

# Application General

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**Product Name:** Eir Women Zipped  
**Product Code:** Other products  
**Client Name:** Ellkay Group Pty Ltd  
**Sponsor Name:** Ellkay Group Pty Ltd

**Is this Application in response to a Section 30:** No  
**Can this product be used as a code stock:** No

**This application is to:** change a current ARTG Entry  
**AUST L:** 386951  
**Submission Cost:** \$0.00  
**Payment Exemption No:**  
**Application Status:** Completed  
**Application Type:** Correction of ARTG Record

**Validation Report:** 24/08/2023 7:07:02 PM

## 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')

Document 1

Chromium sourced from organic materials: Medicines are listable only if the maximum recommended daily dose provides 50 micrograms or less of chromium from organic sources (ie chromium picolinate, chromium nicotinate and 'High chromium yeast'). Chromium sourced from inorganic materials: listable without restrictions. (Ingredient(s) concerned: 'Chromium')

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')

## PRODUCT DETAILS

**Dosage Form:** Tablet, film coated  
**Route of Administration:** Oral  
**Maximum daily dose:** 2

## FORMULATION DETAILS

### ACTIVE INGREDIENTS:

#### STANDARD

**Ingredient:** Trigonella foenum-graecum 20 mg  
**Plant Part:** seed  
**Plant Preparation:** Extract dry concentrate  
**Ratio:** (125:1)  
**Equivalent Preparation:** Dry 2.5 g  
**Preparation Steps:**  
**Plant Preparation:** Extract dry concentrate (125:1)  
**Plant Preparation Step:** 1  
**Solvents:** purified water 100%

**Ingredient:** Gymnema sylvestre 400 mg  
**Plant Part:** leaf  
**Plant Preparation:** Extract dry concentrate  
**Ratio:** (20:1)  
**Equivalent Preparation:** Dry 8 g  
**Preparation Steps:**  
**Plant Preparation:** Extract dry concentrate (20:1)  
**Plant Preparation Step:** 1  
**Solvents:** purified water 30%

<b>Solvents:</b>	ethanol 70%
<b>Ingredient:</b>	Nigella sativa 5 mg
<b>Plant Part:</b>	seed
<b>Plant Preparation:</b>	Extract dry concentrate
<b>Ratio:</b>	(10:1)
<b>Equivalent Preparation:</b>	Dry 50 mg
<b>Preparation Steps:</b>	
<b>Plant Preparation:</b>	Extract dry concentrate (10:1)
<b>Plant Preparation Step:</b>	1
<b>Solvents:</b>	ethanol 30%
<b>Solvents:</b>	purified water 70%
<b>Ingredient:</b>	Cynara scolymus 53.34 mg
<b>Plant Part:</b>	leaf
<b>Plant Preparation:</b>	Extract dry concentrate
<b>Ratio:</b>	(6:1)
<b>Equivalent Preparation:</b>	Dry 320.04 mg
<b>Preparation Steps:</b>	
<b>Plant Preparation:</b>	Extract dry concentrate (6:1)
<b>Plant Preparation Step:</b>	1
<b>Solvents:</b>	purified water 100%
<b>Ingredient:</b>	Petroselinum crispum 50 mg
<b>Plant Part:</b>	leaf
<b>Plant Preparation:</b>	Powder
<b>Ingredient:</b>	Taraxacum officinale 37.5 mg
<b>Plant Part:</b>	root
<b>Plant Preparation:</b>	Extract dry concentrate
<b>Ratio:</b>	(20:1)
<b>Equivalent Preparation:</b>	Dry 750 mg
<b>Preparation Steps:</b>	
<b>Plant Preparation:</b>	Extract dry concentrate (20:1)
<b>Plant Preparation Step:</b>	1
<b>Solvents:</b>	purified water 100%
<b>Ingredient:</b>	Apium graveolens 50 mg
<b>Plant Part:</b>	seed
<b>Plant Preparation:</b>	Powder
<b>Ingredient:</b>	chromium picolinate 200 microgram
<b>Equivalents:</b>	chromium 25 microgram
<b>Ingredient:</b>	pyridoxine hydrochloride 30 mg
<b>Equivalents:</b>	pyridoxine 24.7 mg

**Ingredient:** Laminaria digitata 50 mg  
**Plant Part:** blade  
**Plant Preparation:** Powder  
**Equivalents:** iodine 149.9 microgram

**EXCIPIENT INGREDIENTS:**

STANDARD

**Ingredient:** maltodextrin  
**Ingredient:** magnesium stearate  
**Ingredient:** calcium hydrogen phosphate dihydrate  
**Ingredient:** croscarmellose sodium  
**Ingredient:** microcrystalline cellulose  
**Ingredient:** colloidal anhydrous silica  
**Ingredient:** crospovidone  
**Ingredient:** povidone

PROPRIETARY INGREDIENTS

**Ingredient:** NutraShine Pink 8442-08-PT-S 64.75 mg  
(PI number:143204)

**MANUFACTURER DETAILS**

**Name:** s47  
**Manufacturer ID:**  
**Licence ID:**  
**Location:**  
**Manufacturing Steps:**

**Name:** s47  
**Manufacturer ID:**  
**Licence ID:**  
**Location:**  
**Manufacturing Steps:**

**Name:** s47  
**Manufacturer ID:**  
**Licence ID:**  
**Location:**  
**Manufacturing Steps:**

**Name:** s47  
**Manufacturer ID:**  
**Licence ID:**

**Location:** s47  
**Manufacturing Steps:**

**Name:** s47  
**Manufacturer ID:**  
**Licence ID:**  
**Location:**  
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**Licence ID:**  
**Location:**  
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**Manufacturer ID:**  
**Licence ID:**  
**Location:**  
**Manufacturing Steps:**

**Name:** s47  
**Manufacturer ID:**  
**Licence ID:**  
**Location:**  
**Manufacturing Steps:**

**INDICATIONS & WARNINGS**

**Warning:** (VIT) Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin...  
(S) If symptoms persist consult your healthcare practitioner  
(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].

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# Application General

**Product Name:** Eir Women Show Up  
**Product Code:** Other products  
**Client Name:** HealthREG Solutions Group  
**Sponsor Name:** Ellkay Group Pty Ltd

**Is this Application in response to a Section 30:** No  
**Can this product be used as a code stock:** No

**This application is to:** create a new ARTG Entry  
**Submission Cost:** \$870.00  
**Payment Exemption No:**  
**Application Status:** Completed  
**Application Type:** New (A new AUST L will be generated)

**Validation Report:** 5/04/2022 8:13:08 PM

## 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.

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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](mailto: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')

Pass with conditions: When the ingredient is in a medicine that is for internal use the following warning statement is required on the label: - (VAC) 'Vitex agnus-castus may affect hormones and medicines such as oral contraceptives. Consult your health professional before use' (or words to that effect). (Ingredient(s) concerned: 'Vitex agnus-castus')

The Ginkgo biloba leaf extract used in the manufacture of this medicine must comply with the requirements of Identification Test B of the monograph Powdered Ginkgo Extract in the United States Pharmacopeia 32 - National Formulary 27 (USP32-NF27), as in force or existing from time to time. This condition does not apply to powdered or dried leaf. (Ingredient(s) concerned: 'Ginkgo biloba')

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')

## PRODUCT DETAILS

**Dosage Form:** Tablet, film coated  
**Route of Administration:** Oral

## FORMULATION DETAILS

### ACTIVE INGREDIENTS:

#### STANDARD

**Ingredient:** Panax quinquefolius 25 mg  
**Plant Part:** root  
**Plant Preparation:** Extract dry concentrate  
**Ratio:** (20:1)  
**Equivalent Preparation:** Dry 500 mg  
**Preparation Steps:**  
**Plant Preparation:** Extract dry concentrate (20:1)  
**Plant Preparation Step:** 1  
**Solvents:** Ethanol 65%  
**Solvents:** Water - purified 35%

**Ingredient:** Vitex agnus-castus 50 mg  
**Plant Part:** fruit  
**Plant Preparation:** Extract dry concentrate  
**Ratio:** (20:1)

**Equivalent Preparation:** Dry 1 g

**Preparation Steps:**

**Plant Preparation:** Extract dry concentrate (20:1)

**Plant Preparation Step:** 1

**Solvents:** Ethanol 70%

**Solvents:** Water - purified 30%

**Ingredient:** Ginkgo biloba 30 mg

**Plant Part:** leaf

**Plant Preparation:** Extract dry concentrate

**Ratio:** (50:1)

**Equivalent Preparation:** Dry 1.5 g

**Preparation Steps:**

**Plant Preparation:** Extract dry concentrate (50:1)

**Plant Preparation Step:** 1

**Solvents:** Ethanol 50%

**Solvents:** Water - purified 50%

**Ingredient:** ascorbic acid 125 mg

**Ingredient:** thiamine hydrochloride 11.15 mg

**Equivalents:** thiamine 9.94 mg

**Ingredient:** riboflavin 12.5 mg

**Ingredient:** nicotinamide 12.5 mg

**Ingredient:** calcium pantothenate 12.5 mg

**Equivalents:** pantothenic acid 11.45 mg

**Ingredient:** pyridoxal 5-phosphate monohydrate 12.5 mg

**Equivalents:** pyridoxine 7.98 mg

**Ingredient:** cyanocobalamin 100 microgram

**EXCIPIENT INGREDIENTS:**

STANDARD

**Ingredient:** hypromellose

**Ingredient:** magnesium stearate

**Ingredient:** calcium hydrogen phosphate dihydrate

**Ingredient:** croscarmellose sodium

**Ingredient:** microcrystalline cellulose

**Ingredient:** colloidal anhydrous silica

**Ingredient:** crospovidone

**Ingredient:** povidone

PROPRIETARY INGREDIENTS

**Ingredient:**

NutraShine Yellow 6687-91-PT-S 50.42 mg  
(PI number:143212)

**MANUFACTURER DETAILS**

**Name:**  
**Manufacturer ID:**  
**Licence ID:**  
**Location:**  
**Manufacturing Steps:**

s47  
[Redacted]

**Name:**  
**Manufacturer ID:**  
**Licence ID:**  
**Location:**  
**Manufacturing Steps:**

s47  
[Redacted]

**Name:**  
**Manufacturer ID:**  
**Licence ID:**  
**Location:**  
**Manufacturing Steps:**

s47  
[Redacted]

**Name:**  
**Manufacturer ID:**  
**Licence ID:**  
**Location:**  
**Manufacturing Steps:**

s47  
[Redacted]

**Name:**  
**Manufacturer ID:**  
**Licence ID:**  
**Location:**  
**Manufacturing Steps:**

s47  
[Redacted]

**Name:**  
**Manufacturer ID:**  
**Licence ID:**  
**Location:**  
**Manufacturing Steps:**

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[Redacted]

**Name:**

s47  
[Redacted]

**Manufacturer ID:**  
**Licence ID:**  
**Location:**  
**Manufacturing Steps:**

s47

Document 2

## INDICATIONS & WARNINGS

**Warning:**

(VAC) Vitex agnus-castus may affect hormones and medicines such as oral contraceptives. Consult your health professional before use' (or words to that effect).

(VITMIN) 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.

(GEN2) If symptoms persist, seek the advice of a healthcare professional.

**Subsection 26B(1)  
Notification:**

For the purpose of subsection 26B(1) you are notifying the Secretary that a certificate under subsection 26B(1) is not required for this application.

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# Application General

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**Product Name:** Eir Women Show Up  
**Product Code:** Other products  
**Client Name:** Ellkay Group Pty Ltd  
**Sponsor Name:** Ellkay Group Pty Ltd

**Is this Application in response to a Section 30:** No  
**Can this product be used as a code stock:** No

**This application is to:** change a current ARTG Entry  
**AUST L:** 386939  
**Submission Cost:** \$0.00  
**Payment Exemption No:**  
**Application Status:** Completed  
**Application Type:** Correction of ARTG Record

**Validation Report:** 24/08/2023 6:53:13 PM

## 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.

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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')

Pass with conditions: When the ingredient is in a medicine that is for internal use the following warning statement is required on the label: - (VAC) 'Vitex agnus-castus may affect hormones and medicines such as oral contraceptives. Consult your health professional before use' (or words to that effect). (Ingredient(s) concerned: 'Vitex agnus-castus')

The Ginkgo biloba leaf extract used in the manufacture of this medicine must comply with the requirement of Identification Test B of the monograph Powdered Ginkgo Extract in the United States Pharmacopeia 32 - National Formulary 27 (USP32-NF27), as in force or existing from time to time. This condition does not apply to powdered or dried leaf. (Ingredient(s) concerned: 'Ginkgo biloba')

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')

## PRODUCT DETAILS

**Dosage Form:** Tablet, film coated  
**Route of Administration:** Oral  
**Maximum single dose:** 2  
**Maximum daily dose:** 2

## FORMULATION DETAILS

### ACTIVE INGREDIENTS:

#### STANDARD

**Ingredient:** Panax quinquefolius 25 mg  
**Plant Part:** root  
**Plant Preparation:** Extract dry concentrate  
**Ratio:** (20:1)  
**Equivalent Preparation:** Dry 500 mg  
**Preparation Steps:**  
**Plant Preparation:** Extract dry concentrate (20:1)  
**Plant Preparation Step:** 1  
**Solvents:** ethanol 65%  
**Solvents:** purified water 35%

**Ingredient:** Vitex agnus-castus 50 mg  
**Plant Part:** fruit  
**Plant Preparation:** Extract dry concentrate  
**Ratio:** (20:1)

**Equivalent Preparation:** Dry 1 g

**Preparation Steps:**

**Plant Preparation:** Extract dry concentrate (20:1)

**Plant Preparation Step:** 1

**Solvents:** purified water 30%

**Solvents:** ethanol 70%

**Ingredient:** Ginkgo biloba 30 mg

**Plant Part:** leaf

**Plant Preparation:** Extract dry concentrate

**Ratio:** (50:1)

**Equivalent Preparation:** Dry 1.5 g

**Preparation Steps:**

**Plant Preparation:** Extract dry concentrate (50:1)

**Plant Preparation Step:** 1

**Solvents:** ethanol 50%

**Solvents:** purified water 50%

**Ingredient:** ascorbic acid 125 mg

**Ingredient:** thiamine hydrochloride 11.15 mg

**Equivalents:** thiamine 9.94 mg

**Ingredient:** riboflavin 12.5 mg

**Ingredient:** nicotinamide 12.5 mg

**Ingredient:** calcium pantothenate 12.5 mg

**Equivalents:** pantothenic acid 11.45 mg

**Ingredient:** pyridoxal 5-phosphate monohydrate 12.5 mg

**Equivalents:** pyridoxine 7.98 mg

**Ingredient:** cyanocobalamin 100 microgram

**EXCIPIENT INGREDIENTS:**

STANDARD

**Ingredient:** hypromellose

**Ingredient:** magnesium stearate

**Ingredient:** calcium hydrogen phosphate dihydrate

**Ingredient:** croscarmellose sodium

**Ingredient:** microcrystalline cellulose

**Ingredient:** colloidal anhydrous silica

**Ingredient:** crospovidone

**Ingredient:** povidone

PROPRIETARY INGREDIENTS

**Ingredient:**

NutraShine Yellow 6687-91-PT-S 50.42 mg  
(PI number:143212)

**MANUFACTURER DETAILS**

**Name:**

s47

**Manufacturer ID:**

**Licence ID:**

**Location:**

**Manufacturing Steps:**

**Name:**

s47

**Manufacturer ID:**

**Licence ID:**

**Location:**

**Manufacturing Steps:**

**Name:**

s47

**Manufacturer ID:**

**Licence ID:**

**Location:**

**Manufacturing Steps:**

**Name:**

s47

**Manufacturer ID:**

**Licence ID:**

**Location:**

**Manufacturing Steps:**

**Name:**

s47

**Manufacturer ID:**

**Licence ID:**

**Location:**

**Manufacturing Steps:**

**Name:**

s47

**Manufacturer ID:**

**Licence ID:**

**Location:**

**Manufacturing Steps:**

**Name:**  
**Manufacturer ID:**  
**Licence ID:**  
**Location:**  
**Manufacturing Steps:**

s47

**Name:**  
**Manufacturer ID:**  
**Licence ID:**  
**Location:**  
**Manufacturing Steps:**

s47

## INDICATIONS & WARNINGS

**Warning:**

(VAC) Vitex agnus-castus may affect hormones and medicines such as oral contraceptives. Consult your .....

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

(GEN2) If symptoms persist, seek the advice of a healthcare professional

(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].

---

# Application General

**Product Name:** Eir Women Zipped  
**Product Code:** Other products  
**Client Name:** HealthREG Solutions Group  
**Sponsor Name:** Ellkay Group Pty Ltd

**Is this Application in response to a Section 30:** No  
**Can this product be used as a code stock:** No

**This application is to:** create a new ARTG Entry  
**Submission Cost:** \$870.00  
**Payment Exemption No:**  
**Application Status:** Completed  
**Application Type:** New (A new AUST L will be generated)

**Validation Report:** 5/04/2022 8:14:57 PM

## 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')

Chromium sourced from organic materials: Medicines are listable only if the maximum recommended daily dose provides 50 micrograms or less of chromium from organic sources (ie chromium picolinate, chromium nicotinate and 'High chromium yeast'). Chromium sourced from inorganic materials: listable without restrictions. (Ingredient(s) concerned: 'Chromium')

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')

## PRODUCT DETAILS

**Dosage Form:** Tablet, film coated  
**Route of Administration:** Oral  
**Maximum daily dose:** 2

## FORMULATION DETAILS

### ACTIVE INGREDIENTS:

#### STANDARD

**Ingredient:** Trigonella foenum-graecum 20 mg  
**Plant Part:** seed  
**Plant Preparation:** Extract dry concentrate  
**Ratio:** (125:1)  
**Equivalent Preparation:** Dry 2.5 g  
**Preparation Steps:**  
**Plant Preparation:** Extract dry concentrate (125:1)  
**Plant Preparation Step:** 1  
**Solvents:** purified water 100%

**Ingredient:** Gymnema sylvestre 400 mg  
**Plant Part:** leaf  
**Plant Preparation:** Extract dry concentrate  
**Ratio:** (20:1)  
**Equivalent Preparation:** Dry 8 g  
**Preparation Steps:**  
**Plant Preparation:** Extract dry concentrate (20:1)

<b>Plant Preparation Step:</b>	1
<b>Solvents:</b>	Ethanol 70%
<b>Solvents:</b>	Water - purified 30%
<b>Ingredient:</b>	Nigella sativa 5 mg
<b>Plant Part:</b>	seed
<b>Plant Preparation:</b>	Extract dry concentrate
<b>Ratio:</b>	(10:1)
<b>Equivalent Preparation:</b>	Dry 50 mg
<b>Preparation Steps:</b>	
<b>Plant Preparation:</b>	Extract dry concentrate (10:1)
<b>Plant Preparation Step:</b>	1
<b>Solvents:</b>	Ethanol 30%
<b>Solvents:</b>	Water - purified 70%
<b>Ingredient:</b>	Cynara scolymus 53.34 mg
<b>Plant Part:</b>	leaf
<b>Plant Preparation:</b>	Extract dry concentrate
<b>Ratio:</b>	(6:1)
<b>Equivalent Preparation:</b>	Dry 320.04 mg
<b>Preparation Steps:</b>	
<b>Plant Preparation:</b>	Extract dry concentrate (6:1)
<b>Plant Preparation Step:</b>	1
<b>Solvents:</b>	purified water 100%
<b>Ingredient:</b>	Petroselinum crispum 50 mg
<b>Plant Part:</b>	leaf
<b>Plant Preparation:</b>	Powder
<b>Ingredient:</b>	Taraxacum officinale 37.5 mg
<b>Plant Part:</b>	root
<b>Plant Preparation:</b>	Extract dry concentrate
<b>Ratio:</b>	(20:1)
<b>Equivalent Preparation:</b>	Dry 750 mg
<b>Preparation Steps:</b>	
<b>Plant Preparation:</b>	Extract dry concentrate (20:1)
<b>Plant Preparation Step:</b>	1
<b>Solvents:</b>	purified water 100%
<b>Ingredient:</b>	Apium graveolens 50 mg
<b>Plant Part:</b>	seed
<b>Plant Preparation:</b>	Powder
<b>Ingredient:</b>	chromium picolinate 200 microgram

**Equivalents:** chromium 25 microgram  
**Ingredient:** pyridoxine hydrochloride 30 mg  
**Equivalents:** pyridoxine 24.7 mg  
**Ingredient:** Laminaria digitata 50 mg  
**Plant Part:** blade  
**Plant Preparation:** Powder  
**Equivalents:** iodine 149.9 microgram

**EXCIPIENT INGREDIENTS:**

STANDARD

**Ingredient:** maltodextrin  
**Ingredient:** magnesium stearate  
**Ingredient:** calcium hydrogen phosphate dihydrate  
**Ingredient:** croscarmellose sodium  
**Ingredient:** microcrystalline cellulose  
**Ingredient:** colloidal anhydrous silica  
**Ingredient:** crospovidone  
**Ingredient:** povidone

PROPRIETARY INGREDIENTS

**Ingredient:** NutraShine Pink 8442-08-PT-S 64.75 mg  
(PI number:143204)

**MANUFACTURER DETAILS**

**Name:** s47  
**Manufacturer ID:**  
**Licence ID:**  
**Location:**  
**Manufacturing Steps:**

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Document 4

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## INDICATIONS & WARNINGS

**Warning:** (S) If symptoms persist consult your healthcare practitioner (or words to that effect).  
(VIT) Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR  
Vitamin supplements should not replace a balanced diet.

**Subsection 26B(1)  
Notification:** For the purpose of subsection 26B(1) you are notifying the Secretary that a certificate  
under subsection 26B(1) is not required for this application.

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