daily Dose: 2
Minimum Weight of Divided Dosage Form (tablets, capsules, metered dose sprays etc.): s47

Ingredients

... Active - retinol palmitate
... Equivalent - vitamin A
... Active - calcium ascorbate dihydrate
... Equivalent - ascorbic acid
... Active - zinc citrate dihydrate
... Equivalent - zinc
... Active - Citrus bioflavonoids extract
... Active - Honey
... Active - Sambucus nigra
... Active - colestiferol s47
... s47
...
...
...
...
... Excipient - butylated hydroxytoluene
... Excipient - citric acid
... Excipient - sucrose
... Excipient - thaumatin
... Excipient - colloidal anhydrous silica
... Excipient - maize starch
... Excipient - dextrin
... Excipient - sorbitol
... Excipient - maltodextrin
... Excipient - magnesium stearate

Manufacturers

s47

Indications

Permitted Indications:

... Antioxidant/Reduce free radicals formed in the body
... Helps reduce/decrease free radical damage to body cells
... Maintain/support healthy growth and development
... Maintain/support general health and wellbeing
... Maintain/support immune system health
... Maintain/support healthy immune system function
... Maintain/support (state vitamin/mineral/nutrient) levels in the body
... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold
... Linked indication - Decrease/reduce excess mucous
... Linked indication - Decrease/reduce/relieve cough

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...
-  ... Not suitable for infants under the age of twelve months
-  ... Adults only. OR Not to be used in children under two years of age
-  ... If symptoms persist consult your healthcare practitioner

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:	123550_69187
Last Editor:	123550_69187



Application General

Product Name: Liver detox
Export Names:  ... s47
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 16/11/2022 09:25:29 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$893.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

Pass with conditions - The requirements specified in paragraphs (a) to (b) below apply to a medicine that contains the ingredient that is: - listed in the Register before 1 March 2022; and - released for supply before 1 March 2023. (a) The maximum recommended daily dose must provide no more than 200 mg of pyridoxine. (b) If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].' The requirements specified in paragraphs (c) to (d) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2022; or - released for supply on or after 1 March 2023. (c) The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. (d) If the maximum recommended daily dose of the medicine provides more than 10 mg of pyridoxine, the following warning statement is required on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].' (Ingredient(s) concerned: 'Pyridoxine')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Croscarmellose sodium')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made Report:

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

Ingredients

-  ... Active - Curcuma longa
-  ... Active - Pueraria lobata
-  ... Active - thiamine hydrochloride
-  ... Active - pyridoxine hydrochloride
-  ... Equivalent - pyridoxine
-  ... Active - Silybum marianum
-  ... [s47](#)
-  ... Excipient - vanillin
-  ... Excipient - calcium hydrogen phosphate dihydrate
-  ... Excipient - silicon dioxide
-  ... Excipient - povidone
-  ... Excipient - crospovidone
-  ... Excipient - magnesium stearate
-  ... Excipient - Carnuba Wax
-  ... Excipient - croscarmellose sodium
-  ... Excipient - microcrystalline cellulose
-  ... Excipient - maltodextrin

Manufacturers

[s47](#)

Indications

Permitted Indications:

-  ... Maintain/support general health and wellbeing
-  ... Antioxidant/Reduce free radicals formed in the body
-  ... Maintain/support natural liver cleansing/detoxification processes
-  ... Maintain/support liver health
-  ... Maintain/support healthy liver function
-  ... Helps maintain/support bile secretion/flow
-  ... Traditionally used in Chinese medicine to helps decrease/reduce/relieve symptoms of occasional hangovers
-  ... Linked indication - Helps reduce occurrence of symptoms of headaches
-  ... Relieve weariness/tiredness/fatigue/feeling of weakness
-  ... Traditionally used in Chinese medicine to helps decrease/reduce/relieve symptoms of occasional hangovers
-  ... Linked indication - Relieve irritability
-  ... Helps reduce/decrease free radical damage to body cells
-  ... Maintain/support body metabolism/metabolic rate
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
-  ... Traditionally used in Western herbal medicine to maintain/support healthy digestion
-  ... Traditionally used in Western herbal medicine to relieve digestive discomfort
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention
-  ... Maintain/support immune system health
-  ... Maintain/support healthy immune system function
-  ... Maintain/support nervous system health
-  ... Maintain/support nervous system function
-  ... Aid/assist/helps synthesis of neurotransmitters
-  ... Maintain/support heart health
-  ... Helps maintain/support healthy heart function
-  ... Maintain/support energy production
-  ... Maintain/support energy levels

-  ... Maintain/support muscle function
-  ... Maintain/support nerve conduction

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

Indication Requirements:

-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.
-  ... Product presentation must not imply or refer to chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
-  ... Product presentation must not imply or refer to drugs/alcohol.
-  ... Product presentation must not imply or refer to gastro oesophageal reflux disease.
-  ... Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
-  ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
-  ... Product presentation must not imply or refer to serious cardiovascular conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.
-  ... Product presentation must only refer to detoxification in relation to natural body processes.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:	122701_69187
Last Editor:	122701_69187



Application General

Product Name: Liver Cleanse & Detox
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 04/09/2025 04:55:07 PM
This application is to: Replace an existing listing **AUST L 482812**
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$1014.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

Pass with Condition - When for oral use AND the extract ratio is equal to or more than 25:1 AND the equivalent dry weight per dosage unit is equal to or more than 2g, the medicine requires the following warning statement on the medicine label: - (GINGER) 'Individuals taking anticoagulants should seek medical advice before taking this medicine.' AND 'Individuals at risk of bleeding problems should seek advice from their healthcare practitioner prior to taking this medicine' (Ingredient(s) concerned: 'Zingiber officinale')

The Coded Warning (GLUTEN) is required where gluten (including in ingredients derived from gluten-containing grains) is present in a medicine in a concentration of 20 parts per million or more. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Maltodextrin')

Ingredient Restriction Rule - Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made

Changes Made Report:

s47

Formulation**Dosage Form:** Tablet, film coated**Routes of Administration:** ... Oral**Container Type:****Container Volume:****Container Closure:****Container Condition:****Maximum Single Dose:****Maximum Daily Dose:****Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):****Ingredients** ... Active - Silybum marianum ... Active - inositol ... Active - choline bitartrate ... Equivalent - choline ... Active - Zingiber officinale ... [s47](#) ... Excipient - maltodextrin ... Excipient - microcrystalline cellulose ... Excipient - copovidone ... Excipient - magnesium stearate ... Excipient - silicon dioxide ... Excipient - crospovidone**Manufacturers**[s47](#)**Indications****Permitted Indications:** ... Maintain/support natural liver cleansing/detoxification processes ... Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite ... Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain) ... Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative ... Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal spasm ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia ... Traditionally used in Western herbal medicine to relieve digestive discomfort ... Traditionally used in Western herbal medicine to digestive tonic/improve digestive weakness ... Maintain/support healthy liver function

-  ... Maintain/support liver health
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
-  ... Product presentation must not imply or refer to drugs/alcohol.
-  ... Product presentation must not imply or refer to eating disorders.
-  ... Product presentation must not imply or refer to gastro oesophageal reflux disease.
-  ... Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
-  ... Product presentation must only refer to detoxification in relation to natural body processes.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:	133089_69187
Last Editor:	133089_69187



Application General

Product Name: Iron
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 29/09/2022 12:15:14 PM
This application is to: Replace an existing listing **AUST L 318835**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

Ingredient Restriction Rule - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'ferric pyrophosphate')

Pass with conditions - In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). (Ingredient(s) concerned: 'Iron')

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'Iron')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Sodium chloride')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Powder

Routes of Administration:

 ... Oral

Container Type: Sachet

Container Volume:

Container Closure:

Container Condition:

s47

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - ferric pyrophosphate

 ... Equivalent - iron

 ... Excipient - beetroot

 ... Excipient - dextrin

 ... Excipient - lecithin

... Excipient - sodium chloride
 ... Excipient - maltodextrin
 ... Excipient - sorbitol
 ... Excipient - xylitol

Manufacturers

s47

Indications

Permitted Indications:

... Maintain/support energy levels
 ... Maintain/support energy production
 ... Maintain/support general health and wellbeing
 ... Aid/assist healthy red blood cell production
 ... Maintain/support blood health
 ... Helps maintain/support transport of oxygen in the body
 ... Aid/assist/helps oxygen transport to body tissues
 ... Helps maintain/support haemoglobin formation/synthesis
 ... Maintain/support immune system health
 ... Maintain/support healthy immune system function
 ... Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
 ... Aid/assist/helps synthesis of neurotransmitters

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

... Not for the treatment of iron deficiency conditions (or words to that effect).

Indication Requirements:

... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

... Product presentation must not imply or refer to chronic fatigue syndrome.
 ... Product presentation must not imply or refer to heart disease.
 ... Product presentation must not imply or refer to serious cardiovascular conditions.
 ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:
Audit Trail

Created By:	123550_69187
Last Editor:	123550_69187



Application General

Product Name: Daily Multivitamin
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 17/09/2025 10:43:02 AM
This application is to: Replace an existing listing **AUST L 364115**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose.

The Coded Warning (POTAS1) is required where the total potassium content of the maximum recommended daily dose of the medicine is greater than 39 mg (1mmol) elemental potassium. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Potassium iodide')

Pass with conditions - The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. (Ingredient(s) concerned: 'Pyridoxine')

The Coded Warning (SODIUM) is required where the total sodium content of the maximum recommended daily dose of the medicine is greater than 120 mg of elemental sodium. Refer to the Therapeutic Goods Order No. 92. [s47](#)

The Coded Warning (SUGOLS) is required where total sugar alcohol content of the medicine exceeds 2 g per maximum recommended daily dose. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Mannitol')

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'folic acid')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the

medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Pastille

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

1

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

s47

Ingredients

 ... Active - dl-alpha-tocopheryl acetate
 ... Active - ascorbic acid
 ... Active - zinc sulfate monohydrate
 ... Equivalent - zinc
 ... Active - potassium iodide
 ... Equivalent - iodine
 ... Active - cyanocobalamin
 ... Active - pyridoxine hydrochloride
 ... Equivalent - pyridoxine
 ... Active - colestiferol s47
 ... Active - Biotin
 ... Active - menaquinone 7
 ... Active - nicotinamide
 ... Active - folic acid
 ... Active - retinol palmitate
 ... Equivalent - vitamin A
 ... s47
 ...
 ...
 ...
 ... Excipient - purified water
 ... Excipient - silicon dioxide
 ... Excipient - maize starch
 ... Excipient - dl-alpha-tocopherol
 ... Excipient - citric acid
 ... Excipient - mannitol
 ... Excipient - liquid glucose

-  ... Excipient - Gelatin
-  ... Excipient - glucose
-  ... Excipient - Acacia
-  ... Excipient - Carnauba Wax
-  ... Excipient - sucrose
-  ... Excipient - tricalcium phosphate
-  ... Excipient - modified food starch
-  ... Excipient - medium chain triglycerides

Manufacturers

s47

Indications

Permitted Indications:

-  ... Antioxidant/Reduce free radicals formed in the body
-  ... Maintain/support energy production in children
-  ... Maintain/support healthy growth and development in children
-  ... Maintain/support general health and wellbeing in children
-  ... Maintain/support healthy teeth
-  ... Maintain/support teeth mineralisation in children
-  ... Maintain/support teeth strength in children
-  ... Maintain/support bone health in children
-  ... Aids/assists healthy bone development/growth/building in children
-  ... Maintain/support bone strength in children
-  ... Help maintain/support bone mineralisation in children
-  ... Maintain/support immune system health in children
-  ... Maintain/support healthy immune system function in children
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
-  ... Maintain/support cognitive function/mental function in children

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Contains sugars
-  ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to

osteoporosis specified in column 2 of the table in Part 2 of Schedule 1 to this instrument are also used.



... Product presentation must not imply or refer to mental illnesses, disorders or conditions.



... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:

122703_69187

Last Editor:

122703_69187



Application General

Product Name: Multivitamin liquid for infants
Export Names:
Product Code: Other products
Client Name: s47
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 18/11/2025 12:29:03 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$1014.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

The Coded Warning (SODIUM) is required where the total sodium content of the maximum recommended daily dose of the medicine is greater than 120 mg of elemental sodium. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Riboflavin sodium phosphate')

The Coded Warning (SUGOLS) is required where total sugar alcohol content of the medicine exceeds 2 g per maximum recommended daily dose. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Xylitol')

The Coded Warning (SUGARS) is required where the presence of sugars may have a significant glycaemic effect and the total sugar content (including lactose) exceeds 100 mg per recommended daily dose of the medicine. Refer to the Therapeutic Goods Order No. 92. s47

Pass with conditions - The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. (Ingredient(s) concerned: 'Pyridoxine')

The Coded Warning (POTAS1) is required where the total potassium content of the maximum recommended daily dose of the medicine is greater than 39 mg (1mmol) elemental potassium. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Potassium sorbate')

Changes Made Report:

Formulation

Dosage Form: Oral Liquid

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

s47

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

-  ... Active - retinol palmitate
-  ... Equivalent - vitamin A
-  ... Active - riboflavin sodium phosphate
-  ... Equivalent - riboflavin
-  ... Active - colexcalciferol s47
-  ... Active - nicotinamide
-  ... Active - pyridoxine hydrochloride
-  ... Equivalent - pyridoxine
-  ... Active - thiamine hydrochloride
-  ... Equivalent - thiamine
-  ... Active - calcium ascorbate dihydrate
-  ... Equivalent - ascorbic acid
-  ... s47
-  ...
-  ...
-  ...
-  ... Excipient - silicon dioxide
-  ... Excipient - medium chain triglycerides
-  ... Excipient - lecithin
-  ... Excipient - Acacia
-  ... Excipient - glycerol
-  ... Excipient - Stevia rebaudiana
-  ... Excipient - purified water
-  ... Excipient - Gelatin
-  ... Excipient - citric acid
-  ... Excipient - xylitol

... Excipient - sucrose
 ... Excipient - potassium sorbate
 ... Excipient - dl-alpha-tocopherol
 ... Excipient - maize starch

Manufacturers

s47

Indications

Permitted Indications:

... Maintain/support healthy growth and development
 ... Maintain/support general health and wellbeing
 ... Maintain/support healthy teeth
 ... Maintain/support teeth strength
 ... Maintain/support bone health
 ... Maintain/support bone strength
 ... Maintain/support immune system health
 ... Maintain/support healthy immune system function
 ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
 ... Maintain/support (state vitamin/mineral/nutrient) levels in the body

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

... Contains sorbates

Indication Requirements:

... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
 ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
 ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of the table in Part 2 of Schedule 1 to this instrument are also used.
 ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:
Audit Trail

Created By:	104351_65681
Last Editor:	104351_65681



Application General

Product Name: Multivitamin liquid for infants
Export Names:
Product Code: Other products
Client Name: s47
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 27/01/2026 12:20:48 PM
This application is to: Replace an existing listing **AUST L 520759**
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$1014.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

The Coded Warning (SODIUM) is required where the total sodium content of the maximum recommended daily dose of the medicine is greater than 120 mg of elemental sodium. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Riboflavin sodium phosphate')

The Coded Warning (SUGOLS) is required where total sugar alcohol content of the medicine exceeds 2 g per maximum recommended daily dose. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Xylitol')

The Coded Warning (SUGARS) is required where the presence of sugars may have a significant glycaemic effect and the total sugar content (including lactose) exceeds 100 mg per recommended daily dose of the medicine. Refer to the Therapeutic Goods Order No. 92. s47

Pass with conditions - The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. (Ingredient(s) concerned: 'Pyridoxine')

The Coded Warning (POTAS1) is required where the total potassium content of the maximum recommended daily dose of the medicine is greater than 39 mg (1mmol) elemental potassium. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Potassium sorbate')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: PI - 3195 'Dry Vitamin A Palmitate Type 250 CWS/F' (contains: vitamin a))

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' s47

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the

medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." s47

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form:

Oral Liquid

Routes of Administration:

... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

s47

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

... Active - retinol palmitate s47
 ... Active - riboflavin sodium phosphate
 ... Equivalent - riboflavin
 ... Active - colexcalciferol s47
 ... Active - nicotinamide
 ... Active - pyridoxine hydrochloride
 ... Equivalent - pyridoxine
 ... Active - thiamine hydrochloride
 ... Equivalent - thiamine
 ... Active - calcium ascorbate dihydrate
 ... Equivalent - ascorbic acid
 ... s47
 ...
 ...
 ...
 ...
 ... Excipient - glycerol
 ... Excipient - Stevia rebaudiana

- ... Excipient - purified water
- ... Excipient - citric acid
- ... Excipient - xylitol
- ... Excipient - potassium sorbate
- ... Excipient - lecithin

Manufacturers

S47

Indications

Permitted Indications:

- ... Maintain/support healthy growth and development
- ... Maintain/support general health and wellbeing
- ... Maintain/support healthy teeth
- ... Maintain/support teeth strength
- ... Maintain/support bone health
- ... Maintain/support bone strength
- ... Maintain/support immune system health
- ... Maintain/support healthy immune system function
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... Contains sorbates

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of the table in Part 2 of Schedule 1 to this instrument are also used.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:
Audit Trail

Created By:	104351_65681
Last Editor:	104351_65681



Application General

Product Name: Man Vitality Plus
Export Names:  ... [s47](#)
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 05/02/2026 04:34:29 PM
This application is to: Replace an existing listing [AUST L 459965](#)
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

[s47](#)

s47

For Information Only - Species listed on CITES - if exporting or importing this product please contact the Department of Sustainability, Environment, Water, Population and Communities by telephone (DSEWPaC) on 02 6274 1111, facsimile on 02 6274 1921, or email to wildlifetrade@environment.gov.au to determine whether Australia's wildlife legislation places any controls on this ingredient. Further information is available on the Department of Sustainability, Environment, Water, Population and Communities' Wildlife Trade and Conservation website: <http://www.environment.gov.au/biodiversity/trade-use/index.html> (Ingredient(s) concerned: 'Panax ginseng')

For Information Only - May be a native species - if exporting this product please contact the Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) by telephone on 02 6274 1111, facsimile on 02 6274 1921, or email to wildlifetrade@environment.gov.au to determine whether Australia's wildlife legislation places any controls on this ingredient. Further information is available on the DSEWPaC's Wildlife Trade and Conservation website: <http://www.environment.gov.au/biodiversity/trade-use/index.html> (Ingredient(s) concerned: 'Tribulus terrestris')

The Coded Warning (GLUTEN) is required where gluten (including in ingredients derived from gluten-containing grains) is present in a medicine in a concentration of 20 parts per million or more. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Maltodextrin')

Ingredient Restriction Rule - Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats. (Ingredient(s) concerned: 'Maltodextrin')

The Coded Warning (SODIUM) is required where the total sodium content of the maximum recommended daily dose of the medicine is greater than 120 mg of elemental sodium. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Croscarmellose sodium')

Changes Made**Changes Made Report:**

s47

Formulation**Dosage Form:** Tablet, film coated**Routes of Administration:** ... Oral**Container Type:****Container Volume:****Container Closure:****Container Condition:****Maximum Single Dose:****Maximum Daily Dose:**

3

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):****Ingredients** ... Active - Turnera diffusa ... Equivalent - beta-arbutin ... Active - Panax ginseng ... Active - Tribulus terrestris ... Active - zinc citrate dihydrate ... Equivalent - zinc ... s47 ... Excipient - povidone ... Excipient - maltodextrin ... Excipient - crospovidone ... Excipient - croscarmellose sodium ... Excipient - tricalcium phosphate ... Excipient - microcrystalline cellulose ... Excipient - silicon dioxide ... Excipient - magnesium stearate**Manufacturers**

s47

s47

Indications

Permitted Indications:

- ... Antioxidant/Reduce free radicals formed in the body
- ... Traditionally used in Chinese medicine to engender fluid
- ... Traditionally used in Chinese medicine to enhance/promote energy levels
- ... Maintain/support physical endurance/capacity/stamina
- ... Traditionally used in Chinese medicine to maintain/support vitality
- ... Traditionally used in Chinese medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- ... Traditionally used in Western herbal medicine to body tonic
- ... Maintain/support general health and wellbeing
- ... Maintain/support immune system health
- ... Maintain/support healthy immune system function
- ... Maintain/support mental concentration/focus/clarity
- ... Maintain/support cognitive function/mental function
- ... Traditionally used in Chinese medicine to decrease/reduce/relieve headache symptoms
- ... Maintain/support preconception health in healthy males
- ... Maintain/support reproductive system health in males
- ... Maintain/support healthy reproductive hormones
- ... Traditionally used in Western herbal medicine to aphrodisiac/enhance/improve/promote healthy libido
- ... Traditionally used in Western herbal medicine to maintain/support healthy libido
- ... Traditionally used in Western herbal medicine to maintain/support healthy sexual function
- ... Maintain/support sperm health in healthy males
- ... Maintain/support sperm production in healthy males
- ... Maintain/support testosterone level
- ... Traditionally used in Western herbal medicine to maintain/support urinary tract health
- ... Traditionally used in Western herbal medicine to enhance/promote/increase urine output

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

Indication Requirements:

- ... If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
- ... If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.
- ... Label statement: If symptoms persist, talk to your health professional.
- ... Product presentation must not imply or refer to chronic fatigue syndrome.
- ... Product presentation must not imply or refer to hormone imbalances.
- ... Product presentation must not imply or refer to infertility.
- ... Product presentation must not imply or refer to kidney disease.
- ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:	140658_69187
Last Editor:	140658_69187



Application General

Product Name: Multivitamin liquid for infants
Export Names:
Product Code: Other products
Client Name: S47
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 26/02/2026 09:04:14 PM
This application is to: Replace an existing listing **AUST L 522789**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

S47

s47

The Coded Warning (SODIUM) is required where the total sodium content of the maximum recommended daily dose of the medicine is greater than 120 mg of elemental sodium. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Riboflavin sodium phosphate')

The Coded Warning (SUGOLS) is required where total sugar alcohol content of the medicine exceeds 2 g per maximum recommended daily dose. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Xylitol')

The Coded Warning (SUGARS) is required where the presence of sugars may have a significant glycaemic effect and the total sugar content (including lactose) exceeds 100 mg per recommended daily dose of the medicine. Refer to the Therapeutic Goods Order No. 92. s47

Pass with conditions - The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. (Ingredient(s) concerned: 'Pyridoxine')

The Coded Warning (POTAS1) is required where the total potassium content of the maximum recommended daily dose of the medicine is greater than 39 mg (1mmol) elemental potassium. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Potassium sorbate')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. s47

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' s47

s47

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." s47

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Oral Liquid

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

s47

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

 ... Active - riboflavin sodium phosphate

 ... Equivalent - riboflavin

 ... Active - colexcalciferol s47

 ... Active - nicotinamide

 ... Active - pyridoxine hydrochloride

 ... Equivalent - pyridoxine

 ... Active - thiamine hydrochloride

 ... Equivalent - thiamine

 ... Active - calcium ascorbate dihydrate

 ... Equivalent - ascorbic acid

 ... Active - retinol palmitate s47

 ... s47

 ...

 ...

 ...

 ... Excipient - glycerol

 ... Excipient - Stevia rebaudiana

 ... Excipient - purified water

 ... Excipient - citric acid

 ... Excipient - xylitol

 ... Excipient - potassium sorbate

 ... Excipient - lecithin

Manufacturers

s47

Indications**Permitted Indications:**

- ... Maintain/support healthy growth and development
- ... Maintain/support general health and wellbeing
- ... Maintain/support healthy teeth
- ... Maintain/support teeth strength
- ... Maintain/support bone health
- ... Maintain/support bone strength
- ... Maintain/support immune system health
- ... Maintain/support healthy immune system function
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

- ... Contains sorbates

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of the table in Part 2 of Schedule 1 to this instrument are also used.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents****TRIM Reference:**

Audit Trail

Created By:	104351_65681
Last Editor:	104351_65681



Application General

Product Name: Daily Multivitamin
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 03/11/2022 01:14:28 PM
This application is to: Replace an existing listing **AUST L 364115**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose.

Pass with conditions - The requirements specified in paragraphs (a) to (b) below apply to a medicine that contains the ingredient that is: - listed in the Register before 1 March 2022; and - released for supply before 1 March 2023. (a) The maximum recommended daily dose must provide no more than 200 mg of pyridoxine. (b) If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].' The requirements specified in paragraphs (c) to (d) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2022; or - released for supply on or after 1 March 2023. (c) The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. (d) If the maximum recommended daily dose of the medicine provides more than 10 mg of pyridoxine, the following warning statement is required on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].' (Ingredient(s) concerned: 'Pyridoxine')

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect). [s47](#)

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). [s47](#)

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'folic acid')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the

maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

Changes Made Report:

Formulation

Dosage Form: Pastille

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

Minimum Weight of Divided Dosage Form (tablets, capsules, metered dose sprays etc.):

1

s47

Ingredients

 ... Active - dl-alpha-tocopheryl acetate

 ... Active - ascorbic acid

 ... Active - zinc sulfate monohydrate

 ... Equivalent - zinc

 ... Active - potassium iodide

 ... Equivalent - iodine

 ... Active - cyanocobalamin

 ... Active - pyridoxine hydrochloride

 ... Equivalent - pyridoxine

 ... Active - colecalciferol s47

 ... Active - Biotin

- ... Active - menaquinone 7
- ... Active - nicotinamide
- ... Active - folic acid
- ... Active - retinol palmitate
- ... Equivalent - vitamin A
- ... s47
- ...
- ...
- ...
- ... Excipient - purified water
- ... Excipient - silicon dioxide
- ... Excipient - maize starch
- ... Excipient - dl-alpha-tocopherol
- ... Excipient - citric acid
- ... Excipient - mannitol
- ... Excipient - liquid glucose
- ... Excipient - Gelatin
- ... Excipient - glucose
- ... Excipient - Acacia
- ... Excipient - Carnauba Wax
- ... Excipient - sucrose
- ... Excipient - tricalcium phosphate
- ... Excipient - modified food starch
- ... Excipient - medium chain triglycerides

Manufacturers

s47

Indications

Permitted Indications:

- ... Antioxidant/Reduce free radicals formed in the body
- ... Maintain/support energy production in children
- ... Maintain/support healthy growth and development in children
- ... Maintain/support general health and wellbeing in children
- ... Maintain/support healthy teeth
- ... Maintain/support teeth mineralisation in children
- ... Maintain/support teeth strength in children
- ... Maintain/support bone health in children
- ... Aids/assists healthy bone development/growth/building in children
- ... Maintain/support bone strength in children
- ... Help maintain/support bone mineralisation in children
- ... Maintain/support immune system health in children
- ... Maintain/support healthy immune system function in children
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
- ... Maintain/support cognitive function/mental function in children

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Contains sugars
-  ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
-  ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:	122701_69187
Last Editor:	123550_69187



Application General

Product Name: CoQ10 200mg complex soft capsules
Export Names:  ... s47
 ...
 ...
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 01/04/2026 03:00:01 PM
This application is to: Replace an existing listing **AUST L 423899**
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$1014.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

The Coded Warning (SOYA) Contains soya beans OR Contains soya bean products is required where the medicine contains soya beans or soya bean products. This excludes soya oil that is fully refined amongst other ingredients such as vegetable oil derived phytosterols and phytosterol esters from soybean sources. Refer to the Therapeutic Goods Order No. 92. (Ingredient(s) concerned: 'Soya Oil')

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. (Ingredient(s) concerned: 'titanium dioxide')

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

Pass with conditions: When for internal use in combination with Ubiquinol-10, the maximum recommended daily dose must not provide more than 300 milligrams of ubiquinol-10 and ubidecarenone combined. (Ingredient(s) concerned: 'ubidecarenone')

Changes Made

Changes Made Report:

s47

s47

Formulation**Dosage Form:** Capsule, soft**Routes of Administration:** ... Oral**Container Type:****Container Volume:****Container Closure:****Container Condition:****Maximum Single Dose:****Maximum Daily Dose:**

1

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):****Ingredients**

-  ... Active - d-alpha-tocopherol
-  ... Active - menaquinone 7
-  ... Active - ubidecarenone
-  ... Excipient - Soya Oil
-  ... Excipient - titanium dioxide
-  ... Excipient - sunset yellow FCF
-  ... Excipient - iron oxide red
-  ... Excipient - Gelatin
-  ... Excipient - lecithin
-  ... Excipient - purified water
-  ... Excipient - Olive Oil
-  ... Excipient - glycerol
-  ... Excipient - yellow beeswax

Manufacturers

s47

s22

Indications**Permitted Indications:**

- ... Antioxidant/Reduce free radicals formed in the body
- ... Maintain/support energy levels
- ... Maintain/support energy production
- ... Maintain/support general health and wellbeing
- ... Maintain/support cardiovascular system health
- ... Helps maintain/support healthy heart function
- ... Maintain/support healthy cardiovascular system function
- ... Maintain/support heart health
- ... Maintain/support healthy immune system function
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
- ... Maintain/support (state vitamin/mineral) within normal range
- ... Maintain/support wound healing

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

- ... Do not take while on warfarin therapy without medical advice
- ... Contains soya beans OR Contains soya bean products
- ... Contains sulfites

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
- ... Label statement: If symptoms persist, talk to your health professional.
- ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Product presentation must not imply or refer to chronic fatigue syndrome.
- ... Product presentation must not imply or refer to serious cardiovascular conditions.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:
Last Editor:

140658_69187
140658_69187



Application General

Product Name: Daily Immune Support
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 03/11/2022 01:30:53 PM
This application is to: Replace an existing listing **AUST L 364120**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect). [s47](#)

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

When the route of administration is oral, the medicine requires the following warning statement is required on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). (Ingredient(s) concerned: 'honey')

Changes Made Report:

Formulation

Dosage Form: Pastille

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose: 4

Minimum Weight of Divided Dosage Form [s47](#)
(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - zinc sulfate monohydrate

 ... Equivalent - zinc

 ... Active - Honey

 ... Active - ascorbic acid

 ... Active - Sambucus nigra

 ... [s47](#)

 ...

 ... Excipient - sucrose

 ... Excipient - glucose

 ... Excipient - silicon dioxide

 ... Excipient - Carnauba Wax

- ... Excipient - liquid glucose
- ... Excipient - maltodextrin
- ... Excipient - medium chain triglycerides
- ... Excipient - citric acid
- ... Excipient - Gelatin

Manufacturers

s47

Indications

Permitted Indications:

- ... Antioxidant/Reduce free radicals formed in the body in children
- ... Maintain/support healthy growth and development in children
- ... Maintain/support general health and wellbeing in children
- ... Maintain/support connective tissue health in children
- ... Maintain/support immune system health in children
- ... Maintain/support healthy immune system function in children
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold in children
- ... Linked indication - Decrease/reduce/relieve cough
- ... Maintain/support skin health in children
- ... Maintain/support wound healing in children

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...
- ... Contains sugars
- ... Not suitable for infants under the age of twelve months

Indication Requirements:

- ... Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
- ... Label statement: If symptoms persist, talk to your health professional.
- ... Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:
Audit Trail

Created By:	122701_69187
Last Editor:	122701_69187



Application General

Product Name: Multivitamin + Iron Liquid for Kids
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 08/06/2023 01:48:18 PM
This application is to: Replace an existing listing **AUST L 394200**
Payment Exemption Number:
Application Type: Variation
Application Status: Completed
Submission Cost: \$451.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

S47

s47

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). s47

Pass with conditions - The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. (Ingredient(s) concerned: 'Pyridoxine')

Ingredient Restriction Rule - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). s47

Pass with conditions - In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). s47

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). s47

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. s47

Ingredient Restriction Rule - When the quantity of sugar alcohols per maximum recommended daily dose is more than 2 grams, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea (or words to that effect).' (Ingredient(s) concerned: 'Sorbitol solution (70 per cent) (non-crystallising)')

Changes Made**Changes Made Report:**

s47

Formulation**Dosage Form:**

Oral Liquid

Routes of Administration: ... Oral**Container Type:****Container Volume:****Container Closure:****Container Condition:**

s47

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):****Ingredients**

-  ... Active - thiamine hydrochloride
-  ... Equivalent - thiamine
-  ... Active - riboflavin sodium phosphate
-  ... Equivalent - riboflavin
-  ... Active - nicotinamide
-  ... Active - pyridoxine hydrochloride
-  ... Equivalent - pyridoxine
-  ... Active - ascorbic acid
-  ... Active - colexaliferol s47
-  ... Active - ferric pyrophosphate s47
-  ... s47
-  ...
-  ...
-  ...
-  ... Excipient - purified water
-  ... Excipient - sorbitol solution (70 per cent) (non-crystallising)
-  ... Equivalent - sorbitol
-  ... Excipient - xanthan gum
-  ... Excipient - saccharin sodium
-  ... Excipient - potassium sorbate
-  ... Excipient - polysorbate 80

Manufacturers

s47

Indications

Permitted Indications:

-  ... Maintain/support energy levels
-  ... Maintain/support healthy growth and development
-  ... Maintain/support general health and wellbeing
-  ... Maintain/support immune system health
-  ... Maintain/support healthy immune system function
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

-  ... Contains sorbate(s).
-  ... Contains saccharin sodium

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Product presentation must not imply or refer to chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:	122701_69187
Last Editor:	123550_69187



Application General

Product Name: Multivitamin liquid for infants
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 08/06/2023 01:00:17 PM
This application is to: Replace an existing listing **AUST L 393911**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Riboflavin sodium phosphate')

Pass with conditions - The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. (Ingredient(s) concerned: 'Pyridoxine')

Changes Made**Changes Made Report:**

s47

Formulation**Dosage Form:**

Oral Liquid

Routes of Administration: ... Oral**Container Type:****Container Volume:****Container Closure:****Container Condition:**

s47

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):****Ingredients**

-  ... Active - retinol palmitate
-  ... Equivalent - vitamin A
-  ... Active - riboflavin sodium phosphate
-  ... Equivalent - riboflavin
-  ... Active - nicotinamide
-  ... Active - pyridoxine hydrochloride
-  ... Equivalent - pyridoxine
-  ... Active - colexiferol s47
-  ... Active - thiamine hydrochloride
-  ... Equivalent - thiamine
-  ... Active - calcium ascorbate dihydrate
-  ... Equivalent - ascorbic acid
-  ... s47
-  ...
-  ...
-  ... Excipient - purified water
-  ... Excipient - potassium sorbate
-  ... Excipient - citric acid
-  ... Excipient - glycerol
-  ... Excipient - xylitol
-  ... Excipient - Stevia rebaudiana
-  ... Excipient - sucrose
-  ... Excipient - Gelatin
-  ... Excipient - dl-alpha-tocopherol
-  ... Excipient - maize starch

Manufacturers

s47

S47

Indications**Permitted Indications:**

- ... Maintain/support healthy growth and development
- ... Maintain/support general health and wellbeing
- ... Maintain/support healthy teeth
- ... Maintain/support teeth strength
- ... Maintain/support bone health
- ... Maintain/support bone strength
- ... Maintain/support immune system health
- ... Maintain/support healthy immune system function
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

- ... Contains sorbate(s).

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:
Last Editor:

122701_69187
123550_69187



Application General

Product Name: Multivitamin + iron liquid kids
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 18/07/2023 12:40:22 PM
This application is to: Replace an existing listing **AUST L 410632**
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$939.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). s47

Ingredient Restriction Rule - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). s47

Pass with conditions - In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). s47

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). s47

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. s47

Pass with Conditions - When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'Levomefolate calcium')

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'Levomefolic acid')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

Pass with conditions - The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. (Ingredient(s) concerned: 'Pyridoxine')

Restricted Ingredient Rule - Only for use as an active homeopathic ingredient or for excipient use only as a colour in oral and topical medicines. [s47](#)

Changes Made

Changes Made Report:

[s47](#)

Formulation

Dosage Form:

Oral Liquid

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

[s47](#)

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

Ingredients

-  ... Active - ferric pyrophosphate [s47](#)
-  ... Active - thiamine hydrochloride
-  ... Equivalent - thiamine
-  ... Active - potassium iodide
-  ... Equivalent - iodine
-  ... Active - mecobalamin
-  ... Active - ascorbic acid
-  ... Active - calcium pantothenate
-  ... Equivalent - pantothenic acid
-  ... Active - riboflavin sodium phosphate
-  ... Equivalent - riboflavin
-  ... Active - Biotin
-  ... Active - coilecalciferol [s47](#)
-  ... Active - levomefolate calcium
-  ... Equivalent - levomefolic acid
-  ... Active - nicotinamide
-  ... Active - retinol palmitate
-  ... Equivalent - vitamin A
-  ... Active - zinc citrate dihydrate
-  ... Equivalent - zinc
-  ... Active - pyridoxal 5-phosphate monohydrate
-  ... Equivalent - pyridoxine
-  ... [s47](#)
-  ...
-  ...
-  ...
-  ...
-  ...
-  ... Excipient - xylitol
-  ... Excipient - sucrose
-  ... Excipient - Gelatin
-  ... Excipient - citric acid
-  ... Excipient - Stevia rebaudiana
-  ... Excipient - maize starch
-  ... Excipient - purified water
-  ... Excipient - glycerol
-  ... Excipient - dl-alpha-tocopherol
-  ... Excipient - xanthan gum
-  ... Excipient - potassium sorbate

Manufacturers

[s47](#)

Indications

Permitted Indications:

-  ... Maintain/support energy levels
-  ... Maintain/support healthy growth and development
-  ... Maintain/support general health and wellbeing
-  ... Maintain/support teeth strength

-  ... Maintain/support bone strength
-  ... Maintain/support healthy appetite when dietary intake is inadequate
-  ... Maintain/support healthy immune system function
-  ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Contains sorbate(s).

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
-  ... Product presentation must not imply or refer to chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to eating disorders.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:

123550_69187

Last Editor:

122701_69187



Application General

Product Name: Women's Care & Liver Cleanse
Export Names:  ... [s47](#)
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 28/07/2023 09:21:47 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$939.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

[s47](#)

s47

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Sodium ascorbate', 'Croscarmellose sodium')

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. (Ingredient(s) concerned: 'titanium dioxide')

Changes Made Report:

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

Ingredients

-  ... Active - Reynoutria japonica
-  ... Active - sodium ascorbate
-  ... Equivalent - ascorbic acid
-  ... Active - Silybum marianum
-  ... Active - nicotinamide
-  ... Excipient - croscarmellose sodium
-  ... Excipient - hypromellose
-  ... Excipient - magnesium stearate
-  ... Excipient - iron oxide yellow
-  ... Excipient - crospovidone
-  ... Excipient - calcium phosphate
-  ... Excipient - macrogol 400
-  ... Excipient - titanium dioxide
-  ... Excipient - iron oxide red
-  ... Excipient - Carnauba Wax
-  ... Excipient - silicon dioxide
-  ... Excipient - vanillin
-  ... Excipient - microcrystalline cellulose
-  ... Excipient - povidone

Manufacturers

s47

Indications

Permitted Indications:

-  ... Maintain/support general health and wellbeing
-  ... Maintain/support natural liver cleansing/detoxification processes
-  ... Maintain/support healthy liver function
-  ... Maintain/support liver health
-  ... Traditionally used in Chinese medicine to haemagogue/emmenagogue/promotes menstrual flow
-  ... Maintain/support body mucous membrane health
-  ... Maintain/support energy levels
-  ... Maintain/support energy production
-  ... Maintain/support skin health
-  ... Maintain/support nervous system function
-  ... Maintain/support nervous system health
-  ... Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
-  ... Maintain/support wound healing
-  ... Antioxidant/Reduce free radicals formed in the body
-  ... Maintain/support collagen formation
-  ... Aid/assist/helps connective tissue production/formation
-  ... Maintain/support connective tissue health
-  ... Maintain/support bone health
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
-  ... Maintain/support (state vitamin/mineral) within normal range
-  ... Maintain/support immune system health
-  ... Maintain/support healthy immune system function
-  ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Product presentation must not imply or refer to abortifacient action.
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
-  ... Product presentation must not imply or refer to chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
-  ... Product presentation must not imply or refer to drugs/alcohol.
-  ... Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
-  ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.

 ... Product presentation must only refer to detoxification in relation to natural body processes.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:	122701_69187
Last Editor:	122701_69187



Application General

Product Name: Vitamin D3 & K2 Infant & Kids Liquid
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 25/08/2023 04:08:10 PM
This application is to: Replace an existing listing **AUST L 356023**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

This proprietary ingredient is no longer being maintained for accuracy, please contact the supplier for further information.

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. [s47](#)

Changes Made

Changes Made Report:

[s47](#)

Formulation

Dosage Form: Oral Liquid

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

[s47](#)

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

 ... Active - menaquinone 7 [s47](#)

 ... Active - colecalciferol [s47](#)

 ... [s47](#)

 ...

 ...

 ... Excipient - medium chain triglycerides

Manufacturers

[s47](#)

Indications

Permitted Indications:

-  ... Maintain/support healthy growth and development
-  ... Maintain/support general health and wellbeing
-  ... Aids/assists teeth development
-  ... Maintain/support healthy teeth
-  ... Maintain/support teeth mineralisation
-  ... Maintain/support teeth strength
-  ... Maintain/support bone health
-  ... Aids/assists healthy bone development/growth/building
-  ... Maintain/support bone strength
-  ... Help maintain/support bone mineralisation
-  ... Maintain/support immune system health

-  ... Maintain/support healthy immune system function
-  ... Maintain/support muscle health
-  ... Maintain/support muscle function
-  ... Maintain/support healthy neuromuscular system/function
-  ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin...

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
-  ... Product presentation must not imply or refer to serious immunological diseases.
-  ... Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:	123550_69187
Last Editor:	123550_69187



Application General

Product Name: CoQ10 200 mg + Vitamins
Export Names:  ... [s47](#)
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 12/09/2023 03:16:27 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$939.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

[s47](#)

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Pass with conditions: When for internal use in combination with Ubiquinol-10, the maximum recommended daily dose must not provide more than 300 milligrams of ubiquinol-10 and ubidecarenone combined. (Ingredient(s) concerned: 'ubidecarenone')

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. (Ingredient(s) concerned: 'titanium dioxide')

Changes Made Report:

Formulation

Dosage Form: Capsule, soft

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

1

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

 ... Active - thiamine hydrochloride

 ... Equivalent - thiamine

 ... Active - menaquinone 7

 ... Active - ubidecarenone

 ... Active - d-alpha-tocopherol

 ... Excipient - glycerol

 ... Excipient - medium chain triglycerides

 ... Excipient - yellow beeswax

-  ... Excipient - lecithin
-  ... Excipient - Gelatin
-  ... Excipient - hydrogenated coconut oil
-  ... Excipient - Soya Oil
-  ... Excipient - purified water
-  ... Excipient - sorbitol solution (70 per cent) (non-crystallising)
-  ... Equivalent - sorbitol
-  ... Excipient - iron oxide red
-  ... Excipient - Olive Oil
-  ... Excipient - sunset yellow FCF
-  ... Excipient - titanium dioxide

Manufacturers

s47

Indications

Permitted Indications:

-  ... Antioxidant/Reduce free radicals formed in the body
-  ... Maintain/support healthy cardiovascular system function
-  ... Maintain/support cardiovascular system health
-  ... Maintain/support heart health
-  ... Maintain/support energy production
-  ... Maintain/support energy levels
-  ... Maintain/support healthy immune system function
-  ... Maintain/support general health and wellbeing
-  ... Maintain/support wound healing
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
-  ... Maintain/support (state vitamin/mineral) within normal range
-  ... Maintain/support nervous system function
-  ... Maintain/support nervous system health
-  ... Aid/assist/helps synthesis of neurotransmitters
-  ... Maintain/support muscle function
-  ... Maintain/support nerve conduction
-  ... Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
-  ... Helps maintain/support healthy heart function

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Do not take while on warfarin therapy without medical advice.

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of

dietary calories and increased physical activity.

 ... Label statement: If symptoms persist, talk to your health professional.

 ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

 ... Product presentation must not imply or refer to chronic fatigue syndrome.

 ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.

 ... Product presentation must not imply or refer to serious cardiovascular conditions.

 ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:	122703_69187
Last Editor:	131143_69187



Application General

Product Name: Women's Care & Liver Cleanse
Export Names:  ...s47
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 06/11/2023 10:57:36 AM
This application is to: Replace an existing listing **AUST L 417032**
Payment Exemption Number:
Application Type: 9D(1) Variation
Application Status: Completed
Submission Cost: \$474.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. (Ingredient(s) concerned: 'titanium dioxide')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Sodium ascorbate', 'Croscarmellose sodium')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

Ingredients

-  ... Active - nicotinamide
-  ... Active - Silybum marianum
-  ... Active - sodium ascorbate
-  ... Equivalent - ascorbic acid
-  ... Active - Reynoutria japonica
-  ... Excipient - maize starch
-  ... Excipient - iron oxide red
-  ... Excipient - vanillin
-  ... Excipient - crospovidone
-  ... Excipient - iron oxide yellow
-  ... Excipient - titanium dioxide
-  ... Excipient - magnesium stearate
-  ... Excipient - croscarmellose sodium
-  ... Excipient - calcium phosphate
-  ... Excipient - microcrystalline cellulose
-  ... Excipient - povidone
-  ... Excipient - silicon dioxide
-  ... Excipient - macrogol 400
-  ... Excipient - Carnuba Wax
-  ... Excipient - hypromellose

Manufacturers

s47

s47

Indications**Permitted Indications:**

-  ... Antioxidant/Reduce free radicals formed in the body
-  ... Maintain/support collagen formation
-  ... Maintain/support natural liver cleansing/detoxification processes
-  ... Maintain/support energy levels
-  ... Maintain/support energy production
-  ... Maintain/support body mucous membrane health
-  ... Maintain/support general health and wellbeing
-  ... Maintain/support connective tissue health
-  ... Aid/assist/helps connective tissue production/formation
-  ... Maintain/support bone health
-  ... Maintain/support healthy liver function
-  ... Maintain/support liver health
-  ... Maintain/support immune system health
-  ... Maintain/support healthy immune system function
-  ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
-  ... Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
-  ... Maintain/support (state vitamin/mineral) within normal range
-  ... Maintain/support nervous system health
-  ... Maintain/support nervous system function
-  ... Traditionally used in Chinese medicine to haemagogue/emmenagogue/promotes menstrual flow
-  ... Maintain/support skin health
-  ... Maintain/support wound healing

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:****Indication Requirements:**

-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Product presentation must not imply or refer to abortifacient action.
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
-  ... Product presentation must not imply or refer to chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
-  ... Product presentation must not imply or refer to drugs/alcohol.
-  ... Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

-  ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.
-  ... Product presentation must only refer to detoxification in relation to natural body processes.

Supporting Documents

Electronic Documents

 ... Supporting documentation

TRIM Reference: D23-4214083
Audit Trail

Created By:	122703_69187
Last Editor:	131143_69187



Application General

Product Name: Daily Multivitamin
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 02/01/2024 10:22:43 AM
This application is to: Replace an existing listing **AUST L 364115**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the

medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose.

Pass with conditions - The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. (Ingredient(s) concerned: 'Pyridoxine')

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).^{s47}

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).^{s47}

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'folic acid')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A

can cause birth defects.” NOTE: Position this warning at the beginning of the directions for use. - (VITA3) “The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.” (Ingredient(s) concerned: 'vitamin a')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Pastille

Routes of Administration:

... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

1

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

s47

Ingredients

... Active - dl-alpha-tocopheryl acetate

... Active - ascorbic acid

... Active - zinc sulfate monohydrate

... Equivalent - zinc

... Active - potassium iodide

... Equivalent - iodine

... Active - cyanocobalamin

... Active - pyridoxine hydrochloride

... Equivalent - pyridoxine

... Active - colecalciferol s47

... Active - Biotin

... Active - menaquinone 7

... Active - nicotinamide

... Active - folic acid

... Active - retinol palmitate

... Equivalent - vitamin A

... s47

...

...

...

... Excipient - purified water

... Excipient - silicon dioxide

... Excipient - maize starch

... Excipient - dl-alpha-tocopherol

... Excipient - citric acid

... Excipient - mannitol

... Excipient - liquid glucose

... Excipient - Gelatin

... Excipient - glucose

... Excipient - Acacia

... Excipient - Carnauba Wax

- ... Excipient - sucrose
- ... Excipient - tricalcium phosphate
- ... Excipient - modified food starch
- ... Excipient - medium chain triglycerides

Manufacturers

s47

Indications

Permitted Indications:

- ... Antioxidant/Reduce free radicals formed in the body
- ... Maintain/support energy production in children
- ... Maintain/support healthy growth and development in children
- ... Maintain/support general health and wellbeing in children
- ... Maintain/support healthy teeth
- ... Maintain/support teeth mineralisation in children
- ... Maintain/support teeth strength in children
- ... Maintain/support bone health in children
- ... Aids/assists healthy bone development/growth/building in children
- ... Maintain/support bone strength in children
- ... Help maintain/support bone mineralisation in children
- ... Maintain/support immune system health in children
- ... Maintain/support healthy immune system function in children
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
- ... Maintain/support cognitive function/mental function in children

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...
- ... Contains sugars

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
- ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:	123550_69187
Last Editor:	123550_69187



Application General

Product Name: Daily Immune Support
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 02/01/2024 10:30:18 AM
This application is to: Replace an existing listing **AUST L 364120**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars

(monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect). [s47](#)

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

When the route of administration is oral, the medicine requires the following warning statement is required on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). (Ingredient(s) concerned: 'honey')

Changes Made

Changes Made Report:

[s47](#)

Formulation

Dosage Form: Pastille

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

4

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

[s47](#)

Ingredients

 ... Active - zinc sulfate monohydrate

 ... Equivalent - zinc

 ... Active - Honey

 ... Active - ascorbic acid

 ... Active - Sambucus nigra

 [s47](#)

 ...

 ... Excipient - sucrose

 ... Excipient - glucose

 ... Excipient - silicon dioxide

 ... Excipient - Carnauba Wax

 ... Excipient - liquid glucose

 ... Excipient - maltodextrin

 ... Excipient - medium chain triglycerides

 ... Excipient - citric acid

 ... Excipient - Gelatin

Manufacturers

S47

Indications**Permitted Indications:**

- ... Antioxidant/Reduce free radicals formed in the body in children
- ... Maintain/support healthy growth and development in children
- ... Maintain/support general health and wellbeing in children
- ... Maintain/support connective tissue health in children
- ... Maintain/support immune system health in children
- ... Maintain/support healthy immune system function in children
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold in children
- ... Linked indication - Decrease/reduce/relieve cough
- ... Maintain/support skin health in children
- ... Maintain/support wound healing in children

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...
- ... Contains sugars
- ... Not suitable for infants under the age of twelve months

Indication Requirements:

- ... Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
- ... Label statement: If symptoms persist, talk to your health professional.
- ... Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:

123550_69187

Last Editor:

123550_69187



Application General

Product Name: Daily Calcium + Vit D3
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 02/01/2024 10:32:36 AM
This application is to: Replace an existing listing **AUST L 364119**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars

(monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect). [s47](#)

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). [s47](#)

Changes Made

Changes Made Report:

[s47](#)

Formulation

Dosage Form:

Pastille

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

4

Minimum Weight of Divided Dosage Form

[s47](#)

(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - calcium phosphate

 ... Equivalent - calcium

 ... Active - colecalciferol [s47](#)

 ... [s47](#)

 ...

 ...

 ...

 ... Excipient - Gelatin

 ... Excipient - citric acid

 ... Excipient - sucrose

 ... Excipient - maltodextrin

 ... Excipient - medium chain triglycerides

 ... Excipient - Carnauba Wax

 ... Excipient - liquid glucose

Manufacturers

S47

Indications**Permitted Indications:**

- ... Maintain/support healthy growth and development in children
- ... Maintain/support general health and wellbeing in children
- ... Aids/assists teeth development in children
- ... Maintain/support healthy teeth in children
- ... Maintain/support teeth mineralisation in children
- ... Maintain/support teeth strength in children
- ... Maintain/support bone health in children
- ... Aids/assists healthy bone development/growth/building in children
- ... Maintain/support bone strength in children
- ... Help maintain/support bone mineralisation in children
- ... Maintain/support muscle health in children
- ... Maintain/support muscle function in children
- ... Maintain/support healthy neuromuscular system/function in children
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body in children

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...
- ... Contains sugars

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
- ... Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Supporting Documents**Electronic Documents**

TRIM Reference:
Audit Trail

Created By:	123550_69187
Last Editor:	123550_69187



Application General

Product Name: Immune Active
Export Names:  ... s47
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 15/02/2023 05:01:25 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$893.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

'Sodium bicarbonate' as an 'Active' ingredient is only allowed for Oral use for oral rehydration salts in Powdered and Effervescent tablet dosage forms.

Pass with conditions: The medicine requires the following warning statements on the label: - (CFEDIOL) 'Calcifediol may have similar effects to Vitamin D. Consult your health care professional before taking in combination with other medicines.' (or words to that effect); - (OTHVITD) 'The medicine should not be taken in combination with supplements containing Vitamin D without medical advice' (or words to that effect); - (CHILD9) 'Use in children under 9 years is not recommended' (or words to that effect).

Pass with conditions - The requirements specified in paragraphs (a) to (b) below apply to a medicine that contains the ingredient that is: - listed in the Register before 1 March 2022; and - released for supply before 1 March 2023. (a) The maximum recommended daily dose must provide no more than 200 mg of pyridoxine. (b) If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].' The requirements specified in paragraphs (c) to (d) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2022; or - released for supply on or after 1 March 2023. (c) The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. (d) If the maximum recommended daily dose of the medicine provides more than 10 mg of pyridoxine, the following warning statement is required on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].' (Ingredient(s) concerned: 'Pyridoxine')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). s47

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. s47

Pass with conditions: Calcifediol must not be used in medicines with other Vitamin D analogues; such as ergocalciferol or colecalciferol. (Ingredient(s) concerned: 'calcifediol monohydrate')

Changes Made Report:

Formulation**Dosage Form:** Powder**Routes of Administration:** ... Oral**Container Type:****Container Volume:****Container Closure:****Container Condition:**

s47

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):****Ingredients** ... Active - calcifediol monohydrate ... Active - pyridoxine hydrochloride ... Equivalent - pyridoxine ... Active - ascorbic acid ... Active - cyanocobalamin s47 ... Active - thiamine hydrochloride ... Active - riboflavin ... Active - zinc sulfate monohydrate ... Equivalent - zinc ... Active - calcium pantothenate ... Equivalent - pantothenic acid ... s47 ... Excipient - isomalt ... Excipient - sucralose ... Excipient - maltodextrin ... Excipient - citric acid ... Excipient - sodium bicarbonate ... Excipient - Beta vulgaris ... Excipient - tapioca starch**Manufacturers**

s47

Indications**Permitted Indications:** ... Maintain/support immune system health ... Maintain/support healthy immune system function ... Maintain/support general health and wellbeing ... Maintain/support energy production ... Maintain/support nervous system function ... Antioxidant/Reduce free radicals formed in the body ... Relieve weariness/tiredness/fatigue/feeling of weakness**Standard Indications:**

Specific Indications:**Warnings and Indication Requirements****Coded Warnings:**

-  ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
-  ... Use in children under 9 years is not recommended.
-  ... The medicine should not be taken in combination with supplements containing Vitamin D without medical advice (or words to that effect).
-  ... Calcifediol may have similar effects to Vitamin D. Consult your health care professional before taking in combination with other medicines.
-  ... WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

Indication Requirements:

-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Product presentation must not imply or refer to chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:	112840_69187
Last Editor:	112840_69187



Application General

Product Name: Vitamin D3 & K2 Kids Liquid
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 30/05/2019 02:03:41 PM
This application is to: Replace an existing listing **AUST L 317981**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s22

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. s47

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Oral Liquid

Routes of Administration:

... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

s47

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

... Active - menaquinone 7 s47

... Active - colecalciferol s47

 s47

Manufacturers

s22

Indications

Permitted Indications:

- ... Maintain/support general health and wellbeing

- ... Aids/assists teeth development

... Maintain/support healthy teeth

- ... Maintain/support teeth mineralisation

- ... Maintain/support teeth strength

- ... Maintain/support bone health

... Aids/assists healthy bone development/growth/building

- ... Maintain/support bone strength

- ... Help maintain/support bone mineralisation

- ... Maintain/support immune system health

- ... Maintain/support healthy immune system function

- ... Maintain/support muscle health

- ... Maintain/support muscle function

- ... Maintain/support healthy neuromuscular system/function

- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate

- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

 ... Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin...

Indication Requirements:

 ... If product is indicated for supplementation, Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a

 ... Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

 ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

 ... Product presentation must not imply or refer to serious immunological diseases.

 ... Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:

110450_69187

Last Editor:

110450_69187



Application General

Product Name: Iron
Export Names:
Product Code: Other products
Client Name: s47
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Contact Person:
Contact Telephone:
Contact Email:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 07/06/2019 10:52:02 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$820.00

Description of changes:
9D(1) correction: No

Validation Report:

Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

Ingredient Restriction Rule - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'ferric pyrophosphate')

Pass with conditions - In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). (Ingredient(s) concerned: 'Iron')

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statement on the medicine label if supplied after 1 April 2019: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'Iron')

Pass with conditions - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statement on the medicine label: -(IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect) (Ingredient(s) concerned: 'Iron')

When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Sodium chloride')

Pass with Condition - In a solid preparation containing this ingredient, the pH of a 10 g/L aqueous solution must not be more than 11.5. In a liquid or a semi-solid preparation containing this ingredient, the pH of the preparation must not exceed 11.5. (Ingredient(s) concerned: 'Sodium chloride')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made Report:

Formulation

Dosage Form: Powder

Routes of Administration:

 ... Oral

Container Type: Sachet

Container Volume:

Container Closure:
Container Condition:

s47

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

Ingredients

-  ... Active - ferric pyrophosphate
-  ... Equivalent - iron
-  ... Excipient - beetroot
-  ... Excipient - sorbitol
-  ... Excipient - xylitol
-  ... Excipient - maltodextrin
-  ... Excipient - dextrin
-  ... Excipient - sodium chloride
-  ... Excipient - lecithin

Manufacturers

s47

Indications

Permitted Indications:

-  ... Helps maintain/support transport of oxygen in the body
-  ... Aid/assist healthy red blood cell production
-  ... Aid/assist/helps synthesis of neurotransmitters
-  ... Helps maintain/support haemoglobin formation/synthesis
-  ... Maintain/support immune system health
-  ... Maintain/support general health and wellbeing
-  ... Aid/assist/helps oxygen transport to body tissues
-  ... Maintain/support blood health
-  ... Maintain/support energy levels
-  ... Maintain/support energy production
-  ... Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
-  ... Maintain/support healthy immune system function

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Not for the treatment of iron deficiency conditions (or words to that effect).

Indication Requirements:

-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
-  ... Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

-  ... Product presentation must not imply or refer to heart disease.
-  ... Product presentation must not imply or refer to imply chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to serious cardiovascular conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

TRIM Details:

Audit Trail

Created By:

107930_47972

Last Editor:

Rach_47972



Application General

Product Name: Multivitamin + Iron Kids Powder
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 13/06/2019 04:19:00 PM
This application is to: Replace an existing listing **AUST L 318085**
Payment Exemption Number:
Application Type: 9D(1) Variation
Application Status: Completed
Submission Cost: \$420.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose.

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Ingredient Restrictio Rule - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'ferrous fumarate')

Pass with conditions - In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). (Ingredient(s) concerned: 'Iron')

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statement on the medicine label if supplied after 1 April 2019: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). (Ingredient(s) concerned: 'Iron')

Pass with conditions - When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statement on the medicine label: -(IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect) (Ingredient(s) concerned: 'Iron')

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'folic acid')

When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Riboflavin sodium phosphate')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s)

concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

Changes Made Report:

Formulation

Dosage Form: Powder, oral
 Routes of Administration:
 ... Oral
 Container Type:
 Container Volume:
 Container Closure:
 Container Condition:

s47

Minimum Weight of Divided Dosage Form
 (tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - thiamine nitrate s47
 ... Active - zinc citrate dihydrate
 ... Equivalent - zinc
 ... Active - Beta vulgaris
 ... Active - Malpighia glabra
 ... Active - magnesium phosphate tribasic
 ... Equivalent - magnesium
 ... Active - colestiferol s47
 ... Active - calcium phosphate
 ... Equivalent - calcium
 ... Active - calcium pantothenate
 ... Equivalent - pantothenic acid
 ... Active - ferrous fumarate
 ... Equivalent - iron
 ... Active - folic acid
 ... Active - Biotin
 ... Active - calcium ascorbate dihydrate

- ... Equivalent - ascorbic acid
- ... Active - riboflavin sodium phosphate
- ... Equivalent - riboflavin
- ... Active - pyridoxine hydrochloride s47
- ... Active - lysine hydrochloride
- ... Equivalent - lysine
- ... Active - cyanocobalamin
- ... Active - nicotinamide s47
- ... Active - retinol palmitate
- ... Equivalent - vitamin A
- ... Active - menaquinone 7
- s47
- ...
- ...
- ...
- ...
- ...
- ...
- ...
- ... Excipient - maize starch
- ... Excipient - thaumatin
- ... Excipient - butylated hydroxytoluene
- ... Excipient - malic acid
- ... Excipient - maltodextrin
- ... Excipient - dextrin
- ... Excipient - polydextrose
- ... Excipient - colloidal anhydrous silica
- ... Excipient - sucrose
- ... Excipient - citric acid
- ... Excipient - microcrystalline cellulose

Manufacturers

s47

Indications

Permitted Indications:

- ... Antioxidant/Reduce free radicals formed in the body
- ... Maintain/support energy levels
- ... Relieve weariness/tiredness/fatigue/feeling of weakness
- ... Maintain/support healthy growth and development
- ... Maintain/support general health and wellbeing
- ... Maintain/support teeth strength
- ... Maintain/support bone health
- ... Aids/assists healthy bone development/growth/building
- ... Maintain/support bone strength
- ... Aid/assist healthy red blood cell production
- ... Maintain/support blood health
- ... Aid/assist/helps in the maintenance of blood levels of oxygen
- ... Helps maintain/support transport of oxygen in the body
- ... Aid/assist/helps oxygen transport to body tissues
- ... Maintain/support healthy immune system function
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- ... Maintain/support cognitive function/mental function

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

-  ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...
-  ... If symptoms persist consult your healthcare practitioner
-  ... Not for the treatment of iron deficiency conditions (or words to that effect).

Indication Requirements:

-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
-  ... Product presentation must not imply or refer to heart disease.
-  ... Product presentation must not imply or refer to imply chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
-  ... Product presentation must not imply or refer to serious cardiovascular conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:	110450_69187
Last Editor:	110450_69187



Application General

Product Name: Immune Support Daily Kids Chewables
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 10/10/2019 01:52:13 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$840.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the

maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made Report:

Formulation

Dosage Form: Tablet, chewable

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose: 2

Maximum Daily Dose: 2

Minimum Weight of Divided Dosage Form (tablets, capsules, metered dose sprays etc.): s47

Ingredients

 ... Active - colecalciferol s47
 ... Active - Sambucus nigra
 ... Active - retinol palmitate
 ... Equivalent - vitamin A
 ... Active - Honey
 ... Active - calcium ascorbate dihydrate

- ... Equivalent - ascorbic acid
- ... Active - Citrus bioflavonoids extract
- ... Active - zinc citrate dihydrate
- ... Equivalent - zinc
- ... s47
- ...
- ...
- ...
- ...
- ...
- ... Excipient - colloidal anhydrous silica
- ... Excipient - maltodextrin
- ... Excipient - citric acid
- ... Excipient - sucrose
- ... Excipient - sorbitol
- ... Excipient - dextrin
- ... Excipient - butylated hydroxytoluene
- ... Excipient - magnesium stearate
- ... Excipient - maize starch
- ... Excipient - thaumatin

Manufacturers

s47

Indications

Permitted Indications:

- ... Maintain/support immune system health
- ... Maintain/support healthy immune system function
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of common cold symptoms
- ... Linked indication - Decrease/reduce/relieve cough
- ... Linked indication - Decrease/reduce excess mucous
- ... Maintain/support healthy growth and development
- ... Maintain/support general health and wellbeing
- ... Antioxidant/Reduce free radicals formed in the body
- ... Helps reduce/decrease free radical damage to body cells

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... Not suitable for infants under the age of twelve months (or words to that effect).
- ... Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).
- ... If symptoms persist consult your healthcare practitioner (or words to that effect).
- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Indication Requirements:

- ... Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice.
- ... Label statement: If symptoms persist, talk to your health professional.
- ... Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

 ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:	112837_69187
Last Editor:	112837_69187



Application General

Product Name: Calcium + Vitamin D3 & K2 Kids Chewables
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 03/12/2019 09:57:45 AM
This application is to: Replace an existing listing **AUST L 324882**
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$840.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations

only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Tablet, chewable

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose: 3

Maximum Daily Dose: 3

Minimum Weight of Divided Dosage Form s47
(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - menaquinone 7

 ... Active - calcium citrate tetrahydrate

 ... Equivalent - calcium

 ... Active - colexcalciferol s47

 ... s47

 ...

 ...

 ... Excipient - sorbitol

 ... Excipient - thaumatin

 ... Excipient - citric acid

 ... Excipient - microcrystalline cellulose

 ... Excipient - colloidal anhydrous silica

 ... Excipient - magnesium stearate

Manufacturers

s47

Indications

Permitted Indications:

 ... Maintain/support healthy growth and development

 ... Maintain/support general health and wellbeing

 ... Maintain/support healthy teeth

 ... Maintain/support teeth mineralisation

 ... Maintain/support teeth strength

-  ... Maintain/support bone health
-  ... Aids/assists healthy bone development/growth/building
-  ... Maintain/support bone strength
-  ... Help maintain/support bone mineralisation
-  ... Maintain/support immune system health
-  ... Maintain/support healthy immune system function
-  ... Maintain/support muscle function
-  ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a
-  ... Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not int...
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:
Last Editor:

112837_69187
112837_69187



Application General

Product Name: GRAPE SEED
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 23/12/2019 08:48:57 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$840.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

S47

s47

Ingredient Restriction Rule - When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label: - (ADULT) 'Adults only' (or words to that effect). (Ingredient(s) concerned: 'Camellia sinensis')

Ingredient Restriction Rule - Ingredient Restriction Rule - The requirements specified in paragraph (c) below apply to a medicine that contains the ingredient that: - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. A medicine that contains the ingredient and that: - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; may comply with the requirements in paragraph (c) below. c) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label: -(CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80 mg of caffeine'. -(CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding'. (Ingredient(s) concerned: 'Caffeine')

Changes Made Report:

Formulation

Dosage Form: Capsule, hard
 Routes of Administration:
 ... Oral
 Container Type:
 Container Volume:
 Container Closure:
 Container Condition:

Maximum Single Dose:
 Maximum Daily Dose: 2
 Minimum Weight of Divided Dosage Form s47
 (tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - Camellia sinensis
 ... Equivalent - caffeine
 ... Active - Vitis vinifera
 ... Active - ascorbic acid
 ... s47
 ... Excipient - magnesium stearate
 ... Excipient - silicon dioxide
 ... Excipient - microcrystalline cellulose

Manufacturers

s47

Indications

Permitted Indications:

-  ... Antioxidant/Reduce free radicals formed in the body
-  ... Maintain/support collagen formation
-  ... Maintain/support skin health
-  ... Maintain/support general health and wellbeing
-  ... Helps reduce/decrease free radical damage to body cells

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Contains caffeine [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.
-  ... Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.
-  ... Adults only (or words to that effect).
-  ... Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Indication Requirements:

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:	112838_69187
Last Editor:	112838_69187



Application General

Product Name: Milk Thistle
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 11/06/2020 02:58:57 PM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$840.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Croscarmellose sodium')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. (Ingredient(s) concerned: 'titanium dioxide')

Changes Made Report:

Formulation

Dosage Form: Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

**Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):**

Ingredients

-  ... Active - Curcuma longa
-  ... Active - Silybum marianum
-  ... Active - inositol
-  ... Excipient - vanillin
-  ... Excipient - iron oxide yellow
-  ... Excipient - titanium dioxide
-  ... Excipient - microcrystalline cellulose
-  ... Excipient - Carnauba Wax
-  ... Excipient - croscarmellose sodium
-  ... Excipient - macrogol 400
-  ... Excipient - povidone
-  ... Excipient - hydrogenated vegetable oil
-  ... Excipient - colloidal anhydrous silica
-  ... Excipient - maltodextrin
-  ... Excipient - crospovidone
-  ... Excipient - silicon dioxide
-  ... Excipient - magnesium stearate
-  ... Excipient - hypromellose

■ ... Excipient - calcium hydrogen phosphate dihydrate

Manufacturers

S47



Indications

Permitted Indications:

- ... Traditionally used in Western herbal medicine to maintain/support healthy liver function
- ... Traditionally used in Western herbal medicine to maintain/support liver health

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

Indication Requirements:

- ... Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:

112838_69187

Last Editor:

112838_69187



Application General

Product Name: Calcium + Magnesium + Vitamin D3 Kids Liquid
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 21/08/2020 01:23:58 PM
This application is to: Replace an existing listing **AUST L 319887**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg

in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect) s47

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Liquids

Routes of Administration:

... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

s47

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

Ingredients

... Active - magnesium citrate

... Equivalent - magnesium

... Active - colecalciferol s47

... Active - magnesium citrate

... Equivalent - magnesium

... Active - zinc citrate dihydrate

... Equivalent - zinc

... Active - calcium citrate

... Equivalent - calcium

s47

...

...

...

... Excipient - fructose

... Excipient - purified water

... Excipient - Steviol glycosides

... Excipient - xanthan gum

... Excipient - inulin

... Excipient - potassium sorbate

... Excipient - malic acid

Manufacturers

s47

Indications

Permitted Indications:

-  ... Maintain/support energy levels
-  ... Maintain/support energy production
-  ... Maintain/support healthy growth and development
-  ... Maintain/support general health and wellbeing
-  ... Maintain/support healthy teeth
-  ... Maintain/support teeth strength
-  ... Maintain/support bone health
-  ... Aids/assists healthy bone development/growth/building
-  ... Maintain/support bone strength
-  ... Help maintain/support bone mineralisation
-  ... Maintain/support immune system health
-  ... Maintain/support healthy immune system function
-  ... Maintain/support muscle health
-  ... Maintain/support muscle function
-  ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
-  ... Maintain/support nervous system health
-  ... Maintain/support nervous system function

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

-  ... Contains sorbate(s).
-  ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...
-  ... Contains sugars

Indication Requirements:

-  ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
-  ... Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
-  ... Product presentation must not imply or refer to chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:

112838_69187

Last Editor:

112838_69187



Application General

Product Name: Vitamin D3 & K2 Infant & Kids Liquid
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 28/01/2021 09:17:58 AM
This application is to: Replace an existing listing **AUST L 317981**
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$860.00
Validation Report:
Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. s47

Changes Made

Changes Made Report:
s47

Formulation

Dosage Form: Oral Liquid
Routes of Administration:
 ... Oral
Container Type:
Container Volume:
Container Closure:
Container Condition:

s47

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - menaquinone 7 s47
 ... Active - colecalciferol s47
 ... s47
 ...
 ...
 ... Excipient - medium chain triglycerides

Manufacturers

s47

Indications

Permitted Indications:

 ... Maintain/support general health and wellbeing
 ... Aids/assists teeth development
 ... Maintain/support healthy teeth
 ... Maintain/support teeth mineralisation
 ... Maintain/support teeth strength
 ... Maintain/support bone health
 ... Aids/assists healthy bone development/growth/building
 ... Maintain/support bone strength
 ... Help maintain/support bone mineralisation
 ... Maintain/support immune system health
 ... Maintain/support healthy immune system function
 ... Maintain/support muscle health
 ... Maintain/support muscle function
 ... Maintain/support healthy neuromuscular system/function
 ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
 ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
 ... Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate
 ... Maintain/support healthy growth and development

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

 ... Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin...

Indication Requirements:

 ... If product is indicated for supplementation, Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

 ... Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

 ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

 ... Product presentation must not imply or refer to serious immunological diseases.

 ... Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:

112840_69187

Last Editor:

112838_69187



Application General

Product Name: Daily Multivitamin
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Contact Person:
Contact Telephone:
Contact Email:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 23/04/2021 09:51:39 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$860.00

Description of changes:
9D(1) correction: No

Validation Report:

Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose.

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect). [s47](#)

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). [s47](#)

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic

acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'folic acid')

Changes Made Report:

Formulation

Dosage Form: Pastille
 Routes of Administration:
 ... Oral
 Container Type:
 Container Volume:
 Container Closure:
 Container Condition:

Maximum Single Dose:
 Maximum Daily Dose: 1
 Minimum Weight of Divided Dosage Form s47
 (tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - folic acid
 ... Active - potassium iodide
 ... Equivalent - iodine
 ... Active - menaquinone 7
 ... Active - zinc sulfate monohydrate
 ... Equivalent - zinc
 ... Active - retinol palmitate
 ... Equivalent - vitamin A
 ... Active - ascorbic acid
 ... Active - nicotinamide
 ... Active - dl-alpha-tocopheryl acetate
 ... Active - pyridoxine hydrochloride
 ... Equivalent - pyridoxine
 ... Active - Biotin
 ... Active - colecalciferol s47
 ... Active - cyanocobalamin
 ... s47
 ...
 ...
 ...
 ... Excipient - citric acid
 ... Excipient - dl-alpha-tocopherol
 ... Excipient - tricalcium phosphate
 ... Excipient - purified water
 ... Excipient - Acacia
 ... Excipient - Gelatin
 ... Excipient - liquid glucose
 ... Excipient - medium chain triglycerides
 ... Excipient - silicon dioxide
 ... Excipient - modified food starch
 ... Excipient - maize starch
 ... Excipient - sucrose
 ... Excipient - Carnauba Wax
 ... Excipient - mannitol
 ... Excipient - glucose

Manufacturers

S47

Indications**Permitted Indications:**

- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
- ... Maintain/support bone health in children
- ... Maintain/support teeth mineralisation in children
- ... Help maintain/support bone mineralisation in children
- ... Maintain/support teeth strength in children
- ... Antioxidant/Reduce free radicals formed in the body
- ... Maintain/support immune system health in children
- ... Aids/assists healthy bone development/growth/building in children
- ... Maintain/support healthy growth and development in children
- ... Maintain/support healthy immune system function in children
- ... Maintain/support bone strength in children
- ... Maintain/support general health and wellbeing in children
- ... Maintain/support energy production in children
- ... Maintain/support cognitive function/mental function in children
- ... Maintain/support healthy teeth

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
- ... (If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
- ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents**

TRIM Reference:
TRIM Details:

Audit Trail

Created By:	112840_69187
Last Editor:	112838_69187



Application General

Product Name: Daily Calcium + Vit D3
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 23/04/2021 09:54:15 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$860.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement

on the medicine label: - (LACT) 'Contains lactose' (or words to that effect). s47

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect) s47

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made Report:

Formulation

Dosage Form: Pastille

Routes of Administration:

... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

4

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

s47

Ingredients

... Active - calcium phosphate

... Equivalent - calcium

... Active - colecalciferol s47

... s47

...

...

...

... Excipient - sucrose

... Excipient - liquid glucose

... Excipient - medium chain triglycerides

... Excipient - Carnauba Wax

... Excipient - citric acid

... Excipient - Gelatin

... Excipient - maltodextrin

Manufacturers

s47

Indications

Permitted Indications:

-  ... Maintain/support general health and wellbeing in children
-  ... Maintain/support healthy growth and development in children
-  ... Maintain/support (state vitamin/mineral/nutrient) levels in the body in children
-  ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children
-  ... Maintain/support bone health in children
-  ... Maintain/support bone strength in children
-  ... Help maintain/support bone mineralisation in children
-  ... Aids/assists healthy bone development/growth/building in children
-  ... Maintain/support healthy teeth in children
-  ... Maintain/support teeth strength in children
-  ... Maintain/support teeth mineralisation in children
-  ... Aids/assists teeth development in children
-  ... Maintain/support muscle function in children
-  ... Maintain/support muscle health in children
-  ... Maintain/support healthy neuromuscular system/function in children

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
-  ... (If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Indication Requirements:

-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
-  ... Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:

112840_69187

Last Editor:

112838_69187



Application General

Product Name: Daily Immune Support
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 23/04/2021 09:57:07 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$860.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement

on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).s47

When the route of administration is oral, the medicine requires the following warning statement is required on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). (Ingredient(s) concerned: 'honey')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made Report:

Formulation

Dosage Form: Pastille

Routes of Administration:

... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

4

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

s47

Ingredients

... Active - Sambucus nigra

... Active - zinc sulfate monohydrate

... Equivalent - zinc

... Active - ascorbic acid

... Active - Honey

... s47

...

... Excipient - silicon dioxide

... Excipient - medium chain triglycerides

... Excipient - glucose

... Excipient - sucrose

... Excipient - liquid glucose

... Excipient - Gelatin

... Excipient - Carnauba Wax

... Excipient - maltodextrin

... Excipient - citric acid

Manufacturers

s47

Indications

Permitted Indications:

-  ... Maintain/support general health and wellbeing in children
-  ... Antioxidant/Reduce free radicals formed in the body in children
-  ... Helps enhance/promote connective tissue health in children
-  ... Maintain/support immune system health in children
-  ... Maintain/support healthy immune system function in children
-  ... Maintain/support skin health in children
-  ... Maintain/support wound healing in children
-  ... Maintain/support healthy growth and development
-  ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold in children
-  ... Linked indication - Decrease/reduce/relieve cough

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

-  ... (If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].
-  ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
-  ... Not suitable for infants under the age of twelve months (or words to that effect).

Indication Requirements:

-  ... Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:
Last Editor:

112840_69187
112838_69187



Application General

Product Name: Daily Immune Support
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 06/05/2021 03:47:30 PM
This application is to: Replace an existing listing **AUST L 364120**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label

statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect). (Ingredient(s) concerned: 'Sucrose', 'honey', s47, 'liquid glucose', 'glucose')

When the route of administration is oral, the medicine requires the following warning statement is required on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). (Ingredient(s) concerned: 'honey')

Changes Made

Changes Made Report:
s47

Formulation

Dosage Form: Pastille

Routes of Administration:

... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

4

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

s47

Ingredients

... Active - Honey
... Active - Sambucus nigra
... Active - zinc sulfate monohydrate
... Equivalent - zinc
... Active - ascorbic acid
... s47
...
... Excipient - medium chain triglycerides
... Excipient - Carnauba Wax
... Excipient - maltodextrin
... Excipient - citric acid
... Excipient - sucrose
... Excipient - silicon dioxide
... Excipient - liquid glucose
... Excipient - glucose
... Excipient - Gelatin

Manufacturers

s47

Indications

Permitted Indications:

- ... Antioxidant/Reduce free radicals formed in the body in children
- ... Maintain/support healthy growth and development
- ... Maintain/support general health and wellbeing in children
- ... Helps enhance/promote connective tissue health in children
- ... Maintain/support immune system health in children
- ... Maintain/support healthy immune system function in children
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold in children
- ... Linked indication - Decrease/reduce/relieve cough
- ... Maintain/support skin health in children
- ... Maintain/support wound healing in children

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... Contains sugars
- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...
- ... Not suitable for infants under the age of twelve months

Indication Requirements:

- ... Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
- ... Label statement: If symptoms persist, talk to your health professional.
- ... Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:
Last Editor:

112838_69187
112838_69187



Application General

Product Name: Daily Calcium + Vit D3
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 06/05/2021 03:50:42 PM
This application is to: Replace an existing listing **AUST L 364119**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following

warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect). [s47](#)

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). [s47](#)

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made

Changes Made Report:

[s47](#)

Formulation

Dosage Form: Pastille

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose: 4

Minimum Weight of Divided Dosage Form [s47](#)
(tablets, capsules, metered dose sprays etc.):

Ingredients

 ... Active - calcium phosphate

 ... Equivalent - calcium

 ... Active - colecalciferol [s47](#)

 ... [s47](#)

 ...

 ...

 ...

 ... Excipient - sucrose

 ... Excipient - medium chain triglycerides

 ... Excipient - Carnauba Wax

 ... Excipient - liquid glucose

 ... Excipient - citric acid

 ... Excipient - Gelatin

 ... Excipient - maltodextrin

Manufacturers

s47

Indications

Permitted Indications:

- ... Maintain/support healthy growth and development in children
- ... Maintain/support general health and wellbeing in children
- ... Aids/assists teeth development in children
- ... Maintain/support healthy teeth in children
- ... Maintain/support teeth mineralisation in children
- ... Maintain/support teeth strength in children
- ... Maintain/support bone health in children
- ... Aids/assists healthy bone development/growth/building in children
- ... Maintain/support bone strength in children
- ... Help maintain/support bone mineralisation in children
- ... Maintain/support muscle health in children
- ... Maintain/support muscle function in children
- ... Maintain/support healthy neuromuscular system/function in children
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body in children

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... Contains sugars
- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
- ... Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:	112838_69187
Last Editor:	112838_69187



Application General

Product Name: Daily Multivitamin
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 06/05/2021 03:57:02 PM
This application is to: Replace an existing listing **AUST L 364115**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose.

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect). [s47](#)

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). [s47](#)

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'folic acid')

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

Changes Made Report:

s47

Formulation

Dosage Form: Pastille

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

1

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

s47

Ingredients

 ... Active - nicotinamide
 ... Active - retinol palmitate
 ... Equivalent - vitamin A
 ... Active - zinc sulfate monohydrate
 ... Equivalent - zinc
 ... Active - colecalciferol s47
 ... Active - potassium iodide
 ... Equivalent - iodine
 ... Active - pyridoxine hydrochloride
 ... Equivalent - pyridoxine
 ... Active - folic acid
 ... Active - dl-alpha-tocopheryl acetate
 ... Active - cyanocobalamin
 ... Active - Biotin
 ... Active - menaquinone 7
 ... Active - ascorbic acid
 ... s47
 ...
 ...
 ...
 ... Excipient - Gelatin
 ... Excipient - purified water
 ... Excipient - liquid glucose
 ... Excipient - glucose
 ... Excipient - tricalcium phosphate
 ... Excipient - medium chain triglycerides
 ... Excipient - modified food starch
 ... Excipient - maize starch
 ... Excipient - dl-alpha-tocopherol
 ... Excipient - Acacia
 ... Excipient - mannitol
 ... Excipient - citric acid
 ... Excipient - silicon dioxide
 ... Excipient - sucrose
 ... Excipient - Carnauba Wax

Manufacturers

s47

s47

Indications**Permitted Indications:**

- ... Antioxidant/Reduce free radicals formed in the body
- ... Maintain/support energy production in children
- ... Maintain/support healthy growth and development in children
- ... Maintain/support general health and wellbeing in children
- ... Maintain/support healthy teeth
- ... Maintain/support teeth mineralisation in children
- ... Maintain/support teeth strength in children
- ... Maintain/support bone health in children
- ... Aids/assists healthy bone development/growth/building in children
- ... Maintain/support bone strength in children
- ... Help maintain/support bone mineralisation in children
- ... Maintain/support immune system health in children
- ... Maintain/support healthy immune system function in children
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
- ... Maintain/support cognitive function/mental function in children

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

- ... Contains sugars
- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
- ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:
Last Editor:

112838_69187
112838_69187



Application General

Product Name: Daily Multivitamin
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 04/11/2021 03:47:33 PM
This application is to: Replace an existing listing **AUST L 364115**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose.

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect). [s47](#)

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). [s47](#)

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'folic acid')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

s47

Formulation

Dosage Form: Pastille

Routes of Administration:

... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

1

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

s47

Ingredients

... Active - colecalciferol s47
 ... Active - dl-alpha-tocopheryl acetate
 ... Active - zinc sulfate monohydrate
 ... Equivalent - zinc
 ... Active - Biotin
 ... Active - menaquinone 7
 ... Active - cyanocobalamin
 ... Active - nicotinamide
 ... Active - ascorbic acid
 ... Active - folic acid
 ... Active - retinol palmitate
 ... Equivalent - vitamin A
 ... Active - pyridoxine hydrochloride
 ... Equivalent - pyridoxine
 ... Active - potassium iodide
 ... Equivalent - iodine
 ... s47
 ...
 ...
 ...
 ... Excipient - Acacia
 ... Excipient - sucrose
 ... Excipient - glucose
 ... Excipient - liquid glucose
 ... Excipient - maize starch
 ... Excipient - silicon dioxide
 ... Excipient - Gelatin
 ... Excipient - mannitol
 ... Excipient - purified water
 ... Excipient - tricalcium phosphate
 ... Excipient - modified food starch
 ... Excipient - dl-alpha-tocopherol
 ... Excipient - medium chain triglycerides
 ... Excipient - citric acid
 ... Excipient - Carnauba Wax

Manufacturers

s47

s47

Indications**Permitted Indications:**

- ... Antioxidant/Reduce free radicals formed in the body
- ... Maintain/support energy production in children
- ... Maintain/support healthy growth and development in children
- ... Maintain/support general health and wellbeing in children
- ... Maintain/support healthy teeth
- ... Maintain/support teeth mineralisation in children
- ... Maintain/support teeth strength in children
- ... Maintain/support bone health in children
- ... Aids/assists healthy bone development/growth/building in children
- ... Maintain/support bone strength in children
- ... Help maintain/support bone mineralisation in children
- ... Maintain/support immune system health in children
- ... Maintain/support healthy immune system function in children
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
- ... Maintain/support cognitive function/mental function in children

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

- ... Contains sugars
- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
- ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:
Last Editor:

119976_69187
119976_69187



Application General

Product Name: Daily Immune Support
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 04/11/2021 04:13:49 PM
This application is to: Replace an existing listing **AUST L 364120**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine

contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).s47

When the route of administration is oral, the medicine requires the following warning statement is required on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). (Ingredient(s) concerned: 'honey')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Pastille

Routes of Administration:

... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

4

Minimum Weight of Divided Dosage Form

s47

(tablets, capsules, metered dose sprays etc.):

Ingredients

... Active - zinc sulfate monohydrate

... Equivalent - zinc

... Active - Sambucus nigra

... Active - ascorbic acid

... Active - Honey

... s47

...

... Excipient - citric acid

... Excipient - sucrose

... Excipient - medium chain triglycerides

... Excipient - glucose

... Excipient - silicon dioxide

... Excipient - Gelatin

... Excipient - liquid glucose

... Excipient - Carnauba Wax

... Excipient - maltodextrin

Manufacturers

s47

S47

Indications

Permitted Indications:

- ... Antioxidant/Reduce free radicals formed in the body in children
- ... Maintain/support healthy growth and development
- ... Maintain/support general health and wellbeing in children
- ... Helps enhance/promote connective tissue health in children
- ... Maintain/support immune system health in children
- ... Maintain/support healthy immune system function in children
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold in children
- ... Linked indication - Decrease/reduce/relieve cough
- ... Maintain/support skin health in children
- ... Maintain/support wound healing in children

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... Contains sugars
- ... Not suitable for infants under the age of twelve months
- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...

Indication Requirements:

- ... Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
- ... Label statement: If symptoms persist, talk to your health professional.
- ... Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:
Last Editor:

119976_69187
119976_69187



Application General

Product Name: Daily Calcium + Vit D3
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 04/11/2021 04:23:39 PM
This application is to: Replace an existing listing **AUST L 364119**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

S47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine

contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect). s47

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). s47

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Pastille

Routes of Administration:

... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose: 4

Minimum Weight of Divided Dosage Form s47
(tablets, capsules, metered dose sprays etc.):

Ingredients

... Active - colecalciferol s47

... Active - calcium phosphate

... Equivalent - calcium

s47

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Manufacturers

s47

s47

Indications

Permitted Indications:

- ... Maintain/support healthy growth and development in children
- ... Maintain/support general health and wellbeing in children
- ... Aids/assists teeth development in children
- ... Maintain/support healthy teeth in children
- ... Maintain/support teeth mineralisation in children
- ... Maintain/support teeth strength in children
- ... Maintain/support bone health in children
- ... Aids/assists healthy bone development/growth/building in children
- ... Maintain/support bone strength in children
- ... Help maintain/support bone mineralisation in children
- ... Maintain/support muscle health in children
- ... Maintain/support muscle function in children
- ... Maintain/support healthy neuromuscular system/function in children
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body in children

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... Contains sugars
- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
- ... Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Supporting Documents

Electronic Documents

TRIM Reference:

Audit Trail

Created By:	119976_69187
Last Editor:	119976_69187



Application General

Product Name: Daily Multivitamin
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 25/11/2021 05:04:40 PM
This application is to: Replace an existing listing **AUST L 364115**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

S47

When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose.

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect). [s47](#)

Pass with conditions: When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. (Ingredient(s) concerned: 'folic acid')

Ingredient restriction rule - Menaquinone 7 is available for use in listed medicines in oral preparations only with the following restrictions: - the preparation provide not more than 180 micrograms per daily dose in adults; - the preparation provide not more than 90 micrograms per daily dose in children between 10-18 years; - the preparation provide not more than 45 micrograms per daily dose in children less than 10 years of age. (Ingredient(s) concerned: 'Menaquinone 7')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. (Ingredient(s) concerned: 'vitamin a')

Ingredient Restriction Rule: When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' (Ingredient(s) concerned: 'vitamin a')

When Vitamin A is declared as an equivalent of sources other than Betacarotene, and the preparations for internal use in adults contain more than 33 micrograms of Retinol Equivalents per dosage unit, the medicine requires the following warning statements: - (VITA2) "WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect]." NOTE: Position this warning at the beginning of the directions for use. - (VITA4) "WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects." NOTE: Position this warning at the beginning of the directions for use. - (VITA3) "The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men." (Ingredient(s) concerned: 'vitamin a')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). [s47](#)

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Pastille

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

1

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

s47

Ingredients

 ... Active - nicotinamide
 ... Active - ascorbic acid
 ... Active - zinc sulfate monohydrate
 ... Equivalent - zinc
 ... Active - folic acid
 ... Active - cyanocobalamin
 ... Active - menaquinone 7
 ... Active - dl-alpha-tocopheryl acetate
 ... Active - pyridoxine hydrochloride
 ... Equivalent - pyridoxine
 ... Active - retinol palmitate
 ... Equivalent - vitamin A
 ... Active - Biotin
 ... Active - potassium iodide
 ... Equivalent - iodine
 ... Active - colecalciferol s47
 ... s47
 ...
 ...
 ...
 ... Excipient - medium chain triglycerides
 ... Excipient - purified water
 ... Excipient - liquid glucose
 ... Excipient - silicon dioxide
 ... Excipient - tricalcium phosphate
 ... Excipient - dl-alpha-tocopherol
 ... Excipient - citric acid
 ... Excipient - glucose
 ... Excipient - mannitol
 ... Excipient - modified food starch
 ... Excipient - maize starch
 ... Excipient - Carnauba Wax
 ... Excipient - sucrose
 ... Excipient - Gelatin
 ... Excipient - Acacia

Manufacturers

s47

Indications**Permitted Indications:**

- ... Antioxidant/Reduce free radicals formed in the body
- ... Maintain/support energy production in children
- ... Maintain/support healthy growth and development in children
- ... Maintain/support general health and wellbeing in children
- ... Maintain/support healthy teeth
- ... Maintain/support teeth mineralisation in children
- ... Maintain/support teeth strength in children
- ... Maintain/support bone health in children
- ... Aids/assists healthy bone development/growth/building in children
- ... Maintain/support bone strength in children
- ... Help maintain/support bone mineralisation in children
- ... Maintain/support immune system health in children
- ... Maintain/support healthy immune system function in children
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
- ... Maintain/support cognitive function/mental function in children

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...
- ... Contains sugars

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
- ... Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents**

TRIM Reference:
Audit Trail

Created By:	119976_69187
Last Editor:	119976_69187



Application General

Product Name: Daily Immune Support
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 03/12/2021 08:00:26 AM
This application is to: Replace an existing listing **AUST L 364120**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

S47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect) **s47**

When the route of administration is oral, the medicine requires the following warning statement is required on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). (Ingredient(s) concerned: 'honey')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made

Changes Made Report:

s47

Formulation

Dosage Form: Pastille

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

4

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

s47

Ingredients

-  ... Active - Sambucus nigra
-  ... Active - zinc sulfate monohydrate
-  ... Equivalent - zinc
-  ... Active - Honey
-  ... Active - ascorbic acid
-  ... **s47**
-  ...
-  ... Excipient - sucrose
-  ... Excipient - silicon dioxide
-  ... Excipient - glucose
-  ... Excipient - liquid glucose
-  ... Excipient - medium chain triglycerides
-  ... Excipient - Gelatin
-  ... Excipient - citric acid
-  ... Excipient - Carnauba Wax
-  ... Excipient - maltodextrin

Manufacturers

S47

Indications**Permitted Indications:**

- ... Antioxidant/Reduce free radicals formed in the body in children
- ... Maintain/support healthy growth and development
- ... Maintain/support general health and wellbeing in children
- ... Helps enhance/promote connective tissue health in children
- ... Maintain/support immune system health in children
- ... Maintain/support healthy immune system function in children
- ... Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold in children
- ... Linked indication - Decrease/reduce/relieve cough
- ... Maintain/support skin health in children
- ... Maintain/support wound healing in children

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

- ... Contains sugars
- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...
- ... Not suitable for infants under the age of twelve months

Indication Requirements:

- ... Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
- ... Label statement: If symptoms persist, talk to your health professional.
- ... Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents**Electronic Documents****TRIM Reference:****Audit Trail**

Created By:

119976_69187

Last Editor:

119976_69187



Application General

Product Name: Daily Calcium + Vit D3
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Sponsor Regulatory Correspondence Address: Level 6 476 St Kilda Road Melbourne VIC 3004
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 03/12/2021 08:09:59 AM
This application is to: Replace an existing listing **AUST L 364119**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect). [s47](#)

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). [s47](#)

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made

Changes Made Report:

[s47](#)

Formulation

Dosage Form: Pastille

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

4

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

[s47](#)

Ingredients

 ... Active - colecalciferol [s47](#)

 ... Active - calcium phosphate

 ... Equivalent - calcium

 ... [s47](#)

 ...

 ...

 ...

 ... Excipient - sucrose

 ... Excipient - Gelatin

 ... Excipient - maltodextrin

 ... Excipient - liquid glucose

 ... Excipient - medium chain triglycerides

 ... Excipient - Carnauba Wax

 ... Excipient - citric acid

Manufacturers

s47

Indications**Permitted Indications:**

- ... Maintain/support healthy growth and development in children
- ... Maintain/support general health and wellbeing in children
- ... Aids/assists teeth development in children
- ... Maintain/support healthy teeth in children
- ... Maintain/support teeth mineralisation in children
- ... Maintain/support teeth strength in children
- ... Maintain/support bone health in children
- ... Aids/assists healthy bone development/growth/building in children
- ... Maintain/support bone strength in children
- ... Help maintain/support bone mineralisation in children
- ... Maintain/support muscle health in children
- ... Maintain/support muscle function in children
- ... Maintain/support healthy neuromuscular system/function in children
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body in children

Standard Indications:**Specific Indications:****Warnings and Indication Requirements****Coded Warnings:**

- ... Contains sugars
- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
- ... Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Supporting Documents**Electronic Documents**

TRIM Reference:
Audit Trail

Created By:	119976_69187
Last Editor:	119976_69187



Application General

Product Name: Man Vitality+
Export Names:  ... s47
 ...
 ...
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Contact Person:
Contact Telephone:
Contact Email:

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 11/04/2023 11:21:36 AM
This application is to: Create a new listing
Payment Exemption Number:
Application Type: New (A new AUST L will be generated)
Application Status: Completed
Submission Cost: \$893.00

Description of changes:
9D(1) correction: No

Validation Report:

Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47

For Information Only - Species listed on CITES - if exporting or importing this product please contact the Department of Sustainability, Environment, Water, Population and Communities by telephone (DSEWPaC) on 02 6274 1111, facsimile on 02 6274 1921, or email to wildlifetrade@environment.gov.au to determine whether Australia's wildlife legislation places any controls on this ingredient. Further information is available on the Department of Sustainability, Environment, Water, Population and Communities' Wildlife Trade and Conservation website: <http://www.environment.gov.au/biodiversity/trade-use/index.html> (Ingredient(s) concerned: 'Panax quinquefolius')

For Information Only - May be a native species - if exporting this product please contact the Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) by telephone on 02 6274 1111, facsimile on 02 6274 1921, or email to wildlifetrade@environment.gov.au to determine whether Australia's wildlife legislation places any controls on this ingredient. Further information is available on the DSEWPaC's Wildlife Trade and Conservation website: <http://www.environment.gov.au/biodiversity/trade-use/index.html> (Ingredient(s) concerned: 'Tribulus terrestris')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). (Ingredient(s) concerned: 'Croscarmellose sodium', 'Sodium starch glycollate')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

Changes Made Report:

Formulation

Dosage Form:

Tablet, film coated

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:
Container Condition:

Maximum Single Dose:
Maximum Daily Dose:
Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

3

Ingredients

- ... Active - Turnera diffusa
- ... Equivalent - beta-arbutin
- ... Active - Epimedium sagittatum
- ... Active - Panax quinquefolius
- ... Active - Tribulus terrestris
- ... Active - zinc citrate dihydrate
- ... Equivalent - zinc
- ... s47
- ... Excipient - croscarmellose sodium
- ... Excipient - microcrystalline cellulose
- ... Excipient - magnesium stearate
- ... Excipient - crospovidone
- ... Excipient - maltodextrin
- ... Excipient - calcium hydrogen phosphate dihydrate
- ... Excipient - colloidal anhydrous silica
- ... Excipient - sodium starch glycollate
- ... Excipient - povidone

Manufacturers

s47

Indications

Permitted Indications:

- ... Maintain/support reproductive system health in males
- ... Traditionally used in Western herbal medicine to maintain/support urinary tract health
- ... Traditionally used in Chinese medicine to maintain/support vitality
- ... Maintain/support preconception health in healthy males
- ... Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body
- ... Maintain/support sperm production in healthy males
- ... Traditionally used in Chinese medicine to help decrease/reduce/relieve mild muscle spasms/twitches
- ... Traditionally used in Chinese medicine to aphrodisiac/enhance/improve/promote healthy libido
- ... Traditionally used in Chinese medicine to maintain/support general health and wellbeing
- ... Traditionally used in Western herbal medicine to enhance/promote/increase urine output
- ... Traditionally used in Chinese medicine to maintain/support healthy sexual function
- ... Traditionally used in Western herbal medicine to body tonic
- ... Traditionally used in Chinese medicine to warm and nourish/strengthen/tonify/enrich kidneys/kidney-yang
- ... Maintain/support healthy reproductive hormones
- ... Maintain/support healthy immune system function
- ... Maintain/support (state vitamin/mineral) within normal range
- ... Maintain/support general health and wellbeing
- ... Traditionally used in Western herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness

-  ... Traditionally used in Western herbal medicine to aphrodisiac/enhance/improve/promote healthy libido
-  ... Maintain/support testosterone level
-  ... Traditionally used in Western herbal medicine to maintain/support healthy libido
-  ... Aid/assist/helps protein synthesis in the body
-  ... Maintain/support immune system health
-  ... Traditionally used in Western herbal medicine to maintain/support healthy sexual function
-  ... Maintain/support sperm health in healthy males
-  ... Traditionally used in Chinese medicine to relieve weariness/tiredness/fatigue/feeling of weakness

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

Indication Requirements:

-  ... If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
-  ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.
-  ... Label statement: If symptoms persist, talk to your health professional.
-  ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
-  ... Product presentation must not imply or refer to chronic fatigue syndrome.
-  ... Product presentation must not imply or refer to hormone imbalances.
-  ... Product presentation must not imply or refer to infertility.
-  ... Product presentation must not imply or refer to kidney disease.
-  ... Product presentation must not imply or refer to serious immunological diseases.

Supporting Documents

Electronic Documents

TRIM Reference:

TRIM Details:

Audit Trail

Created By:

122703_69187

Last Editor:

122701_69187



Application General

Product Name: Daily Calcium + Vit D3
Export Names:
Product Code: Other products
Client Name: Pentavite Pty Ltd
Sponsor Name: Pentavite Pty Ltd
Sponsor Billing Address: 74-86 Garden Road Clayton VIC 3168
Sponsor Regulatory Correspondence Address: 74-86 Garden Road Clayton VIC 3168
Version: 1

Is this Application in response to a Section 30? No

Can this product be used as a code stock? No

Validation Results

Valid from: 03/11/2022 01:28:12 PM
This application is to: Replace an existing listing **AUST L 364119**
Payment Exemption Number:
Application Type: Correction of ARTG Record
Application Status: Completed
Submission Cost: \$0.00
Validation Report:
 Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

S47

Where the ingredient 'gelatin' is eligible for self-assessment for TSE, the sponsor must hold all relevant information to demonstrate compliance with the Ph. Eur monograph.

Gelatin sourced from TSE Controlled Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Gelatin sourced from TSE Negligible Risk countries must comply with the European Pharmacopoeial monograph in relation to minimising TSE risk.

Pass with Conditions - When the medicine is for oral use and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect). [s47](#)

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). [s47](#)

Changes Made Report:

Formulation

Dosage Form: Pastille

Routes of Administration:

 ... Oral

Container Type:

Container Volume:

Container Closure:

Container Condition:

Maximum Single Dose:

Maximum Daily Dose:

4

Minimum Weight of Divided Dosage Form
(tablets, capsules, metered dose sprays etc.):

[s47](#)

Ingredients

 ... Active - calcium phosphate

 ... Equivalent - calcium

 ... Active - colecalciferol [s47](#)

 ... [s47](#)

 ...

 ...

 ...

 ... Excipient - Gelatin

 ... Excipient - citric acid

- ... Excipient - sucrose
- ... Excipient - maltodextrin
- ... Excipient - medium chain triglycerides
- ... Excipient - Carnauba Wax
- ... Excipient - liquid glucose

Manufacturers

S47

Indications

Permitted Indications:

- ... Maintain/support healthy growth and development in children
- ... Maintain/support general health and wellbeing in children
- ... Aids/assists teeth development in children
- ... Maintain/support healthy teeth in children
- ... Maintain/support teeth mineralisation in children
- ... Maintain/support teeth strength in children
- ... Maintain/support bone health in children
- ... Aids/assists healthy bone development/growth/building in children
- ... Maintain/support bone strength in children
- ... Help maintain/support bone mineralisation in children
- ... Maintain/support muscle health in children
- ... Maintain/support muscle function in children
- ... Maintain/support healthy neuromuscular system/function in children
- ... Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children
- ... Maintain/support (state vitamin/mineral/nutrient) levels in the body in children

Standard Indications:

Specific Indications:

Warnings and Indication Requirements

Coded Warnings:

- ... Contains sugars
- ... Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or...

Indication Requirements:

- ... If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- ... Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
- ... Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Supporting Documents

Electronic Documents

TRIM Reference: Audit Trail

Created By:	122701_69187
Last Editor:	122701_69187