Public Summary

Summary for ARTG Entry: 149005 Pregcel Benefishoil Omega 3 Softgel Capsule

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	10/01/2008
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm as amended from time to time.

Products

1. Pregcel Benefishoil Omega 3 Softgel Capsule

Product Type Single Medicine Product **Effective date** 28/08/2009 9:44:39 AM

Warnings

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

If symptoms persist consult your healthcare practitioner (or words to that effect).

Standard Indications

Specific Indications

Rich source of Omega-3 fatty acids which assist in maintaining health skin.
Helps to assist in the maintenance of normal eye and brain function.
It is also high in DHA which is necessary for the normal function of the brain and nervous system.
Assists in promoting the health of mother and baby.

Additional Product information

Pack Size/Poison Information

Pack Size **Poison Schedule**

Components

1. Medicine component

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients

d-alpha-Tocopherol	**33.56 mg**
Fish oil - natural	**500 mg**

Public Summary

Public Summary

Summary for ARTG Entry: 140258 Swisse Teenace Ultivite Multi-Vitamin, Mineral & Anti-Oxidant with Herbs Teenage Women's W

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	8/06/2007
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm, as amended from time to time.,

Where the medicine is a conventional release folic acid supplement preparation, in tablet form, of strength of 100 micrograms or more per dosage unit, the additional conditions are as follows: Where the medicine contains folic acid as a single active ingredient, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Folic Acid Tablets. Where the medicine contains multiple active ingredients, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Nutritional Supplements, as amended by its First Supplement. The dissolution characteristics for this medicine must comply with the dissolution requirements of the relevant USP24 monograph over the shelf life of the product when stored under the conditions included on the product label. It is the responsibility of manufacturers to develop and validate the analytical methods for the determination of folic acid that should be used in conjunction with the USP24 dissolution criteria. This condition does not apply to chewable, effervescent or dispersible tablets or sustained release tablets.

Products

1. Swisse Teenace Ultivite Multi-Vitamin, Mineral & Anti-Oxidant with Herbs Teenage Women's W

Product Type Single Medicine Product **Effective date** 28/08/2009 9:44:39 AM

Warnings

If symptoms persist consult your healthcare practitioner (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.,

This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.,

Do not take while on warfarin therapy without medical advice.,

(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].

Standard Indications

For mineral (may state the mineral) supplementation.,

For vitamin (may state the vitamin) supplementation.,

Prevention/treatment of vitamin [XX] and/or mineral [YY] and/or nutritional deficiencies (This indication is not be to used for the treatment of iron deficiency conditions).,

Aids, assists or helps in the maintenance or improvement of general well-being.,

Helps maintain normal blood/blood tonic (Note: These claims are appropriate for folic acid, vitamin B12 and iron, but must not imply anaemic conditions),

Helps maintain healthy digestive function.,

Liver tonic. Helps maintain healthy digestive function.,

Beneficial during times of stress. [Warning S required],

May assist in maintaining peripheral circulation and promoting general health.

Specific Indications

Provides support for memory function and stamina
Assists in enhancing mental alertness and improving short term memory.
May assist in support of general healthy brain function
Provides support for the nervous system and is beneficial during times of stress.
May assist in helping the body adapt to mentally and physically draining circumstances.
Contains antioxidants to assist in decreasing the risk of cell damage from free radicals.
Assists in maintaining healthy looking skin.
Assists in the maintenance of a health urinary system

Additional Product Information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1. Medicine component

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Arctostaphylos uva-ursi	**12.5 mg**
Equivalent: Arctostaphylos uva-ursi (Dry)	50 mg
Bacopa monnieri	**10 mg**
Bifidobacterium longum	
Biotin	**20 microgram**
Calcium ascorbate dihydrate	**41.24 mg**
Calcium orotate	**70 mg**
Calcium pantothenate	**4 mg**
Cholecalciferol	**.005 mg**
Choline bitartrate	**120 mg**
Chromium picolinate	**169 microgram**
Citrus bioflavonoids extract	**100 mg**
Copper gluconate	**7.86 mg**
Cyanocobalamin	**1.8 microgram**
d-alpha-Tocopheryl acid succinate	**7.9968 mg**
Dunaliella salina	
Ferrous fumarate	**16.01 mg**
Folic acid	**400 microgram**
Ginkgo biloba	**3 mg**
Equivalent: Ginkgo biloba (Dry)	150 mg
Glycyrrhiza glabra	
Inositol	**35 mg**
Lactobacillus acidophilus	
Lactobacillus rhamnosus	
Lemon Oil	**2 mg**
Lutein	**1.13 mg**
Magnesium aspartate dihydrate	**70 mg**
Manganese amino acid chelate	**25 mg**
Molybdenum trioxide	**67.5 microgram**
Nicotinamide	**14 mg**
Olea europaea	**8.33 mg**
Equivalent: Olea europaea (Dry)	50 mg
Passiflora incarnata	**12.5 mg**
Equivalent: Passiflora incarnata (Dry)	50 mg
Phytomenadione	**45 microgram**
Potassium iodide	**196 microgram**

Pyridoxine hydrochloride	**10 mg**
Riboflavine	**900 microgram**
Silica - colloidal anhydrous	**100 mg**
Silybum marianum	**8.57 mg**
Equivalent: Silybum marianum (Dry)	600 mg
Thiamine hydrochloride	**900 microgram**
Vaccinium macrocarpon	**10 mg**
Equivalent: Vaccinium macrocarpon (Fresh)	500 mg
Vitex agnus-castus	**5 mg**
Equivalent: Vitex agnus-castus (Dry)	50 mg
Withania somnifera	**10 mg**
Equivalent: Withania somnifera (Dry)	100 mg
Zinc amino acid chelate	**55 mg**

Public Summary

Summary for ARTG Entry: 140137 Swisse Men's Ultivite Multi-Vitamin, Mineral & Anti-Oxidant with Herbs Gluten Free G

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	6/06/2007
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

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). This condition does not apply to powdered or dried leaf.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm,as amended from time to time.,

Where the medicine is a conventional release folic acid supplement preparation, in tablet form, of strength of 100 micrograms or more per dosage unit, the additional conditions are as follows: Where the medicine contains folic acid as a single active ingredient, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Folic Acid Tablets. Where the medicine contains multiple active ingredients, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Nutritional Supplements, as amended by its First Supplement. The dissolution characteristics for this medicine must comply with the dissolution requirements of the relevant USP24 monograph over the shelf life of the product when stored under the conditions included on the product label. It is the responsibility of manufacturers to develop and validate the analytical methods for the determination of folic acid that should be used in conjunction with the USP24 dissolution criteria. This condition does not apply to chewable, effervescent or dispersible tablets or sustained release tablets.

Products

1. Swisse Men's Ultivite Multi-Vitamin, Mineral & Anti-Oxidant with Herbs Gluten Free G

Product Type Single Medicine Product **Effective date** 3/03/2010 3:59:14 PM

Warnings

Do not take while on warfarin therapy without medical advice.,

This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.,

If symptoms persist consult your healthcare practitioner (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.

Standard Indications

Helps maintain normal blood/blood tonic (Note: These claims are appropriate for folic acid, vitamin B12 and iron, but must not imply anaemic conditions),

Helps maintain healthy digestive function.,

Liver tonic. Helps maintain healthy digestive function.,

Male support. Balances and supports normal male physiology and function.,

May assist in maintaining peripheral circulation and promoting general health.,

For mineral (may state the mineral) supplementation.,

For vitamin (may state the vitamin) supplementation.,

Prevention/treatment of vitamin [XX] and/or mineral [YY] and/or nutritional deficiencies (This indication is not be to used for the treatment of iron deficiency conditions).,

May assist in the management of dietary folate deficiency.,

Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life,

Aids, assists or helps in the maintenance or improvement of general well-being.

Specific Indications

Provides support for memory function and stamina
Provides support for the nervous system and is beneficial during times of stress.
May assist in helping the body adapt to mentally and physically draining circumstances.
Contains antioxidants to assist in decreasing the risk of cell damage from free radicals.
Assists in the maintenance of a healthy urinary system
Assists in maintaining a healthy and normal immune system.
Low allergy formula
Antioxidant rich.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1. Medicine component

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Armoracia rusticana	**10 mg**
Equivalent: Armoracia rusticana (Dry)	50 mg
Bifidobacterium longum	
Biotin	**200 microgram**
Calcium ascorbate dihydrate	**170 mg**
Calcium orotate	**100 mg**
Calcium pantothenate	**80 mg**
Cholecalciferol	**.005 mg**
Choline bitartrate	**20 mg**
Chromium picolinate	**402 microgram**
Citrus bioflavonoids extract	**50 mg**
Copper gluconate	**28.57 mg**
Cyanocobalamin	**150 microgram**
Cynara scolymus	**25 mg**
Equivalent: Cynara scolymus (Fresh)	100 mg
d-alpha-Tocopheryl acid succinate	**19.9968 mg**
Ferrous fumarate	**16.01 mg**
Folic acid	**500 microgram**
Ginkgo biloba	**30 mg**
Equivalent: Ginkgo biloba (Dry)	1.5 g
Inositol	**20 mg**
Lactobacillus acidophilus	
Lactobacillus rhamnosus	
Magnesium aspartate dihydrate	**100 mg**
Manganese amino acid chelate	**50 mg**
Molybdenum trioxide	**165 microgram**
Nicotinamide	**55 mg**
Passiflora incarnata	**12.5 mg**
Equivalent: Passiflora incarnata (Dry)	50 mg
Phytomenadione	**90 microgram**
Pyridoxine hydrochloride	**50 mg**
Riboflavine	**30 mg**
Selenomethionine	**65 microgram**

Serenoa repens	**10 mg**
Equivalent: Serenoa repens (Dry)	100 mg
Silybum marianum	**17.14 mg**
Equivalent: Silybum marianum (Dry)	1.2 g
Spearmint Oil	**2 mg**
Tanacetum parthenium	**12.5 mg**
Equivalent: Tanacetum parthenium (Dry)	50 mg
Thiamine hydrochloride	**30 mg**
Tribulus terrestris	**5 mg**
Equivalent: Tribulus terrestris (Dry)	250 mg
Tribulus terrestris	**5 mg**
Equivalent: Tribulus terrestris (Dry)	250 mg
Trigonella foenum-graecum	**25 mg**
Equivalent: Trigonella foenum-graecum (Dry)	100 mg
Urtica dioica	**20 mg**
Equivalent: Urtica dioica (Dry)	100 mg
Vaccinium macrocarpon	**30 mg**
Equivalent: Vaccinium macrocarpon (Fresh)	1.5 g
Zinc amino acid chelate	**100 mg**

Public Summary

Summary for ARTG Entry: 156917 Swisse Women's Ultivite Multi-vitamin Mineral & Anti-Oxidant With Herbs Formula1

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	18/11/2008
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

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). This condition does not apply to powdered or dried leaf.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm,as amended from time to time.

Products

1. Swisse Women's Ultivite Multi-vitamin Mineral & Anti-Oxidant With Herbs Formula1

Product Type Single Medicine Product **Effective date** 29/06/2012

Warnings

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).,

Contains [insert name of ingredient] (or words to that effect).,

Not for the treatment of iron deficiency conditions (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].,

The recommended dose of this medicine provides small amounts of caffeine,

Do not take while on warfarin therapy without medical advice.,

Contains lactose (or words to that effect).,

This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.,

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

If symptoms persist consult your healthcare practitioner (or words to that effect).

Standard Indications

Source of folic acid. Can assist in maintaining normal blood.,

Aids, assists or helps in the maintenance or improvement of general well-being.,

Helps relieve nervous tension, stress and mild anxiety. [Warning S required],

Beneficial during times of stress. [Warning S required],

For vitamin (may state the vitamin) supplementation.,

For mineral (may state the mineral) supplementation.,

Prevention/treatment of vitamin [XX] and/or mineral [YY] and/or nutritional deficiencies (This indication is not be to used for the treatment of iron deficiency conditions).,

May assist in the management of dietary folate deficiency.,

Provides a daily dose of 400-500mcg of folic acid or folate. Contains folic acid which, if taken daily for one month before conception and during pregnancy, may reduce the risk of women having a child with birth defects of the brain and/or spinal chord such as the neural tube defects known as spina bifida and anencephaly. [Warning NEUR required.]

Specific Indications

Swisse WOMEN?S ULTIVITE is clinically tested, with proven relief and is based on over 25 years of research. Swisse WOMEN?S ULTIVITE has been developed to assist women in meeting their nutritional needs and help in the maintenance of general well-being. Swisse WOMEN?S ULTIVITE may assist in the relief of pre-menstrual symptoms and improve stress adaptation.
Relief from tiredness.
You'll Feel Better on Swisse.
Assists with energy production and stamina.
Assists maintenance of the immune system.
Assists in reducing homocysteine levels.
For the symptomatic relief of mood swings.
Clinically proven.
Assists in supporting general brain function, enhancing mental alertness and maintaining healthy looking hair, nails and skin.

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison Information

Pack Size

Poison Schedule

Components

1. COMPONENT ONE

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

Apium graveolens	**1 mg**
Arctostaphylos uva-ursi	**3.12 mg**
Astragalus membranaceus	**2.5 mg**
Avena sativa	**25 mg**
Betacarotene	**2.5 mg**
Biotin	**25 microgram**
Calcium ascorbate dihydrate	**100 mg**
Calcium citrate	**50 mg**
Calcium pantothenate	**37.5 mg**
Camellia sinensis	**1.67 mg**
Carica papaya	**5 mg**
Centella asiatica	**1.25 mg**
Cholecalciferol	**.0025 mg**
Choline bitartrate	**12.5 mg**
Chromium picolinate	**25 microgram**
Citrus bioflavonoids extract	**20 mg**
Copper gluconate	**208.5 microgram**
Crataegus monogyna	**3.75 mg**
Cyanocobalamin	**25 microgram**
Cynara scolymus	**6.25 mg**
d-alpha-Tocopheryl acid succinate	**20.66 mg**
Eleutherococcus senticosus	**1.25 mg**
Equisetum arvense	**3.75 mg**
Ferrous fumarate	**7.94 mg**
Foeniculum vulgare	**1.7 mg**
Folic acid	**250 microgram**
Ginkgo biloba	**50 microgram**
Glycyrrhiza glabra	**1.25 mg**

Inositol	**12.5 mg**
Lutein	**100 microgram**
Lycopersicon esculentum	**1 mg**
Lysine hydrochloride	**25 mg**
Magnesium oxide	**42.5 mg**
Manganese amino acid chelate	**8 mg**
Matricaria chamomilla	**1.88 mg**
Nicotinamide	**25 mg**
Petroselinum crispum	**5 mg**
Potassium iodide	**32.7 microgram**
Potassium sulfate	**2.23 mg**
Pyridoxine hydrochloride	**25 mg**
Riboflavine	**25 mg**
Selenomethionine	**32.5 microgram**
Silybum marianum	**357 microgram**
Spearmint Oil	**750 microgram**
Thiamine hydrochloride	**25 mg**
Ubidecarenone	**500 microgram**
Vaccinium myrtillus	**125 microgram**
Vitis vinifera	**4.17 mg**
Zinc amino acid chelate	**12.5 mg**
Zingiber officinale	**1.5 mg**

Public Summary

Summary for ARTG Entry: 156418 Swisse Pregnancy Ultivite Pregnancy Multi-Vitamin Mineral & Anti-Oxidant Formula

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	29/10/2008
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm as amended from time to time.

Where the medicine is a conventional release folic acid supplement preparation, in tablet form, of strength of 100 micrograms or more per dosage unit, the additional conditions are as follows: Where the medicine contains folic acid as a single active ingredient, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Folic Acid Tablets. Where the medicine contains multiple active ingredients, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Nutritional Supplements, as amended by its First Supplement. The dissolution characteristics for this medicine must comply with the dissolution requirements of the relevant USP24 monograph over the shelf life of the product when stored under the conditions included on the product label. It is the responsibility of manufacturers to develop and validate the analytical methods for the determination of folic acid that should be used in conjunction with the USP24 dissolution criteria. This condition does not apply to chewable, effervescent or dispersible tablets or sustained release tablets.

Products

1. Swisse Pregnancy Ultivite Pregnancy Multi-Vitamin Mineral & Anti-Oxidant Formula

Product Type Single Medicine Product **Effective date** 29/06/2012

Warnings

Do not take while on warfarin therapy without medical advice.,

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

This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.,

If symptoms persist consult your healthcare practitioner (or words to that effect).,

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).

Standard Indications

Source of folic acid. Can assist in maintaining normal blood. Blood tonic.,

Provides a daily dose of 400-500mcg of folic acid or folate. Contains folic acid which, if taken daily for one month before conception and during pregnancy, may reduce the risk of women having a child with birth defects of the brain and/or spinal chord such as the neural tube defects known as spina bifida and anencephaly. [Warning NEUR required.],

For mineral (may state the mineral) supplementation.,

For vitamin (may state the vitamin) supplementation.,

Prevention/treatment of vitamin [XX] and/or mineral [YY] and/or nutritional deficiencies (This indication is not be to used for the treatment of iron deficiency conditions).,

May assist in the management of dietary folate deficiency.,

Aids, assists or helps in the maintenance or improvement of general well-being.

Specific Indications

Pregnancy Ultivite provides nutritional support for both mother and baby during pregnancy and breastfeeding.
Assists in the maintenance of immune system.
Clinically Tested, Proven Relief. This product contains ingredients proven in clinical trials to reduce the risk of having a child with birth defects of the brain and/or spinal cord, whilst providing relief from tiredness, stress and supporting wellbeing. For more information on the Clinical Trials, please see our website.
Designed to assist in meeting women's needs and maintaining general well-being to help women perform in peak condition.
You'll Feel Better on Swisse.
Provides vitamin D3 to support calcium absorption to assist with healthy development of baby's bones.
Provides over-all multivitamin support with 31 nutrients.

Additional Product information

Pack Size/Poison information

Pack Size | **Poison Schedule**

Components

1. Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Betacarotene	**3 mg**
Biotin	**30 microgram**
Calcium ascorbate dihydrate	**72.62 mg**
Calcium citrate	**189.57 mg**
Calcium pantothenate	**5 mg**
Cholecalciferol	**.005 mg**
Choline bitartrate	**100 mg**
Chromic chloride	**154 microgram**
Citrus bioflavonoids extract	**100 mg**
Copper gluconate	**14.29 mg**
Cyanocobalamin	**2.6 microgram**
d-alpha-Tocopheryl acid succinate	**49.9968 mg**
Folic acid	**500 microgram**
Iron amino acid chelate	**50 mg**
Magnesium aspartate dihydrate	**100 mg**
Manganese amino acid chelate	**50 mg**
Matricaria chamomilla	**25 mg**
Molybdenum trioxide	**75 microgram**
Nicotinamide	**18 mg**
Phytomenadione	**60 microgram**
Potassium iodide	**327 microgram**
Pyridoxine hydrochloride	**20 mg**
Riboflavin	**1.4 mg**
Selenomethionine	**65 microgram**
Silybum marianum	**3.57 mg**
Spearmint Oil	**1 mg**
Thiamine hydrochloride	**1.4 mg**
Vitis vinifera	**833 microgram**
Zinc amino acid chelate	**100 mg**

Public Summary

Summary for ARTG Entry: 156396 Swisse Women's Ultivite Multivitamin Mineral & Antioxidant With Herbs No Iron or Iodine

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	29/10/2008
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

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). This condition does not apply to powdered or dried leaf.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm,as amended from time to time.,

Where the medicine is a conventional release folic acid supplement preparation, in tablet form, of strength of 100 micrograms or more per dosage unit, the additional conditions are as follows: Where the medicine contains folic acid as a single active ingredient, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Folic Acid Tablets. Where the medicine contains multiple active ingredients, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Nutritional Supplements, as amended by its First Supplement. The dissolution characteristics for this medicine must comply with the dissolution requirements of the relevant USP24 monograph over the shelf life of the product when stored under the conditions included on the product label. It is the responsibility of manufacturers to develop and validate the analytical methods for the determination of folic acid that should be used in conjunction with the USP24 dissolution criteria. This condition does not apply to chewable, effervescent or dispersible tablets or sustained release tablets.

Products

1. Swisse Women's Ultivite Multivitamin Mineral & Antioxidant With Herbs No Iron or Iodine

Product Type Single Medicine Product **Effective date** 29/06/2012

Warnings

The recommended dose of this medicine provides small amounts of caffeine,

Do not take while on warfarin therapy without medical advice.,

Contains lactose (or words to that effect).,

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).,

This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.,

If symptoms persist consult your healthcare practitioner (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.

Standard Indications

Aids, assists or helps in the maintenance or improvement of general well-being.,

Beneficial during times of stress. [Warning S required],

Source of folic acid. Can assist in maintaining normal blood. Blood tonic.,

Liver tonic. Aids digestion.,

Helps relieve nervous tension, stress and mild anxiety. [Warning S required],

May assist in the management of dietary folate deficiency.,

Prevention/treatment of vitamin [XX] and/or mineral [YY] and/or nutritional deficiencies (This indication is not be to used for the treatment of iron deficiency conditions).,

For mineral (may state the mineral) supplementation.,

Relief of pre-menstrual symptoms/syndrome. [Warning S required],

Provides a daily dose of 400-500mcg of folic acid or folate. Contains folic acid which, if taken daily for one month before conception and during pregnancy, may reduce the risk of women having a child with birth defects of the brain and/or spinal chord such as the neural tube defects known as spina bifida and anencephaly. [Warning NEUR required.]

Specific Indications

Provides support for memory function and stamina
Assists in supporting healthy brain and memory function.
May assist in support of general healthy brain function
Assists in supporting a healthy cardiovascular system
Provides support for the nervous system and is beneficial during times of stress.
May assist in helping the body adapt to mentally and physically draining circumstances.
Contains antioxidants to assist in decreasing the risk of potential cell damage from free radicals.
Assists in the maintenance of a healthy urinary tract system
Assists in maintaining a healthy and normal immune system.
Designed to be suitable for women who should avoid supplementing with additional iron or iodine.

Additional Product Information

Pack Size/Poison Information

Pack Size

Poison Schedule

Components

1. Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Apium graveolens	**2 mg**
Equivalent: Apium graveolens (Dry)	20 mg
Arctostaphylos uva-ursi	**6.25 mg**
Equivalent: Arctostaphylos uva-ursi (Dry)	25 mg
Astragalus membranaceus	**5 mg**
Equivalent: Astragalus membranaceus (Dry)	50 mg
Avena sativa	**50 mg**
Equivalent: Avena sativa (Fresh)	500 mg
Betacarotene	**5.0002 mg**
Biotin	**50 microgram**
Calcium ascorbate dihydrate	**50 mg**
Calcium citrate	**200 mg**
Calcium pantothenate	**75 mg**
Camellia sinensis	**3.34 mg**
Equivalent: Camellia sinensis (Dry)	20 mg
Carica papaya	**5 mg**
Centella asiatica	**2.5 mg**
Equivalent: Centella asiatica (Dry)	10 mg
Cholecalciferol	**.005 mg**
Choline bitartrate	**25 mg**
Chromium picolinate	**50 microgram**
Citrus bioflavonoids extract	**40 mg**
Copper gluconate	**417 microgram**
Crataegus monogyna	**7.5 mg**
Equivalent: Crataegus monogyna (Dry)	30 mg
Cyanocobalamin	**50 microgram**
Cynara scolymus	**12.5 mg**
Equivalent: Cynara scolymus (Fresh)	50 mg

d-alpha-Tocopheryl acid succinate	**37.1904 mg**
Eleutherococcus senticosus	**2.5 mg**
Equivalent: Eleutherococcus senticosus (Dry)	25 mg
Equisetum arvense	**7.5 mg**
Equivalent: Equisetum arvense (Dry)	30 mg
Foeniculum vulgare	**3.41 mg**
Equivalent: Foeniculum vulgare (Dry)	15 mg
Folic acid	**500 microgram**
Ginkgo biloba	**100 microgram**
Equivalent: Ginkgo biloba (Dry)	5 mg
Glycyrrhiza glabra	**2.5 mg**
Equivalent: Glycyrrhizą glabra (Dry)	10 mg
Inositol	**25 mg**
Lutein	**.2 mg**
Lycopersicon esculentum	**2 mg**
Magnesium oxide	**88.1 mg**
Manganese amino acid chelate	**16 mg**
Matricaria chamomilla	**3.75 mg**
Equivalent: Matricaria chamomilla (Dry)	15 mg
Nicotinamide	**50 mg**
Petroselinum crispum	**5 mg**
Potassium sulfate	**4.45 mg**
Pyridoxine hydrochloride	**50 mg**
Riboflavine	**50 mg**
Selenomethionine	**65 microgram**
Silybum marianum	**14.29 mg**
Spearmint Oil	**1.5 mg**
Thiamine hydrochloride	**50 mg**
Ubidecarenone	**1 mg**
Vaccinium myrtillus	**250 microgram**
Vitis vinifera	**8.34 mg**
Zinc amino acid chelate	**25 mg**
Zingiber officinale	**3 mg**
Equivalent: Zingiber officinale (Dry)	15 mg

Public Summary

Summary for ARTG Entry: 140131 Swisse Men's Ultivite Multi-Vitamin, Mineral & Anti-Oxidant with Herbs No Iron Iodine I

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	6/06/2007
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

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). This condition does not apply to powdered or dried leaf.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm,as amended from time to time.,

Where the medicine is a conventional release folic acid supplement preparation, in tablet form, of strength of 100 micrograms or more per dosage unit, the additional conditions are as follows: Where the medicine contains folic acid as a single active ingredient, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Folic Acid Tablets. Where the medicine contains multiple active ingredients, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Nutritional Supplements, as amended by its First Supplement. The dissolution characteristics for this medicine must comply with the dissolution requirements of the relevant USP24 monograph over the shelf life of the product when stored under the conditions included on the product label. It is the responsibility of manufacturers to develop and validate the analytical methods for the determination of folic acid that should be used in conjunction with the USP24 dissolution criteria. This condition does not apply to chewable, effervescent or dispersible tablets or sustained release tablets.

Products

1. Swisse Men's Ultivite Multi-Vitamin, Mineral & Anti-Oxidant with Herbs No Iron Iodine I

Product Type Single Medicine Product **Effective date** 3/03/2010 3:59:14 PM

Warnings

This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.,

Do not take while on warfarin therapy without medical advice.,

The recommended adult daily amount of vitamin A from all sources is 2500 IU (or words to that effect).,

Contains lactose (or words to that effect).,

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.,

If symptoms persist consult your healthcare practitioner (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.

Standard Indications

Helps maintain healthy digestive function.,

Liver tonic. Helps maintain healthy digestive function.,

Male support. Balances and supports normal male physiology and function.,

May assist in maintaining peripheral circulation and promoting general health.,

For mineral (may state the mineral) supplementation.,

For vitamin (may state the vitamin) supplementation.,

Prevention/treatment of vitamin [XX] and/or mineral [YY] and/or nutritional deficiencies (This indication is not be to used for the treatment of iron deficiency conditions).,

May assist in the management of dietary folate deficiency.,

Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life,

Aids, assists or helps in the maintenance or improvement of general well-being.

Specific Indications

Provides support for memory function and stamina
Assists in enhancing mental alertness and improving short term memory.
May assist in support of general healthy brain function
Assists in supporting a healthy cardiovascular system
May assist in the stimulation of flow of bile from the gall bladder.
Provides support for the nervous system and is beneficial during times of stress.
May assist in helping the body adapt to mentally and physically draining circumstances.
Contains antioxidants to assist in decreasing the risk of cell damage from free radicals.
Assists in the maintenance of a healthy urinary tract system
Assists in maintaining a healthy and normal immune system.
Designed to assist in meeting the nutritional needs of men who have ben diagnosed with iron overload (hemochromatosis), or should not take Iodine.

Additional Product information

Pack Size/Poison information

Pack Size	**Poison Schedule**

Components

1. Medicine component

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Bifidobacterium longum	
Biotin	**50 microgram**
Calcium ascorbate dihydrate	**50 mg**
Calcium orotate	**100 mg**
Calcium pantothenate	**70 mg**
Cholecalciferol	**.005 mg**
Choline bitartrate	**30 mg**
Chromium picolinate	**402 microgram**
Citrus bioflavonoids extract	**80 mg**
Copper gluconate	**14.29 mg**
Cyanocobalamin	**30 microgram**
Cynara scolymus	**25 mg**
Equivalent: Cynara scolymus (Fresh)	100 mg
d-alpha-Tocopheryl acid succinate	**41.328 mg**
Folic acid	**500 microgram**
Ginkgo biloba	**10 mg**
Equivalent: Ginkgo biloba (Dry)	500 mg
Inositol	**30 mg**
Lactobacillus acidophilus	
Lactobacillus rhamnosus	
Magnesium aspartate dihydrate	**100 mg**
Manganese amino acid chelate	**50 mg**
Molybdenum trioxide	**67.5 microgram**
Nicotinamide	**30 mg**
Phytomenadione	**80 microgram**
Pyridoxine hydrochloride	**30 mg**
Retinyl acetate	**.8625 mg**
Riboflavine	**30 mg**
Selenomethionine	**65 microgram**

Serenoa repens	**10 mg**
Equivalent: Serenoa repens (Dry)	100 mg
Silybum marianum	**15.71 mg**
Equivalent: Silybum marianum (Dry)	1.1 g
Spearmint Oil	**2 mg**
Thiamine hydrochloride	**30 mg**
Tribulus terrestris	**2 mg**
Equivalent: Tribulus terrestris (Dry)	100 mg
Tribulus terrestris	**2 mg**
Equivalent: Tribulus terrestris (Dry)	100 mg
Ubidecarenone	**1.0005 mg**
Urtica dioica	**20 mg**
Equivalent: Urtica dioica (Dry)	100 mg
Vaccinium macrocarpon	**10 mg**
Equivalent: Vaccinium macrocarpon (Fresh)	500 mg
Vitis vinifera	**8.33 mg**
Equivalent: Vitis vinifera (Dry)	1 g
Zinc amino acid chelate	**100 mg**

Public Summary

Summary for ARTG Entry: 140134 Swisse Women's Ultivite Multi-Vitamin, Mineral & Anti-Oxidant with Herbs Glucose Balance D

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	6/06/2007
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm as amended from time to time.

Where the medicine is a conventional release folic acid supplement preparation, in tablet form, of strength of 100 micrograms or more per dosage unit, the additional conditions are as follows: Where the medicine contains folic acid as a single active ingredient, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Folic Acid Tablets. Where the medicine contains multiple active ingredients, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Nutritional Supplements, as amended by its First Supplement. The dissolution characteristics for this medicine must comply with the dissolution requirements of the relevant USP24 monograph over the shelf life of the product when stored under the conditions included on the product label. It is the responsibility of manufacturers to develop and validate the analytical methods for the determination of folic acid that should be used in conjunction with the USP24 dissolution criteria. This condition does not apply to chewable, effervescent or dispersible tablets or sustained release tablets.

Products

1. Swisse Women's Ultivite Multi-Vitamin, Mineral & Anti-Oxidant with Herbs Glucose Balance D

Product Type Single Medicine Product **Effective date** 19/08/2009 12:02:37 PM

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].,

Contains lactose (or words to that effect).,

The recommended adult daily amount of vitamin A from all sources is 2500 IU (or words to that effect).,

Do not take while on warfarin therapy without medical advice.,

This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.,

If symptoms persist consult your healthcare practitioner (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.,

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

Standard Indications

Aids, assists or helps in the maintenance or improvement of general well-being.,

Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life,

May assist in the management of dietary folate deficiency.,

Prevention/treatment of vitamin [XX] and/or mineral [YY] and/or nutritional deficiencies (This indication is not be to used for the treatment of iron deficiency conditions).,

For vitamin (may state the vitamin) supplementation.,

For mineral (may state the mineral) supplementation.,

May assist in maintaining peripheral circulation and promoting general health.,

Liver tonic. Helps maintain healthy digestive function.,

Helps maintain healthy digestive function.

Specific Indications

Assists in supporting a healthy cardiovascular system
May assist in the stimulation of flow of bile from the gall bladder.
Provides support for the nervous system and is beneficial during times of stress.
Contains antioxidants to assist in decreasing the risk of cell damage from free radicals.
Assists in maintaining a healthy and normal immune system.
Assists in the maintenance of normal healthy blood sugar levels providing a positive effect on sugar balance.
Assists in providing management of plasma glocose levels with an overall balance effect on glucose metabolism.
Assists in the management of flutuating blood glucose levels.
Improves insulin's function

Additional Product Information

Pack Size/Poison Information

Pack Size

Poison Schedule

Components

1. Medicine component

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Bifidobacterium longum	
Biotin	**200 microgram**
Calcium ascorbate dihydrate	**200 mg**
Calcium orotate	**30 mg**
Calcium pantothenate	**55 mg**
Cholecalciferol	**.005 mg**
Choline bitartrate	**15 mg**
Chromium picolinate	**402 microgram**
Cinnamomum cassia	**6.67 mg**
Equivalent: Cinnamomum cassia (Dry)	100 mg
Citrus bioflavonoids extract	**20 mg**
Copper gluconate	**14.29 mg**
Crataegus monogyna	**12.5 mg**
Equivalent: Crataegus monogyna (Dry)	50 mg
Cyanocobalamin	**120 microgram**
Cynara scolymus	**12.5 mg**
Equivalent: Cynara scolymus (Fresh)	50 mg
d-alpha-Tocopheryl acid succinate	**20.0064 mg**
Folic acid	**500 microgram**
Ginkgo biloba	**20 mg**
Equivalent: Ginkgo biloba (Dry)	1 g
Gymnema sylvestre	**6.25 mg**
Inositol	**15 mg**
Lactobacillus acidophilus	
Lactobacillus rhamnosus	
Magnesium aspartate dihydrate	**110 mg**
Manganese amino acid chelate	**40 mg**
Molybdenum trioxide	**67.5 microgram**
Nicotinamide	**50 mg**
Phytomenadione	**60 microgram**
Potassium iodide	**52.32 microgram**
Pyridoxine hydrochloride	**30 mg**
Retinyl acetate	**.8625 mg**

Riboflavine	**30 mg**
Selenomethionine	**65 microgram**
Silybum marianum	**14.29 mg**
Equivalent: Silybum marianum (Dry)	1 g
Spearmint Oil	**2 mg**
Thiamine hydrochloride	**55 mg**
Trigonella foenum-graecum	**150 mg**
Equivalent: Trigonella foenum-graecum (Dry)	18.75 g
Ubidecarenone	**1.0005 mg**
Urtica dioica	**20 mg**
Equivalent: Urtica dioica (Dry)	100 mg
Vaccinium macrocarpon	**20 mg**
Equivalent: Vaccinium macrocarpon (Fresh)	1 g
Vaccinium myrtillus	
Vitis vinifera	**8.33 mg**
Equivalent: Vitis vinifera (Dry)	1 g
Withania somnifera	**20 mg**
Equivalent: Withania somnifera (Dry)	200 mg
Zinc amino acid chelate	**85 mg**

Public Summary

Summary for ARTG Entry: 140133 Swisse Men's Ultivite Multi-Vitamin, Mineral & Anti-Oxidant with Herbs Glucose Balance D

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	6/06/2007
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm,as amended from time to time.

Where the medicine is a conventional release folic acid supplement preparation, in tablet form, of strength of 100 micrograms or more per dosage unit, the additional conditions are as follows: Where the medicine contains folic acid as a single active ingredient, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Folic Acid Tablets. Where the medicine contains multiple active ingredients, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Nutritional Supplements, as amended by its First Supplement. The dissolution characteristics for this medicine must comply with the dissolution requirements of the relevant USP24 monograph over the shelf life of the product when stored under the conditions included on the product label. It is the responsibility of manufacturers to develop and validate the analytical methods for the determination of folic acid that should be used in conjunction with the USP24 dissolution criteria. This condition does not apply to chewable, effervescent or dispersible tablets or sustained release tablets.

Products

1. Swisse Men's Ultivite Multi-Vitamin, Mineral & Anti-Oxidant with Herbs Glucose Balance D

Product Type Single Medicine Product **Effective date** 19/08/2009 12:05:34 PM

Warnings

Do not take while on warfarin therapy without medical advice.,

The recommended adult daily amount of vitamin A from all sources is 2500 IU (or words to that effect).,

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.,

Contains lactose (or words to that effect).,

This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.,

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

If symptoms persist consult your healthcare practitioner (or words to that effect).

Standard Indications

Aids, assists or helps in the maintenance or improvement of general well-being.,

Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life,

May assist in the management of dietary folate deficiency.,

Prevention/treatment of vitamin [XX] and/or mineral [YY] and/or nutritional deficiencies (This indication is not be to used for the treatment of iron deficiency conditions).,

For vitamin (may state the vitamin) supplementation.,

For mineral (may state the mineral) supplementation.,

May assist in maintaining peripheral circulation and promoting general health.,

Liver tonic. Helps maintain healthy digestive function.,

Helps maintain healthy digestive function.

Specific Indications

Assists in supporting a healthy cardiovascular system
May assist in the stimulation of flow of bile from the gall bladder.
Provides support for the nervous system and is beneficial during times of stress.
Contains antioxidants to assist in decreasing the risk of cell damage from free radicals.
Assists in maintaining a healthy and normal immune system.
Assists in the maintenance of normal healthy blood sugar levels providing a positive effect on sugar balance.
Assists in providing management of plasma glocose levels with an overall balance effect on glucose metabolism.
Assists in the management of flutuating blood glucose levels.
Improves insulin's function

Additional Product Information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1. Medicine component

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Bifidobacterium longum	
Biotin	**200 microgram**
Calcium ascorbate dihydrate	**200 mg**
Calcium orotate	**20 mg**
Calcium pantothenate	**60 mg**
Cholecalciferol	**.005 mg**
Choline bitartrate	**20 mg**
Chromium picolinate	**402 microgram**
Cinnamomum cassia	**6.67 mg**
Equivalent: Cinnamomum cassia (Dry)	100 mg
Citrus bioflavonoids extract	**100 mg**
Copper gluconate	**21.43 mg**
Crataegus monogyna	**25 mg**
Equivalent: Crataegus monogyna (Dry)	100 mg
Cyanocobalamin	**120 microgram**
Cynara scolymus	**12.5 mg**
Equivalent: Cynara scolymus (Fresh)	50 mg
d-alpha-Tocopheryl acid succinate	**24.9984 mg**
Folic acid	**500 microgram**
Ginkgo biloba	**20 mg**
Equivalent: Ginkgo biloba (Dry)	1 g
Gymnema sylvestre	**6.25 mg**
Inositol	**20 mg**
Lactobacillus acidophilus	
Lactobacillus rhamnosus	
Magnesium aspartate dihydrate	**110 mg**
Manganese amino acid chelate	**50 mg**
Molybdenum trioxide	**67.5 microgram**
Nicotinamide	**55 mg**
Phytomenadione	**70 microgram**
Potassium iodide	**52.32 microgram**
Pyridoxine hydrochloride	**20 mg**
Retinyl acetate	**.8625 mg**
Riboflavine	**35 mg**

Selenomethionine	**65 microgram**
Serenoa repens	**10 mg**
Equivalent: Serenoa repens (Dry)	100 mg
Silybum marianum	**17.14 mg**
Equivalent: Silybum marianum (Dry)	1.2 g
Spearmint Oil	**2 mg**
Thiamine hydrochloride	**60 mg**
Trigonella foenum-graecum	**150 mg**
Equivalent: Trigonella foenum-graecum (Dry)	18.75 g
Ubidecarenone	**1.0005 mg**
Urtica dioica	**20 mg**
Equivalent: Urtica dioica (Dry)	100 mg
Vaccinium macrocarpon	**20 mg**
Equivalent: Vaccinium macrocarpon (Fresh)	1 g
Vaccinium myrtillus	
Vitis vinifera	**8.33 mg**
Equivalent: Vitis vinifera (Dry)	1 g
Zinc amino acid chelate	**100 mg**

Public Summary

Summary for ARTG Entry: 137246 Pregcel Nausea Relief

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	5/04/2007
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm,as amended from time to time.

Products

1. Pregcel Nausea Relief

Product Type Single Medicine Product **Effective date** 28/08/2009 9:44:39 AM

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].,

If symptoms persist consult your healthcare practitioner (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.

Standard Indications

Prevention/treatment of vitamin [XX] and/or mineral [YY] and/or nutritional deficiencies (This indication is not be to used for the treatment of iron deficiency conditions).

Specific Indications

Assists in the relief of the symptoms of morning sickness, nausea and vomiting during pregnancy.

Additional Product information

Pack Size/Poison Information

Pack Size **Poison Schedule**

Components

1. Medicine component

Dosage Form	Powder, oral
Route of Administration	Oral
Visual Identification	

Active Ingredients

Pyridoxine hydrochloride	**2.27 mg/g**
Zingiber officinale	**3.41 mg/g**

Equivalent: Zingiber officinale (Dry)	68.18 mg/g

Public Summary

Summary for ARTG Entry: 140130 Swisse Women's Ultivite Multi-Vitamin, Mineral & Anti-Oxidant with Herbs 50+ Years F

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	6/06/2007
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Products

1. Swisse Women's Ultivite Multi-Vitamin, Mineral & Anti-Oxidant with Herbs 50+ Years F

Product Type Single Medicine Product **Effective date** 28/08/2009 9:44:39 AM

Warnings

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.,

Warning: Black cohosh may harm the liver in some individuals. Use under the supervision of a healthcare professional.,

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

If symptoms persist consult your healthcare practitioner (or words to that effect).,

This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.,

Do not take while on warfarin therapy without medical advice.,

The recommended adult daily amount of vitamin A from all sources is 2500 IU (or words to that effect).,

Contains lactose (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].

Standard Indications

Helps maintain normal blood/blood tonic (Note: These claims are appropriate for folic acid, vitamin B12 and iron, but must not imply anaemic conditions),

Helps maintain healthy digestive function.,

Liver tonic. Helps maintain healthy digestive function.,

Male support. Balances and supports normal male physiology and function.,

Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life,

Aids, assists or helps in the maintenance or improvement of general well-being.,

May assist in maintaining peripheral circulation and promoting general health.,

For mineral (may state the mineral) supplementation.,

For vitamin (may state the vitamin) supplementation.,

Prevention/treatment of vitamin [XX] and/or mineral [YY] and/or nutritional deficiencies (This indication is not be to used for the treatment of iron deficiency conditions).,

May assist in the management of dietary folate deficiency.

Specific Indications

Provides support for memory function and stamina
Assists in enhancing mental alertness and improving short term memory.
May assist in support of general healthy brain function
Assists in supporting a healthy cardiovascular system
May assist in the stimulation of flow of bile from the gall bladder.
Provides support for the nervous system and is beneficial during times of stress.
May assist in helping the body adapt to mentally and physically draining circumstances.
Contains antioxidants to assist in decreasing the risk of cell damage from free radicals.
Assists in the maintenance of a healthy urinary tract system
Assists in the elimination of excess fluid from the body
Assists in maintaining a healthy and normal immune system.
Assists in the maintenance of health and wellbeing of women during and after menopause

Additional Product Information

Pack Size/Poison Information

Pack Size **Poison Schedule**

Components

1. Medicine component

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification	
Active Ingredients	
Bacopa monnieri	**2.5 mg**
Bifidobacterium longum	
Biotin	**150 microgram**
Calcium ascorbate dihydrate	**200 mg**
Calcium orotate	**100 mg**
Calcium pantothenate	**70 mg**
Cholecalciferol	**.005 mg**
Chromium picolinate	**402 microgram**
Cimicifuga racemosa	**40 mg**
Equivalent: Cimicifuga racemosa (Dry)	200 mg
Citrus bioflavonoids extract	**20 mg**
Copper gluconate	**8.57 mg**
Crataegus monogyna	**25 mg**
Equivalent: Crataegus monogyna (Dry)	100 mg
Curcuma longa	**10 mg**
Equivalent: Curcuma longa (Dry)	100 mg
Cyanocobalamin	**115 microgram**
Cynara scolymus	**12.5 mg**
Equivalent: Cynara scolymus (Fresh)	50 mg
d-alpha-Tocopheryl acid succinate	**19.9968 mg**
Ferrous fumarate	**16.01 mg**
Folic acid	**500 microgram**
Ginkgo biloba	**20 mg**
Equivalent: Ginkgo biloba (Dry)	1000 mg
Lactobacillus acidophilus	
Lactobacillus rhamnosus	
Lecithin powder - soy phosphatidylserine-enriched soy	**10 mg**
Lutein	**1 mg**
Magnesium aspartate dihydrate	**100 mg**
Manganese amino acid chelate	**30 mg**
Molybdenum trioxide	**67.5 microgram**
Nicotinamide	**20 mg**
Phytomenadione	**60 microgram**
Potassium iodide	**196 microgram**
Pyridoxine hydrochloride	**30 mg**
Retinyl acetate	**.8625 mg**
Riboflavine	**30 mg**
Scutellaria lateriflora	**12.5 mg**
Equivalent: Scutellaria lateriflora (Dry)	50 mg
Selenomethionine	**65 microgram**
Silica - colloidal anhydrous	**20 mg**
Silybum marianum	**21.43 mg**
Equivalent: Silybum marianum (Dry)	1.5 g
Spearmint Oil	**2 mg**
Thiamine hydrochloride	**30 mg**
Turnera diffusa	**50 mg**
Equivalent: Turnera diffusa (Dry)	500 mg
Ubidecarenone	**1.9995 mg**
Urtica dioica	**20 mg**
Equivalent: Urtica dioica (Dry)	100 mg
Vaccinium macrocarpon	**16 mg**
Equivalent: Vaccinium macrocarpon (Fresh)	800 mg
Vaccinium myrtillus	
Vitis vinifera	**8.33 mg**

Equivalent: Vitis vinifera (Dry)	1 g
Withania somnifera	**50 mg**
Equivalent: Withania somnifera (Dry)	500 mg
Zinc amino acid chelate	**75 mg**

Public Summary

Summary for ARTG Entry: 137243 Pregcel Benefishoil- Fish Oil from Wild Atlantic Salmon 500mg Softgel Capsule

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	5/04/2007
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm as amended from time to time.

Products

1. Pregcel Benefishoil- Fish Oil from Wild Atlantic Salmon 500mg Softgel Capsule

Product Type Single Medicine Product **Effective date** 18/06/2008

Warnings

If symptoms persist consult your healthcare practitioner (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.

Standard Indications

Specific Indications

Rich source of Omega-3 fatty acids which assist in maintaining health skin.
Helps to assist in the maintenance of normal eye and brain function.
Can assist in maintaining a healthy heart and also improve the texture of blood, thereby maintaining healthy circulatory function and supporting cardiovascular health.
It is also high in DHA which is necessary for the normal function of the brain and nervous system.
Assist in the maintenance of healthy triglyceride levels and can positively influence LDL:HDL cholesterol levels.
Assists in promoting the health of mother and baby.

Additional Product Information

Pack Size/Poison Information

Pack Size **Poison Schedule**

Components

1.

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients

Alpha tocopherol	**33.56 mg**

Fish oil - natural	**500 mg**

Public Summary

Summary for ARTG Entry: 140129 Swisse Men's Ultivite Multi-Vitamin, Mineral & Anti-Oxidant with Herbs 50+ Years F

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	6/06/2007
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Products

1. Swisse Men's Ultivite Multi-Vitamin, Mineral & Anti-Oxidant with Herbs 50+ Years F

Product Type Single Medicine Product **Effective date** 28/08/2009 9:44:39 AM

Warnings

This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.,

Do not take while on warfarin therapy without medical advice.,

The recommended adult daily amount of vitamin A from all sources is 2500 IU (or words to that effect).,

Contains lactose (or words to that effect).,

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.,

If symptoms persist consult your healthcare practitioner (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.

Standard Indications

Helps maintain normal blood/blood tonic (Note: These claims are appropriate for folic acid, vitamin B12 and iron, but must not imply anaemic conditions),

Helps maintain healthy digestive function.,

Liver tonic. Helps maintain healthy digestive function.,

Male support. Balances and supports normal male physiology and function.,

May assist in maintaining peripheral circulation and promoting general health.,

For mineral (may state the mineral) supplementation.,

For vitamin (may state the vitamin) supplementation,

Prevention/treatment of vitamin [XX] and/or mineral [YY] and/or nutritional deficiencies (This indication is not be to used for the treatment of iron deficiency conditions).,

May assist in the management of dietary folate deficiency.,

Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life,

Aids, assists or helps in the maintenance or improvement of general well-being.

Specific Indications

Provides support for memory function and stamina
Assists in enhancing mental alertness and improving short term memory.
May assist in support of general healthy brain function
Assists in supporting a healthy cardiovascular system
May assist in the stimulation of flow of bile from the gall bladder.
Provides support for the nervous system and is beneficial during times of stress.
May assist in helping the body adapt to mentally and physically draining circumstances.
Contains antioxidants to assist in decreasing the risk of cell damage from free radicals.
Assists in the maintenance of a healthy urinary tract system
Assists in the elimination of excess fluid from the body
Assists in maintaining a healthy and normal immune system.

Additional Product Information

Pack Size/Poison Information

Pack Size **Poison Schedule**

Components

1. Medicine component

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Bifidobacterium longum	
Biotin	**200 microgram**
Calcium ascorbate dihydrate	**200 mg**
Calcium orotate	**100 mg**
Calcium pantothenate	**75 mg**
Cholecalciferol	**.005 mg**
Chromium picolinate	**402 microgram**
Citrus bioflavonoids extract	**20 mg**
Copper gluconate	**12.14 mg**
Crataegus monogyna	**30 mg**
Equivalent: Crataegus monogyna (Dry)	120 mg
Cyanocobalamin	**120 microgram**
Cynara scolymus	**12.5 mg**
Equivalent: Cynara scolymus (Fresh)	50 mg
d-alpha-Tocopheryl acid succinate	**24.9984 mg**
Dulacia inopiflora	**20 mg**
Equivalent: Dulacia inopiflora (Dry)	200 mg
Ferrous fumarate	**16.01 mg**
Folic acid	**500 microgram**
Ginkgo biloba	**20 mg**
Equivalent: Ginkgo biloba (Dry)	1000 mg
Lactobacillus acidophilus	
Lactobacillus rhamnosus	
Lecithin powder - soy phosphatidylserine-enriched soy	**10 mg**
Lutein	**1 mg**
Magnesium aspartate dihydrate	**100 mg**
Manganese amino acid chelate	**40 mg**
Molybdenum trioxide	**67.5 microgram**
Nicotinamide	**25 mg**
Phytomenadione	**70 microgram**
Potassium iodide	**196 microgram**
Pyridoxine hydrochloride	**25 mg**
Retinyl acetate	**.8625 mg**
Riboflavine	**35 mg**
Scutellaria lateriflora	**12.5 mg**
Equivalent: Scutellaria lateriflora (Dry)	50 mg
Selenomethionine	**65 microgram**
Serenoa repens	**30 mg**
Equivalent: Serenoa repens (Dry)	300 mg
Silybum marianum	**24.29 mg**
Equivalent: Silybum marianum (Dry)	1.7 g
Spearmint Oil	**2 mg**
Thiamine hydrochloride	**35 mg**
Tribulus terrestris	**10 mg**
Equivalent: Tribulus terrestris (Dry)	500 mg
Tribulus terrestris	**10 mg**
Equivalent: Tribulus terrestris (Dry)	500 mg
Ubidecarenone	**3 mg**
Urtica dioica	**10 mg**
Equivalent: Urtica dioica (Dry)	50 mg
Vaccinium macrocarpon	**20 mg**
Equivalent: Vaccinium macrocarpon (Fresh)	1000 mg
Vaccinium myrtillus	
Vitis vinifera	**8.33 mg**
Equivalent: Vitis vinifera (Dry)	1 g
Zinc amino acid chelate	**100 mg**

Public Summary

Public Summary

Summary for ARTG Entry: 137244 Pregcel Calcium Magnesium

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	5/04/2007
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm as amended from time to time.

Products

1. Pregcel Calcium Magnesium

Product Type Single Medicine Product **Effective date** 4/06/2008

Warnings

If symptoms persist consult your healthcare practitioner (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.,

(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].

Standard Indications

Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults.,

Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone.,

Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.,

Relief of muscular cramps and spasms. [Warning S required],

For mineral (may state the mineral) supplementation.,

Prevention/treatment of vitamin [XX] and/or mineral [YY] and/or nutritional deficiencies (This indication is not be to used for the treatment of iron deficiency conditions).

Specific Indications

Contains chelated minerals for increased bioavailability.
Assists in replacing calcium being utilised during pregnancy in the mother

Additional Product information

Pack Size/Poison Information

Pack Size **Poison Schedule**

Components

1.

Dosage Form	Powder, oral
Route of Administration	Oral
Visual Identification	

Active Ingredients

Calcium orotate	**172.89 mg/g**
Magnesium aspartate dihydrate	**120.89 mg/g**

Public Summary

Summary for ARTG Entry: 137240 Pregcel Benefishoil - Fish Oil from Wild Atlantic Salmon 1000mg Softgel Capsule

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	5/04/2007
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm as amended from time to time.

Products

1. Pregcel Benefishoil - Fish Oil from Wild Atlantic Salmon 1000mg Softgel Capsule

Product Type Single Medicine Product **Effective date** 4/10/2007 11:00:00 PM

Warnings

If symptoms persist consult your healthcare practitioner (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.

Standard Indications

May assist in the management of mood swings. [Warning S required]

Specific Indications

Rich source of Omega-3 fatty acids which assist in maintaining health skin.
Anti-Inflammatory action that can be of benefit in relief of the inflammation associated with both osteoarthritis and arthritis.
Can assist in maintaining a healthy heart and also improve the texture of blood, thereby maintaining healthy circulatory function and supporting cardiovascular health.
Assist in the maintenance of healthy triglyceride levels and can positively influence LDL:HDL cholesterol levels.
It is also high in DHA which is necessary for the normal function of the brain and nervous system.
Helps to assist in the maintenance of normal eye and brain function.
Assists in promoting the health of mother and baby.

Additional Product information

Pack Size/Poison Information

Pack Size **Poison Schedule**

Components

1.

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients	
Alpha tocopherol	33.56 mg
Fish oil - natural	1000 mg

Public Summary

Summary for ARTG Entry: 140135 Swisse Teenace Ultivite Multi-Vitamin, Mineral & Anti-Oxidant with Herbs Teenage Men's M

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	6/06/2007
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm as amended from time to time.,

Where the medicine is a conventional release folic acid supplement preparation, in tablet form, of strength of 100 micrograms or more per dosage unit, the additional conditions are as follows: Where the medicine contains folic acid as a single active ingredient, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Folic Acid Tablets. Where the medicine contains multiple active ingredients, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Nutritional Supplements, as amended by its First Supplement. The dissolution characteristics for this medicine must comply with the dissolution requirements of the relevant USP24 monograph over the shelf life of the product when stored under the conditions included on the product label. It is the responsibility of manufacturers to develop and validate the analytical methods for the determination of folic acid that should be used in conjunction with the USP24 dissolution criteria. This condition does not apply to chewable, effervescent or dispersible tablets or sustained release tablets.

Products

1. Swisse Teenace Ultivite Multi-Vitamin, Mineral & Anti-Oxidant with Herbs Teenage Men's M

Product Type Single Medicine Product **Effective date** 28/08/2009 9:44:39 AM

Warnings

Do not take while on warfarin therapy without medical advice.,

This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.,

If symptoms persist consult your healthcare practitioner (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 can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Standard Indications

Helps maintain normal blood/blood tonic (Note: These claims are appropriate for folic acid, vitamin B12 and iron, but must not imply anaemic conditions),

Helps maintain healthy digestive function.,

Liver tonic. Helps maintain healthy digestive function.,

Beneficial during times of stress. [Warning S required],

May assist in maintaining peripheral circulation and promoting general health.,

For mineral (may state the mineral) supplementation.,

For vitamin (may state the vitamin) supplementation.,

Prevention/treatment of vitamin [XX] and/or mineral [YY] and/or nutritional deficiencies (This indication is not be to used for the treatment of iron

deficiency conditions).,

Aids, assists or helps in the maintenance or improvement of general well-being.

Specific Indications

Provides support for memory function and stamina
Assists in enhancing mental alertness and improving short term memory.
May assist in support of general healthy brain function
Provides support for the nervous system and is beneficial during times of stress.
May assist in helping the body adapt to mentally and physically draining circumstances.
Contains antioxidants to assist in decreasing the risk of cell damage from free radicals.
Assists in maintaining healthy looking skin.
Assists in the maintenance of a health urinary system.

Additional Product Information

Pack Size/Poison Information

Pack Size | **Poison Schedule**

Components

1. Medicine component

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Bacopa monnieri	**12.5 mg**
Bifidobacterium longum	
Biotin	**20 microgram**
Calcium ascorbate dihydrate	**41.24 mg**
Calcium orotate	**50 mg**
Calcium pantothenate	**5 mg**
Cholecalciferol	**.005 mg**
Choline bitartrate	**120 mg**
Chromium picolinate	**201 microgram**
Citrus bioflavonoids extract	**100 mg**
Copper gluconate	**10.72 mg**
Cyanocobalamin	**1.8 microgram**
d-alpha-Tocopheryl acid succinate	**10.0032 mg**
Dunaliella salina	
Ferrous fumarate	**12.81 mg**
Folic acid	**400 microgram**
Ginkgo biloba	**3 mg**
Equivalent: Ginkgo biloba (Dry)	150 mg
Glycyrrhiza glabra	
Inositol	**35 mg**
Lactobacillus acidophilus	
Lactobacillus rhamnosus	
Lemon Oil	**2 mg**
Lutein	**1.13 mg**
Magnesium aspartate dihydrate	**50 mg**
Manganese amino acid chelate	**30 mg**
Molybdenum trioxide	**67.5 microgram**
Nicotinamide	**18 mg**
Olea europaea	**8.33 mg**
Equivalent: Olea europaea (Dry)	50 mg
Passiflora incarnata	**25 mg**
Equivalent: Passiflora incarnata (Dry)	100 mg
Phytomenadione	**45 microgram**
Potassium iodide	**196 microgram**
Pyridoxine hydrochloride	**1 mg**
Riboflavine	**900 microgram**

Scutellaria lateriflora	**12.5 mg**
Equivalent: Scutellaria lateriflora (Dry)	50 mg
Silica - colloidal anhydrous	**50 mg**
Silybum marianum	**10.71 mg**
Equivalent: Silybum marianum (Dry)	750 mg
Thiamine hydrochloride	**900 microgram**
Vaccinium macrocarpon	**10 mg**
Equivalent: Vaccinium macrocarpon (Fresh)	500 mg
Zinc amino acid chelate	**75 mg**

Public Summary

Summary for ARTG Entry: 137097 Swisse Pregnancy Ultivite Pregnancy Multi-Vitamin Mineral & Anti-Oxidant Formula

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	3/04/2007
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm as amended from time to time.,

Where the medicine is a conventional release folic acid supplement preparation, in tablet form, of strength of 100 micrograms or more per dosage unit, the additional conditions are as follows: Where the medicine contains folic acid as a single active ingredient, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Folic Acid Tablets. Where the medicine contains multiple active ingredients, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Nutritional Supplements, as amended by its First Supplement. The dissolution characteristics for this medicine must comply with the dissolution requirements of the relevant USP24 monograph over the shelf life of the product when stored under the conditions included on the product label. It is the responsibility of manufacturers to develop and validate the analytical methods for the determination of folic acid that should be used in conjunction with the USP24 dissolution criteria. This condition does not apply to chewable, effervescent or dispersible tablets or sustained release tablets.

Products

1. Swisse Pregnancy Ultivite Pregnancy Multi-Vitamin Mineral & Anti-Oxidant Formula

Product Type Single Medicine Product **Effective date** 28/08/2009 9:44:39 AM

Warnings

Do not take while on warfarin therapy without medical advice.,

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

This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.,

If symptoms persist consult your healthcare practitioner (or words to that effect).,

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).

Standard Indications

Helps maintain normal blood/blood tonic (Note: These claims are appropriate for folic acid, vitamin B12 and iron, but must not imply anaemic conditions),

Helps maintain healthy digestive function.,

Provides a daily dose of 400-500mcg of folic acid or folate. Contains folic acid which, if taken daily for one month before conception and during pregnancy, may reduce the risk of women having a child with birth defects of the brain and/or spinal chord such as the neural tube defects known as spina bifida and anencephaly. [Warning NEUR required.],

For mineral (may state the mineral) supplementation.,

For vitamin (may state the vitamin) supplementation.,

Prevention/treatment of vitamin [XX] and/or mineral [YY] and/or nutritional deficiencies (This indication is not be to used for the treatment of iron

deficiency conditions).,

May assist in the management of dietary folate deficiency.,

Aids, assists or helps in the maintenance or improvement of general well-being.

Specific Indications

Pregnancy Ultivite provides nutritional support for both mother and baby during pregnancy and breastfeeding.

Additional Product Information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1. Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Bifidobacterium longum	**0 mg**
Biotin	**30 microgram**
Calcium ascorbate dihydrate	**72.62 mg**
Calcium citrate	**189.57 mg**
Calcium pantothenate	**5 mg**
Cholecalciferol	**.005 mg**
Choline bitartrate	**100 mg**
Chromic chloride	**154 microgram**
Citrus bioflavonoids extract	**100 mg**
Copper gluconate	**14.29 mg**
Cyanocobalamin	**2.6 microgram**
d-alpha-Tocopheryl acid succinate	**49.9968 mg**
Dunaliella salina	**40 mg**
Folic acid	**500 microgram**
Iron amino acid chelate	**50 mg**
Lactobacillus acidophilus	**0 mg**
Magnesium aspartate dihydrate	**100 mg**
Manganese amino acid chelate	**50 mg**
Matricaria recutita	**25 mg**
Molybdenum trioxide	**75 microgram**
Nicotinamide	**18 mg**
Phytomenadione	**60 microgram**
Potassium iodide	**327 microgram**
Pyridoxine hydrochloride	**20 mg**
Riboflavin	**1.4 mg**
Selenomethionine	**65 microgram**
Silybum marianum	**3.57 mg**
Spearmint Oil	**1 mg**
Thiamine hydrochloride	**1.4 mg**
Vitis vinifera	**833 microgram**
Zinc amino acid chelate	**100 mg**

Public Summary

Summary for ARTG Entry: 136511 Swisse Ultiboost Fish Oil

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	23/03/2007
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm as amended from time to time.

Products

1. Swisse Ultiboost Fish Oil

Product Type Single Medicine Product **Effective date** 23/06/2010 10:12:53 AM

Warnings

If symptoms persist consult your healthcare practitioner (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.

Standard Indications

May assist in the management of mood swings. [Warning S required]

Specific Indications

Swisse Ultiboost FISH OIL is extracted using a low heat process, similar to the extraction process of virgin COLD-PRESSED olive oil, to decrease degradation that can occur during heated extraction methods.
To assist in maintaining a healthy cardiovascular system, healthy skin and triglyceride levels.
May reduce swelling associated with osteoarthritis and arthritis

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1. Medicine component

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients

Alpha tocopherol	**33.56 mg**

Fish oil - natural	**1000 mg**

Public Summary

Summary for ARTG Entry: 134521 Swisse Men's Ultivite Multi-Vitamin Mineral & Anti-Oxidant With Herbs Formula 1 Dietary Supplement

ARTG entry for	Medicine Listed (Export Only)
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	19/01/2007
Product category	Medicine
Status	Revoked
Approval area	Export only Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm as amended from time to time.

Where the medicine is a conventional release folic acid supplement preparation, in tablet form, of strength of 100 micrograms or more per dosage unit, the additional conditions are as follows: Where the medicine contains folic acid as a single active ingredient, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Folic Acid Tablets. Where the medicine contains multiple active ingredients, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Nutritional Supplements, as amended by its First Supplement. The dissolution characteristics for this medicine must comply with the dissolution requirements of the relevant USP24 monograph over the shelf life of the product when stored under the conditions included on the product label. It is the responsibility of manufacturers to develop and validate the analytical methods for the determination of folic acid that should be used in conjunction with the USP24 dissolution criteria. This condition does not apply to chewable, effervescent or dispersible tablets or sustained release tablets.

Products

1. Swisse Men's Ultivite Multi-Vitamin Mineral & Anti-Oxidant With Herbs Formula 1 Dietary Supplement

Product Type Single Medicine Product **Effective date** 31/05/2011 12:08:48 PM

Warnings

This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.,

Not for the treatment of iron deficiency conditions (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].,

The recommended dose of this medicine provides small amounts of caffeine,

Contains lactose (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.,

If symptoms persist consult your healthcare practitioner (or words to that effect).,

Do not take while on warfarin therapy without medical advice.,

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).

Standard Indications

Specific Indications

Designed to meet man's nutritional needs and help in the maintenance or improvement of general well-being.,

Swisse formulae are updated regularly to remain at the forefront of medical research.

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Jar/Can	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1. Medicine Component

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Apium graveolens	**2 mg**
Astragalus membranaceus	**5 mg**
Avena sativa	**50 mg**
Barosma betulina	**2.5 mg**
Berberis vulgaris	**2.5 mg**
Betacarotene	**5.0002 mg**
Biotin	**50 microgram**
Calcium ascorbate dihydrate	**200 mg**
Calcium citrate	**100 mg**
Calcium pantothenate	**70 mg**
Camellia sinensis	**3.34 mg**
Carica papaya	**10 mg**
Centella asiatica	**12.5 mg**
Cholecalciferol	**.005 mg**
Choline bitartrate	**25 mg**
Chromium picolinate	**50 microgram**
Citrus bioflavonoids extract	**40 mg**
Copper gluconate	**200 microgram**
Crataegus monogyna	**25 mg**
Cyanocobalamin	**30 microgram**
Cynara scolymus	**12.5 mg**
d-alpha-Tocopheryl acid succinate	**41.3184 mg**
Equisetum arvense	**7.5 mg**
Ferrous fumarate	**9.61 mg**
Foeniculum vulgare	**3.41 mg**
Folic acid	**300 microgram**
Ginkgo biloba	**2 mg**
Inositol	**25 mg**
Lutein	**.2 mg**
Lycopersicon esculentum	**2 mg**
Lysine hydrochloride	**50 mg**
Magnesium oxide - heavy	**100 mg**
Manganese amino acid chelate	**12 mg**
Nicotinamide	**30 mg**
Panax ginseng	**16.67 mg**
Petroselinum crispum	**10 mg**
Potassium iodide	**66 microgram**
Potassium sulfate	**8.92 mg**
Pyridoxine hydrochloride	**30 mg**
Riboflavine	**30 mg**
Selenomethionine	**65 microgram**
Serenoa repens	**20 mg**

Silybum marianum	**715 microgram**
Smilax officinalis	**12.5 mg**
Spearmint Oil	**1.5 mg**
Thiamine hydrochloride	**30 mg**
Turnera diffusa	**24 mg**
Tyrosine	**1 mg**
Ubidecarenone	**1 mg**
Vaccinium myrtillus	**250 microgram**
Vitis vinifera	**8.34 mg**
Zinc amino acid chelate	**30 mg**
Zingiber officinale	**1 mg**

Public Summary

Summary for ARTG Entry: 140136 Swisse Women's Ultivite Multi-Vitamin, Mineral & Anti-Oxidant with Herbs Gluten Free G

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	6/06/2007
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

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). This condition does not apply to powdered or dried leaf.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm,as amended from time to time.,

Where the medicine is a conventional release folic acid supplement preparation, in tablet form, of strength of 100 micrograms or more per dosage unit, the additional conditions are as follows: Where the medicine contains folic acid as a single active ingredient, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Folic Acid Tablets. Where the medicine contains multiple active ingredients, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Nutritional Supplements, as amended by its First Supplement. The dissolution characteristics for this medicine must comply with the dissolution requirements of the relevant USP24 monograph over the shelf life of the product when stored under the conditions included on the product label. It is the responsibility of manufacturers to develop and validate the analytical methods for the determination of folic acid that should be used in conjunction with the USP24 dissolution criteria. This condition does not apply to chewable, effervescent or dispersible tablets or sustained release tablets.

Products

1. Swisse Women's Ultivite Multi-Vitamin, Mineral & Anti-Oxidant with Herbs Gluten Free G

Product Type Single Medicine Product **Effective date** 3/03/2010 3:59:14 PM

Warnings

Do not take while on warfarin therapy without medical advice.,

This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.,

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

If symptoms persist consult your healthcare practitioner (or words to that effect).

Standard Indications

Aids, assists or helps in the maintenance or improvement of general well-being.,

Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life,

May assist in the management of dietary folate deficiency.,

Prevention/treatment of vitamin [XX] and/or mineral [YY] and/or nutritional deficiencies (This indication is not be to used for the treatment of iron deficiency conditions).,

For vitamin (may state the vitamin) supplementation.,

For mineral (may state the mineral) supplementation.,

May assist in maintaining peripheral circulation and promoting general health.,

Liver tonic. Helps maintain healthy digestive function.,

Helps maintain healthy digestive function.,

Helps maintain normal blood/blood tonic (Note: These claims are appropriate for folic acid, vitamin B12 and iron, but must not imply anaemic conditions)

Specific Indications

Provides support for memory function and stamina
Provides support for the nervous system and is beneficial during times of stress.
May assist in helping the body adapt to mentally and physically draining circumstances.
Contains antioxidants to assist in decreasing the risk of cell damage from free radicals.
Assists in the maintenance of a healthy urinary system
Assists in maintaining a healthy and normal immune system.
Low allergy formula
Antioxidant rich.

Additional Product Information

Pack Size/Poison Information

Pack Size	Poison Schedule

Components

1. Medicine component

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Armoracia rusticana	**10 mg**
Equivalent: Armoracia rusticana (Dry)	50 mg
Bifidobacterium longum	
Biotin	**150 microgram**
Calcium ascorbate dihydrate	**170 mg**
Calcium orotate	**110 mg**
Calcium pantothenate	**80 mg**
Cholecalciferol	**.005 mg**
Choline bitartrate	**10 mg**
Chromium picolinate	**402 microgram**
Citrus bioflavonoids extract	**50 mg**
Copper gluconate	**21.43 mg**
Cyanocobalamin	**150 microgram**
Cynara scolymus	**25 mg**
Equivalent: Cynara scolymus (Fresh)	100 mg
d-alpha-Tocopheryl acid succinate	**15.0048 mg**
Ferrous fumarate	**16.01 mg**
Folic acid	**500 microgram**
Ginkgo biloba	**30 mg**
Equivalent: Ginkgo biloba (Dry)	1.5 g
Inositol	**10 mg**
Lactobacillus acidophilus	
Lactobacillus rhamnosus	
Magnesium aspartate dihydrate	**110 mg**
Manganese amino acid chelate	**40 mg**
Molybdenum trioxide	**165 microgram**
Nicotinamide	**50 mg**
Phytomenadione	**90 microgram**
Pyridoxine hydrochloride	**50 mg**
Riboflavine	**25 mg**
Selenomethionine	**65 microgram**
Silica - colloidal anhydrous	**20 mg**
Silybum marianum	**14.29 mg**
Equivalent: Silybum marianum (Dry)	1 g

Spearmint Oil	**2 mg**
Tanacetum parthenium	**12.5 mg**
Equivalent: Tanacetum parthenium (Dry)	50 mg
Thiamine hydrochloride	**25 mg**
Trigonella foenum-graecum	**25 mg**
Equivalent: Trigonella foenum-graecum (Dry)	100 mg
Turnera diffusa	**50 mg**
Equivalent: Turnera diffusa (Dry)	500 mg
Urtica dioica	**20 mg**
Equivalent: Urtica dioica (Dry)	100 mg
Vaccinium macrocarpon	**30 mg**
Equivalent: Vaccinium macrocarpon (Fresh)	1.5 g
Withania somnifera	**40 mg**
Equivalent: Withania somnifera (Dry)	400 mg
Zinc amino acid chelate	**75 mg**

Public Summary

Summary for ARTG Entry: 134520 Swisse Women's Ultivite Multi-Vitamin Mineral & Anti-Oxidant with Herbs Formula 1 Dietary Supplement

ARTG entry for	Medicine Listed (Export Only)
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	19/01/2007
Product category	Medicine
Status	Revoked
Approval area	Export only Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm,as amended from time to time.,

Where the medicine is a conventional release folic acid supplement preparation, in tablet form, of strength of 100 micrograms or more per dosage unit, the additional conditions are as follows: Where the medicine contains folic acid as a single active ingredient, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Folic Acid Tablets. Where the medicine contains multiple active ingredients, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Nutritional Supplements, as amended by its First Supplement. The dissolution characteristics for this medicine must comply with the dissolution requirements of the relevant USP24 monograph over the shelf life of the product when stored under the conditions included on the product label. It is the responsibility of manufacturers to develop and validate the analytical methods for the determination of folic acid that should be used in conjunction with the USP24 dissolution criteria. This condition does not apply to chewable, effervescent or dispersible tablets or sustained release tablets.

Products

1. Swisse Women's Ultivite Multi-Vitamin Mineral & Anti-Oxidant with Herbs Formula 1 Dietary Supplement

Product Type Single Medicine Product **Effective date** 31/05/2011 12:08:48 PM

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].,

Do not take while on warfarin therapy without medical advice.,

If symptoms persist consult your healthcare practitioner (or words to that effect).,

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).,

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

This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.,

Contains [insert name of ingredient] (or words to that effect).,

The recommended dose of this medicine provides small amounts of caffeine,

Contains lactose (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.

Standard Indications

Specific Indications

Designed to meet Women's nutritional needs and help in the maintenance of general well-being.,

Swisse formulae are updated regularly to remain at the forefront of medical research.

Additional Product Information

Container Information

Type	Material	Life Time	Temperature	Closure	Conditions
Jar/Can	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison Information

Pack Size

Poison Schedule

Components

1. Medicine Component

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Apium graveolens	**2 mg**
Arctostaphylos uva-ursi	**6.25 mg**
Astragalus membranaceus	**5 mg**
Avena sativa	**50 mg**
Betacarotene	**5.0002 mg**
Biotin	**50 microgram**
Calcium ascorbate dihydrate	**200 mg**
Calcium citrate	**200 mg**
Calcium pantothenate	**75 mg**
Camellia sinensis	**3.34 mg**
Carica papaya	**10 mg**
Centella asiatica	**2.5 mg**
Cholecalciferol	**.005 mg**
Choline bitartrate	**25 mg**
Chromium picolinate	**50 microgram**
Citrus bioflavonoids extract	**40 mg**
Copper gluconate	**417 microgram**
Crataegus monogyna	**7.5 mg**
Cyanocobalamin	**50 microgram**
Cynara scolymus	**12.5 mg**
d-alpha-Tocopheryl acid succinate	**41.33 mg**
Eleutherococcus senticosus	**2.5 mg**
Equisetum arvense	**7.5 mg**
Ferrous fumarate	**16.01 mg**
Foeniculum vulgare	**3.41 mg**
Folic acid	**300 microgram**
Ginkgo biloba	**100 microgram**
Glycyrrhiza glabra	**2.5 mg**
Inositol	**25 mg**
Lutein	**.2 mg**
Lycopersicon esculentum	**2 mg**
Lysine hydrochloride	**50 mg**
Magnesium oxide - heavy	**81.46 mg**
Manganese amino acid chelate	**16 mg**
Matricaria recutita	**3.75 mg**
Nicotinamide	**50 mg**
Petroselinum crispum	**10 mg**
Potassium iodide	**66 microgram**
Potassium sulfate	**4.45 mg**
Pyridoxine hydrochloride	**50 mg**
Riboflavine	**50 mg**

Selenomethionine	**65 microgram**
Silybum marianum	**715 microgram**
Spearmint Oil	**1.5 mg**
Thiamine hydrochloride	**50 mg**
Ubidecarenone	**1 mg**
Vaccinium myrtillus	**250 microgram**
Vitis vinifera	**8.34 mg**
Zinc amino acid chelate	**25 mg**
Zingiber officinale	**3 mg**

Public Summary

Summary for ARTG Entry: 129846 SWISSE MEN'S ULTIVITE MULTIVITAMIN, MINERAL AND ANTI-OXIDANT FORMULA 1 WITH HERBS (CAPSULE)

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	31/07/2006
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm,as amended from time to time.

Products

1. SWISSE MEN'S ULTIVITE MULTIVITAMIN, MINERAL AND ANTI-OXIDANT FORMULA 1 WITH HERBS (CAPSULE)

Product Type Single Medicine Product **Effective date** 28/08/2009 9:44:39 AM

Warnings

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

Contains caffeine [state quantity per dosage unit or per mL or per gram of product] [must be clear and legible].,

This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.,

Do not take while on warfarin therapy without medical advice.,

Contains lactose (or words to that effect).,

If symptoms persist consult your healthcare practitioner (or words to that effect).,

Contains [insert name of ingredient] (or words to that effect).

Standard Indications

Source of folic acid. Can assist in maintaining normal blood.,

Source of folic acid. Can assist in maintaining normal blood. Blood tonic.,

Male support. Balances and supports normal male physiology and function.,

Aids, assists or helps in the maintenance or improvement of general well-being.,

Beneficial during times of stress. [Warning S required],

Helps relieve nervous tension, stress and mild anxiety. [Warning S required],

For mineral (may state the mineral) supplementation.,

For vitamin (may state the vitamin) supplementation.,

Prevention/treatment of vitamin [XX] and/or mineral [YY] and/or nutritional deficiencies (This indication is not be to used for the treatment of iron deficiency conditions).,

May assist in the management of dietary folate deficiency.

Specific Indications

Designed to meet men's nutritional needs and general well-being. The herbal ingredients in this formulation may help men perform in peak condition and improve stress adaptation.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1. COMPONENT ONE

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

Apium graveolens	**1 mg**
Equivalent: Apium graveolens (Dry)	10 mg
Astragalus membranaceus	**2.5 mg**
Equivalent: Astragalus membranaceus (Dry)	25 mg
Avena sativa	**25 mg**
Equivalent: Avena sativa (Fresh)	250 mg
Barosma betulina	**1.25 mg**
Equivalent: Barosma betulina (Dry)	5 mg
Berberis vulgaris	**1.25 mg**
Equivalent: Berberis vulgaris (Dry)	7.5 mg
Biotin	**25 microgram**
Calcium ascorbate dihydrate	**100 mg**
Calcium citrate	**50 mg**
Calcium pantothenate	**35 mg**
Camellia sinensis	**1.67 mg**
Equivalent: Camellia sinensis (Dry)	10 mg
Carica papaya	**5 mg**
Centella asiatica	**6.25 mg**
Equivalent: Centella asiatica (Dry)	25 mg
Cholecalciferol	**.0025 mg**
Choline bitartrate	**12.5 mg**
Chromium picolinate	**25 microgram**
Citrus bioflavonoids extract	**20 mg**
Copper gluconate	**100 microgram**
Crataegus monogyna	**12.5 mg**
Equivalent: Crataegus monogyna (Dry)	50 mg
Cyanocobalamin	**15 microgram**
Cynara scolymus	**6.25 mg**
Equivalent: Cynara scolymus (Fresh)	25 mg
d-alpha-Tocopheryl acid succinate	**20.256 mg**
Dunaliella salina	
Equisetum arvense	**3.75 mg**
Equivalent: Equisetum arvense (Dry)	15 mg
Ferrous fumarate	**4.8 mg**
Foeniculum vulgare	**1.7 mg**
Equivalent: Foeniculum vulgare (Dry)	7.5 mg
Folic acid	**250 microgram**
Ginkgo biloba	**1 mg**
Equivalent: Ginkgo biloba (Dry)	50 mg
Inositol	**12.5 mg**
Lutein	**100 microgram**
Lycopersicon esculentum	
Lysine hydrochloride	**25 mg**
Magnesium oxide - heavy	**50 mg**

Manganese amino acid chelate	**6 mg**
Nicotinamide	**15 mg**
Panax ginseng	**8.33 mg**
Equivalent: Panax ginseng (Dry)	25 mg
Petroselinum crispum	**5 mg**
Potassium iodide	**33 microgram**
Potassium sulfate	**4.46 mg**
Pyridoxine hydrochloride	**15 mg**
Riboflavine	**15 mg**
Selenomethionine	**32.5 microgram**
Serenoa repens	**10 mg**
Equivalent: Serenoa repens (Dry)	100 mg
Silybum marianum	**357 microgram**
Smilax officinalis	**6.25 mg**
Equivalent: Smilax officinalis (Dry)	25 mg
Spearmint Oil	**750 microgram**
Thiamine hydrochloride	**15 mg**
Turnera diffusa	**12 mg**
Equivalent: Turnera diffusa (Dry)	60 mg
Tyrosine	**500 microgram**
Ubidecarenone	**500 microgram**
Vaccinium myrtillus	
Vitis vinifera	**4.17 mg**
Zinc amino acid chelate	**15 mg**
Zingiber officinale	**500 microgram**
Equivalent: Zingiber officinale (Dry)	2.5 mg

Public Summary

Summary for ARTG Entry: 122501 Cerexl

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	7/10/2005
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm as amended from time to time.,

Where the medicine is a conventional release folic acid supplement preparation, in tablet form, of strength of 100 micrograms or more per dosage unit, the additional conditions are as follows: Where the medicine contains folic acid as a single active ingredient, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Folic Acid Tablets. Where the medicine contains multiple active ingredients, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Nutritional Supplements, as amended by its First Supplement. The dissolution characteristics for this medicine must comply with the dissolution requirements of the relevant USP24 monograph over the shelf life of the product when stored under the conditions included on the product label. It is the responsibility of manufacturers to develop and validate the analytical methods for the determination of folic acid that should be used in conjunction with the USP24 dissolution criteria. This condition does not apply to chewable, effervescent or dispersible tablets or sustained release tablets.

Products

1. Cerexl

Product Type Single Medicine Product **Effective date** 3/04/2009 8:39:00 AM

Warnings

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

If symptoms persist consult your healthcare practitioner (or words to that effect).

Standard Indications

Assisting in the maintenance of blood flow in the hands, feet and legs.,

To help maintain blood circulation to the peripheral areas of the body such as the legs, hands and feet.,

May assist peripheral circulation.,

Eyes formula. Support of healthy eye function.,

Aids or assists in the prevention of muscular cramps and spasms.,

Aids, assists or helps in the maintenance or improvement of general well-being.

Specific Indications

Support of Memory and Stamina CLINICALS CEREXL by Swisse has been developed by a professor and contains scientifically validated ingredients that help maintain memory function and stamina. CEREXL is based on the assessment of clinical studies, which showed certain ingredients in CEREXL can improve short-term memory and enhance mental alertness. CEREXL helps improve brain function such as learning or concentration as well as helping relieve the symptoms of absentmindedness. Used as directed, CEREXL may deliver positive results relatively quickly.For better results: CEREXL may be effective when used on it's own, however we recommend you use this product in conjunction with Swisse Women's or Men's Ultivite, which act as a foundation to provide the body with the important nutrients for general wellbeing. Reduces muscular pain and leg cramps and improves blood

circulation. Relieves symptoms of cold hands and feet.

Additional Product Information

Pack Size/Poison Information

Pack Size	**Poison Schedule**

Components

1. Medicine Component

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Calcium ascorbate dihydrate	**60 mg**
Citrus bioflavonoids extract	**20 mg**
Cyanocobalamin	**25 microgram**
Folic acid	**250 microgram**
Ginkgo biloba	**30 mg**
Equivalent: Ginkgo biloba (Dry)	1.5 g
Glutamine	**125 mg**
Lecithin powder - soy phosphatidylserine-enriched soy	**75 mg**
Levocarnitine	**50 mg**
Magnesium aspartate dihydrate	**250 mg**
R,S-alpha Lipoic acid	**75 mg**
Thiamine hydrochloride	**50 mg**
Tyrosine	**50 mg**
Zinc amino acid chelate	**12.5 mg**

Public Summary

Summary for ARTG Entry: 123100 H BIO-JUVEN HAIR NAILS SKIN MINERAL & HERBAL FORMULA WITH ADDED VITAMINS

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	26/10/2005
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm as amended from time to time.

Products

1. H BIO-JUVEN HAIR NAILS SKIN MINERAL & HERBAL FORMULA WITH ADDED VITAMINS

Product Type Single Medicine Product **Effective date** 28/08/2009 9:44:39 AM

Warnings

If symptoms persist consult your healthcare practitioner (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.

Standard Indications

Aids, assists or helps in the maintenance or improvement of general well-being.,

Aids or assists in the maintenance of peripheral circulation.

Specific Indications

H Bio-Juven contains vitamins and minerals known to science today to assist in making hair, nails and skin look and feel better, plus herbs to help aid in the maintenance of peripheral circulation so that these nutrients can travel to their destination and fulfil the desired objectives. To PERI and healthy hair, skin and nails.

Additional Product Information

Pack Size/Poison Information

Pack Size **Poison Schedule**

Components

1. COMPONENT ONE

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

Biotin	**200 microgram**

Calcium ascorbate dihydrate	**60 mg**
Calcium citrate	**50 mg**
Calcium pantothenate	**25 mg**
Cholecalciferol	**.25 microgram**
Citrus bioflavonoids extract	**40 mg**
Cyanocobalamin	**25 microgram**
Cysteine hydrochloride	**60 mg**
Cystine	**20 mg**
d-alpha-Tocopheryl acid succinate	**10.0032 mg**
Dunaliella salina	
Equisetum arvense	**12.5 mg**
Equivalent: Equisetum arvense (Dry)	50 mg
Ferrous fumarate	**9.61 mg**
Folic acid	**50 microgram**
Ginkgo biloba	**10 mg**
Magnesium oxide - heavy	**51.82 mg**
Nicotinamide	**10 mg**
Panicum miliaceum	**25.46 mg**
Potassium iodide	**65.4 microgram**
Pyridoxine hydrochloride	**10 mg**
Riboflavine	**10 mg**
Salvia officinalis	**50 mg**
Thiamine hydrochloride	**10 mg**
Zinc amino acid chelate	**25 mg**
Zingiber officinale	**50 mg**

Public Summary

Summary for ARTG Entry: 130053 SWISSE WOMEN'S ULTIVITE MULTI-VITAMIN MINERAL & ANTI-OXIDANT WITH HERBS NO IRON OR IODINE (TABLET)

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	4/08/2006
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm,as amended from time to time.

Where the medicine is a conventional release folic acid supplement preparation in tablet form, of strength of 100 micrograms or more per dosage unit, the additional conditions are as follows: Where the medicine contains folic acid as a single active ingredient, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Folic Acid Tablets. Where the medicine contains multiple active ingredients, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Nutritional Supplements, as amended by its First Supplement. The dissolution characteristics for this medicine must comply with the dissolution requirements of the relevant USP24 monograph over the shelf life of the product when stored under the conditions included on the product label. It is the responsibility of manufacturers to develop and validate the analytical methods for the determination of folic acid that should be used in conjunction with the USP24 dissolution criteria. This condition does not apply to chewable, effervescent or dispersible tablets or sustained release tablets.

Products

1. SWISSE WOMEN'S ULTIVITE MULTI-VITAMIN MINERAL & ANTI-OXIDANT WITH HERBS NO IRON OR IODINE (TABLET)

Product Type Single Medicine Product **Effective date** 28/08/2009 9:44:39 AM

Warnings

This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.,

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

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).,

Do not take while on warfarin therapy without medical advice.,

Contains lactose (or words to that effect).,

If symptoms persist consult your healthcare practitioner (or words to that effect).,

Contains [insert name of ingredient] (or words to that effect).,

Contains caffeine [state quantity per dosage unit or per mL or per gram of product] [must be clear and legible].

Standard Indications

Source of folic acid. Can assist in maintaining normal blood.,

Liver tonic. Aids digestion.,

Aids, assists or helps in the maintenance or improvement of general well-being.,

Source of folic acid. Can assist in maintaining normal blood. Blood tonic.,

Provides a daily dose of 400-500mcg of folic acid or folate. Contains folic acid which, if taken daily for one month before conception and during pregnancy, may reduce the risk of women having a child with birth defects of the brain and/or spinal chord such as the neural tube defects known as spina bifida and anencephaly. [Warning NEUR required.]

Specific Indications

Designed to assist in meeting the nutritional needs of women who have been diagnosed with iron overload (hemochromatosis), or should not take Iodine. Assists with the relief of pre-menstrual symptoms/syndrome.

Additional Product information

Pack Size/Poison Information

Pack Size | **Poison Schedule**

Components

1. COMPONENT ONE

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Apium graveolens	**2 mg**
Equivalent: Apium graveolens (Dry)	20 mg
Arctostaphylos uva-ursi	**6.25 mg**
Equivalent: Arctostaphylos uva-ursi (Dry)	25 mg
Astragalus membranaceus	**5 mg**
Equivalent: Astragalus membranaceus (Dry)	50 mg
Avena sativa	**50 mg**
Equivalent: Avena sativa (Fresh)	500 mg
Biotin	**50 microgram**
Calcium ascorbate dihydrate	**50 mg**
Calcium citrate	**200 mg**
Calcium pantothenate	**75 mg**
Camellia sinensis	**3.34 mg**
Equivalent: Camellia sinensis (Dry)	20 mg
Carica papaya	**5 mg**
Centella asiatica	**2.5 mg**
Equivalent: Centella asiatica (Dry)	10 mg
Cholecalciferol	**.005 mg**
Choline bitartrate	**25 mg**
Chromium picolinate	**50 microgram**
Citrus bioflavonoids extract	**40 mg**
Copper gluconate	**417 microgram**
Crataegus monogyna	**7.5 mg**
Equivalent: Crataegus monogyna (Dry)	30 mg
Cyanocobalamin	**50 microgram**
Cynara scolymus	**12.5 mg**
Equivalent: Cynara scolymus (Fresh)	50 mg
d-alpha-Tocopheryl acid succinate	**37.1904 mg**
Dunaliella salina	
Eleutherococcus senticosus	**2.5 mg**
Equivalent: Eleutherococcus senticosus (Dry)	25 mg
Equisetum arvense	**7.5 mg**
Equivalent: Equisetum arvense (Dry)	30 mg
Foeniculum vulgare	**3.41 mg**
Equivalent: Foeniculum vulgare (Dry)	15 mg
Folic acid	**500 microgram**
Ginkgo biloba	**100 microgram**
Equivalent: Ginkgo biloba (Dry)	5 mg
Glycyrrhiza glabra	**2.5 mg**

Equivalent: Glycyrrhiza glabra (Dry)	10 mg
Inositol	**25 mg**
Lutein	**.2 mg**
Lycopersicon esculentum	
Magnesium oxide	**88.1 mg**
Manganese amino acid chelate	**16 mg**
Matricaria recutita	**3.75 mg**
Equivalent: Matricaria recutita (Dry)	15 mg
Nicotinamide	**50 mg**
Petroselinum crispum	**5 mg**
Potassium sulfate	**4.45 mg**
Pyridoxine hydrochloride	**50 mg**
Riboflavine	**50 mg**
Selenomethionine	**65 microgram**
Silybum marianum	**14.29 mg**
Spearmint Oil	**1.5 mg**
Thiamine hydrochloride	**50 mg**
Tocopherols concentrate - mixed (low-alpha type)	**3.353 mg**
Ubidecarenone	**1 mg**
Vaccinium myrtillus	
Vitis vinifera	**8.34 mg**
Zinc amino acid chelate	**25 mg**
Zingiber officinale	**3 mg**
Equivalent: Zingiber officinale (Dry)	15 mg

Public Summary

Summary for ARTG Entry: 122511 Swisse Women's Ultivite Multi-Vitamin Mineral & Anti-oxidant Formula 1 with herbs (tablets)

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	7/10/2005
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm, as amended from time to time.,

Where the medicine is a conventional release folic acid supplement preparation, in tablet form, of strength of 100 micrograms or more per dosage unit, the additional conditions are as follows: Where the medicine contains folic acid as a single active ingredient, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Folic Acid Tablets. Where the medicine contains multiple active ingredients, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Nutritional Supplements, as amended by its First Supplement. The dissolution characteristics for this medicine must comply with the dissolution requirements of the relevant USP24 monograph over the shelf life of the product when stored under the conditions included on the product label. It is the responsibility of manufacturers to develop and validate the analytical methods for the determination of folic acid that should be used in conjunction with the USP24 dissolution criteria. This condition does not apply to chewable, effervescent or dispersible tablets or sustained release tablets.

Products

1. Swisse Women's Ultivite Multi-Vitamin Mineral & Anti-oxidant Formula 1 with herbs (tablets)

Product Type Single Medicine Product **Effective date** 28/08/2009 9:44:39 AM

Warnings

Contains [insert name of ingredient] (or words to that effect).,

Do not take while on warfarin therapy without medical advice.,

Contains lactose (or words to that effect).,

Contains caffeine [state quantity per dosage unit or per mL or per gram of product] [must be clear and legible].,

This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.,

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

If symptoms persist consult your healthcare practitioner (or words to that effect).

Standard Indications

Beneficial during times of stress. [Warning S required],

For mineral (may state the mineral) supplementation.,

For vitamin (may state the vitamin) supplementation.,

Prevention/treatment of vitamin [XX] and/or mineral [YY] and/or nutritional deficiencies (This indication is not be to used for the treatment of iron deficiency conditions).,

May assist in the management of dietary folate deficiency.,

Aids, assists or helps in the maintenance or improvement of general well-being.,

Source of folic acid. Can assist in maintaining normal blood. Blood tonic.,

Source of folic acid. Can assist in maintaining normal blood.,

Helps relieve nervous tension, stress and mild anxiety. [Warning S required]

Specific Indications

Designed to assist in meeting women's nutritional needs and maintaining general well-being.The herbal ingredients may help women perform in peak condition and improve stress adaptation.
Assist in the relief of pre-menstrual symptoms/syndrome

Additional Product information

Pack Size/Poison information

Pack Size	**Poison Schedule**

Components

1. COMPONENT ONE

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Apium graveolens	**2 mg**
Equivalent: Apium graveolens (Dry)	20 mg
Arctostaphylos uva-ursi	**6.25 mg**
Equivalent: Arctostaphylos uva-ursi (Dry)	25 mg
Astragalus membranaceus	**5 mg**
Equivalent: Astragalus membranaceus (Dry)	50 mg
Avena sativa	**50 mg**
Equivalent: Avena sativa (Fresh)	500 mg
Biotin	**50 microgram**
Calcium ascorbate dihydrate	**200 mg**
Calcium citrate	**200 mg**
Calcium pantothenate	**75 mg**
Camellia sinensis	**3.34 mg**
Equivalent: Camellia sinensis (Dry)	20 mg
Carica papaya	**10 mg**
Centella asiatica	**2.5 mg**
Equivalent: Centella asiatica (Dry)	10 mg
Cholecalciferol	**.005 mg**
Choline bitartrate	**25 mg**
Chromium picolinate	**50 microgram**
Citrus bioflavonoids extract	**40 mg**
Copper gluconate	**417 microgram**
Crataegus monogyna	**7.5 mg**
Equivalent: Crataegus monogyna (Dry)	30 mg
Cyanocobalamin	**50 microgram**
Cynara scolymus	**12.5 mg**
Equivalent: Cynara scolymus (Fresh)	50 mg
d-alpha-Tocopheryl acid succinate	**41.33 mg**
Dunaliella salina	
Eleutherococcus senticosus	**2.5 mg**
Equivalent: Eleutherococcus senticosus (Dry)	25 mg
Equisetum arvense	**7.5 mg**
Equivalent: Equisetum arvense (Dry)	30 mg
Ferrous fumarate	**16.01 mg**
Foeniculum vulgare	**3.41 mg**
Equivalent: Foeniculum vulgare (Dry)	15 mg
Folic acid	**500 microgram**
Ginkgo biloba	**100 microgram**

Equivalent: Ginkgo biloba (Dry)	5 mg
Glycyrrhiza glabra	**2.5 mg**
Equivalent: Glycyrrhiza glabra (Dry)	10 mg
Inositol	**25 mg**
Lutein	**.2 mg**
Lycopersicon esculentum	
Lysine hydrochloride	**50 mg**
Magnesium oxide	**81.46 mg**
Manganese amino acid chelate	**16 mg**
Matricaria recutita	**3.75 mg**
Equivalent: Matricaria recutita (Dry)	15 mg
Nicotinamide	**50 mg**
Petroselinum crispum	**10 mg**
Potassium iodide	**66 microgram**
Potassium sulfate	**4.45 mg**
Pyridoxine hydrochloride	**50 mg**
Riboflavine	**50 mg**
Selenomethionine	**65 microgram**
Silybum marianum	**715 microgram**
Spearmint Oil	**1.7 mg**
Thiamine hydrochloride	**50 mg**
Tocopherols concentrate - mixed (low-alpha type)	**466.2 microgram**
Ubidecarenone	**1 mg**
Vaccinium myrtillus	
Vitis vinifera	**8.34 mg**
Zinc amino acid chelate	**25 mg**
Zingiber officinale	**3 mg**
Equivalent: Zingiber officinale (Dry)	15 mg

Public Summary

Summary for ARTG Entry: 124329 Swisse Ultiboost Bone Dense

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	19/12/2005
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm as amended from time to time.

Products

1. Swisse Ultiboost Bone Dense

Product Type Single Medicine Product **Effective date** 31/05/2011 12:08:48 PM

Warnings

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

Standard Indications

Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life,

Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.

Specific Indications

Swisse Ultiboost Bone Dense is best taken at night because the mineral flux in your body that maintains bone growth is greatest during sleep.
It has been shown that taking excessive amounts of calcium without the necessary supplementary nutrients may hinder the rate of calcium absorption.
Swisse Ultiboost Bone Dense should be combined with weight bearing exercises, as determined by your Health Care Practitioner, to assist in increasing bone density to minimize the risk of osteoporosis in later life.
Formulated to strengthen and protect bones and teeth

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Jar/Can	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1. Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients	
Calcium ascorbate dihydrate	50 mg
Calcium carbonate	750 mg
Cholecalciferol	.012 mg
Chromic chloride	51 microgram
Copper gluconate	250 microgram
Magnesium aspartate	80 mg
Magnesium oxide - heavy	461.95 mg
Magnesium phosphate	150 mg
Manganese amino acid chelate	25 mg
Potassium aspartate	27.28 mg
Potassium iodide	66 microgram
Zinc sulfate monohydrate	33.34 mg

Public Summary

Summary for ARTG Entry: 126720 SWISSE CHILDVITE 2

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	6/04/2006
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm as amended from time to time.

Products

1. SWISSE CHILDVITE 2

Product Type Single Medicine Product **Effective date** 28/08/2009 9:44:39 AM

Warnings

Not for the treatment of iron deficiency conditions (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.

Standard Indications

Aids, assists or helps in the maintenance or improvement of general well-being.

Specific Indications

A Children's Multivitamin, Mineral and Antioxidant Formula with selected herbs which help to promote stamina, endurance and well-being. Childvite 2 has been specially formulated with selected herbs to assist children who are low in stamina and endurance. The vitamin, mineral and antioxidant ingredients have been added to assist in the promotion of general well-being, while the herbs promote stamina and endurance levels, assisting children to perform in peak condition. Childvite 2 has been developed by the Swisse team of medical researchers in consultation with parents, to provide a pleasant tasting chewable tablet with natural colours and flavours, and no preservatives.

Additional Product Information

Pack Size/Poison Information

Pack Size **Poison Schedule**

Components

1. COMPONENT ONE

Dosage Form	Tablet, chewable
Route of Administration	Oral
Visual Identification	

Active Ingredients

Ascorbic acid	**50 mg**

Betacarotene	**.2 mg**
Biotin	**30 microgram**
Calcium citrate	**100 mg**
Calcium pantothenate	**2 mg**
Cholecalciferol	**.5 microgram**
Citrus bioflavonoids extract	**2 mg**
Cyanocobalamin	**3 microgram**
d-alpha-Tocopheryl acid succinate	**4.9632 mg**
Dunaliella salina	
Eleutherococcus senticosus	**650 microgram**
Equivalent: Eleutherococcus senticosus (Dry)	6.5 mg
Ferrous fumarate	**7.36 mg**
Folic acid	**15 microgram**
Magnesium phosphate	**8 mg**
Manganese sulfate monohydrate	**500 microgram**
Nicotinamide	**9.99 mg**
Pyridoxine hydrochloride	**1.998 mg**
Riboflavine	**1.002 mg**
Rosa canina	**2.5 mg**
Equivalent: Rosa canina (Dry)	10 mg
Thiamine nitrate	**.999 mg**
Urtica dioica	**2.5 mg**
Equivalent: Urtica dioica (Dry)	10 mg
Zinc sulfate monohydrate	**1 mg**

Public Summary

Summary for ARTG Entry: 122923 Swisse Ultiboost Student Focus

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	19/10/2005
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

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). This condition does not apply to powdered or dried leaf.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm,as amended from time to time.

Products

1. Swisse Ultiboost Student Focus

Product Type Single Medicine Product **Effective date** 31/05/2011 12:08:48 PM

Warnings

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

If symptoms persist consult your healthcare practitioner (or words to that effect).

Standard Indications

Helps relieve nervous tension, stress and mild anxiety. [Warning S required],

Beneficial during times of stress. [Warning S required]

Specific Indications

Vitamin supplement with added minerals and herbs to help perform in peak condition. A vitamin, mineral and herbal supplement formulated to address the needs of students in today's demanding, competitive environment. The herbs in Swisse Student HD may be of benefit in times of stress, or when peak condition and stamina are desired. A special formulation designed to help improve stress adaptation. The herbs have been especially chosen for their beneficial effects in providing relief of nervous tension, mild anxiety and stress tension.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1. Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients	
Avena sativa	**50 mg**
Equivalent: Avena sativa (Fresh)	500 mg
Calcium pantothenate	**25 mg**
Calcium phosphate	**160 mg**
Cyanocobalamin	**10 microgram**
Ginkgo biloba	**5 mg**
Equivalent: Ginkgo biloba (Dry)	250 mg
Magnesium phosphate	**130 mg**
Nicotinamide	**10 mg**
Panax ginseng	**35 mg**
Equivalent: Panax ginseng (Dry)	350 mg
Potassium phosphate - dibasic	**65 mg**
Pyridoxine hydrochloride	**10 mg**
Riboflavine	**15 mg**
Smilax ornata	**12.5 mg**
Equivalent: Smilax ornata (Dry)	50 mg
Thiamine nitrate	**10 mg**
Zinc amino acid chelate	**25 mg**

Public Summary

Summary for ARTG Entry: 122392 SWISSE STUDENT HD

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	4/10/2005
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm,as amended from time to time.

Products

1. SWISSE STUDENT HD

Product Type Single Medicine Product **Effective date** 4/10/2007 11:00:00 PM

Warnings

Contains [insert name of ingredient] (or words to that effect).,

If symptoms persist consult your healthcare practitioner (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.

Standard Indications

Helps relieve nervous tension, stress and mild anxiety. [Warning S required],

Beneficial during times of stress. [Warning S required]

Specific Indications

Vitamin supplement with added minerals and herbs to help perform in peak condition. A vitamin, mineral and herbal supplement formulated to address the needs of students in today's demanding, competitive environment. The herbs in Swisse Student HD may be of benefit in times of stress, or when peak condition and stamina are desired. A special formulation designed to help improve stress adaptation. The herbs have been especially chosen for their beneficial effects in providing relief of nervous tension, mild anxiety and stress tension.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1. COMPONENT ONE

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

Avena sativa	**50 mg**
Equivalent: Avena sativa (Fresh)	500 mg
Calcium pantothenate	**25 mg**
Calcium phosphate	**160 mg**
Cyanocobalamin	**10 microgram**
Ginkgo biloba	**5 mg**
Equivalent: Ginkgo biloba (Dry)	250 mg
Magnesium phosphate	**130 mg**
Nicotinamide	**10 mg**
Panax ginseng	**35 mg**
Equivalent: Panax ginseng (Dry)	350 mg
Potassium phosphate - dibasic	**65 mg**
Pyridoxine hydrochloride	**10 mg**
Riboflavine	**15 mg**
Smilax ornata	**12.5 mg**
Equivalent: Smilax ornata (Dry)	50 mg
Thiamine nitrate	**10 mg**
Zinc amino acid chelate	**25 mg**

Public Summary

Summary for ARTG Entry: 127001 SWISSE CHILDVITE 1

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	18/04/2006
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm as amended from time to time.

Products

1. SWISSE CHILDVITE 1

Product Type Single Medicine Product **Effective date** 28/08/2009 9:44:39 AM

Warnings

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

If symptoms persist consult your healthcare practitioner (or words to that effect).

Standard Indications

Helps relieve nervous tension, stress and mild anxiety. [Warning S required],

Beneficial during times of stress. [Warning S required],

Relief of sleeplessness. [Warning S required],

Aids, assists or helps in the maintenance or improvement of general well-being.

Specific Indications

A children's multivitamin, mineral and antioxidant formula, with selected herbs which help to promote calmness in very active children. . Childvite 1 has been specially formulated with selected vitamins, minerals, antioxidants and herbs to address the nutritional needs of very active children. These ingredients are known to be important for well being and the herbs have been selected to promote calmness while relieving stress and nervous tension in very active children. Childvite 1 may also be used to assist the child to prepare for sleep. Childvite 1 has been developed by the Swisse team of medical researchers in consultation with parents, to provide a pleasant tasting, chewable tablet with natural colours and flavours, and no preservatives.

Additional Product information

Pack Size/Poison Information

Pack Size **Poison Schedule**

Components

1. COMPONENT ONE

Dosage Form	Tablet, chewable
Route of Administration	Oral

Visual Identification

Active Ingredients

Ascorbic acid	**50 mg**
Betacarotene	**.2 mg**
Biotin	**30 microgram**
Calcium citrate	**100 mg**
Calcium pantothenate	**2 mg**
Cholecalciferol	**.5 microgram**
Citrus bioflavonoids extract	**2 mg**
Cyanocobalamin	**2 microgram**
d-alpha-Tocopheryl acid succinate	**4.9632 mg**
Dunaliella salina	
Ferrous fumarate	**3.16 mg**
Folic acid	**10 microgram**
Humulus lupulus	**267 microgram**
Equivalent: Humulus lupulus (Dry)	2 mg
Magnesium phosphate	**8 mg**
Manganese sulfate monohydrate	**500 microgram**
Matricaria recutita	**3.75 mg**
Equivalent: Matricaria recutita (Dry)	15 mg
Nicotinamide	**9.99 mg**
Pyridoxine hydrochloride	**2.9903 mg**
Riboflavine	**1.2024 mg**
Thiamine nitrate	**1.4985 mg**
Zinc sulfate monohydrate	**1 mg**

Public Summary

Summary for ARTG Entry: 122610 Swisse Men's Ultivite Multi-Vitamin Mineral & Anti-oxidant Formula 1 with herbs (tablets)

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	12/10/2005
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm as amended from time to time.

Where the medicine is a conventional release folic acid supplement preparation, in tablet form, of strength of 100 micrograms or more per dosage unit, the additional conditions are as follows: Where the medicine contains folic acid as a single active ingredient, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Folic Acid Tablets. Where the medicine contains multiple active ingredients, the dissolution characteristics for folic acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Nutritional Supplements, as amended by its First Supplement. The dissolution characteristics for this medicine must comply with the dissolution requirements of the relevant USP24 monograph over the shelf life of the product when stored under the conditions included on the product label. It is the responsibility of manufacturers to develop and validate the analytical methods for the determination of folic acid that should be used in conjunction with the USP24 dissolution criteria. This condition does not apply to chewable, effervescent or dispersible tablets or sustained release tablets.

Products

1. Swisse Men's Ultivite Multi-Vitamin Mineral & Anti-oxidant Formula 1 with herbs (tablets)

Product Type Single Medicine Product **Effective date** 28/08/2009 9:44:39 AM

Warnings

Contains [insert name of ingredient] (or words to that effect).,

Do not take while on warfarin therapy without medical advice.,

Contains lactose (or words to that effect).,

This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.,

Contains caffeine [state quantity per dosage unit or per mL or per gram of product] [must be clear and legible].,

If symptoms persist consult your healthcare practitioner (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.

Standard Indications

Aids, assists or helps in the maintenance or improvement of general well-being.,

May assist in the management of dietary folate deficiency.,

Source of folic acid. Can assist in maintaining normal blood.,

Source of folic acid. Can assist in maintaining normal blood. Blood tonic.,

Male support. Balances and supports normal male physiology and function.,

Helps relieve nervous tension, stress and mild anxiety. [Warning S required],

Prevention/treatment of vitamin [XX] and/or mineral [YY] and/or nutritional deficiencies (This indication is not be to used for the treatment of iron deficiency conditions).,

For vitamin (may state the vitamin) supplementation.,

For mineral (may state the mineral) supplementation.,

Beneficial during times of stress. [Warning S required]

Specific Indications

Designed to meet men's nutritional needs and general well-being. The herbal ingredients in this formulation may help men perform in peak condition and improve stress adaptation.

Additional Product Information

Pack Size/Poison information

Pack Size	**Poison Schedule**

Components

1. COMPONENT ONE

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Apium graveolens	**2 mg**
Equivalent: Apium graveolens (Dry)	20 mg
Astragalus membranaceus	**5 mg**
Equivalent: Astragalus membranaceus (Dry)	50 mg
Avena sativa	**50 mg**
Equivalent: Avena sativa (Fresh)	500 mg
Barosma betulina	**2.5 mg**
Equivalent: Barosma betulina (Dry)	10 mg
Berberis vulgaris	**2.5 mg**
Equivalent: Berberis vulgaris (Dry)	15 mg
Biotin	**50 microgram**
Calcium ascorbate dihydrate	**200 mg**
Calcium citrate	**100 mg**
Calcium pantothenate	**70 mg**
Camellia sinensis	**3.34 mg**
Equivalent: Camellia sinensis (Dry)	20 mg
Carica papaya	**10 mg**
Centella asiatica	**12.5 mg**
Equivalent: Centella asiatica (Dry)	50 mg
Cholecalciferol	**.005 mg**
Choline bitartrate	**25 mg**
Chromium picolinate	**50 microgram**
Citrus bioflavonoids extract	**40 mg**
Copper gluconate	**200 microgram**
Crataegus monogyna	**25 mg**
Equivalent: Crataegus monogyna (Dry)	100 mg
Cyanocobalamin	**30 microgram**
Cynara scolymus	**12.5 mg**
Equivalent: Cynara scolymus (Fresh)	50 mg
d-alpha-Tocopheryl acid succinate	**41.33 mg**
Dunaliella salina	
Equisetum arvense	**7.5 mg**
Equivalent: Equisetum arvense (Dry)	30 mg
Ferrous fumarate	**9.61 mg**
Foeniculum vulgare	**3.41 mg**
Equivalent: Foeniculum vulgare (Dry)	15 mg
Folic acid	**500 microgram**
Ginkgo biloba	**2 mg**

Equivalent: Ginkgo biloba (Dry)	100 mg
Inositol	**25 mg**
Lutein	**.2 mg**
Lycopersicon esculentum	
Lysine hydrochloride	**50 mg**
Magnesium oxide - heavy	**100 mg**
Manganese amino acid chelate	**12 mg**
Nicotinamide	**30 mg**
Panax ginseng	**16.67 mg**
Equivalent: Panax ginseng (Dry)	50 mg
Petroselinum crispum	**10 mg**
Potassium iodide	**66 microgram**
Potassium sulfate	**8.92 mg**
Pyridoxine hydrochloride	**30 mg**
Riboflavine	**30 mg**
Selenomethionine	**65 microgram**
Serenoa repens	**20 mg**
Equivalent: Serenoa repens (Dry)	200 mg
Silybum marianum	**715 microgram**
Smilax officinalis	**12.5 mg**
Equivalent: Smilax officinalis (Dry)	50 mg
Spearmint Oil	**1.7 mg**
Thiamine hydrochloride	**30 mg**
Tocopherols concentrate - mixed (low-alpha type)	**466.2 microgram**
Turnera diffusa	**24 mg**
Equivalent: Turnera diffusa (Dry)	120 mg
Tyrosine	**1 mg**
Ubidecarenone	**1 mg**
Vaccinium myrtillus	
Vitis vinifera	**8.34 mg**
Zinc amino acid chelate	**30 mg**
Zingiber officinale	**1 mg**
Equivalent: Zingiber officinale (Dry)	5 mg

Public Summary

Summary for ARTG Entry: 179232 Swisse Ultiboost Wild Fish Oil Concentrate

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	18/01/2011
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm,as amended from time to time.

Products

1. Swisse Ultiboost Wild Fish Oil Concentrate

Product Type Single Medicine Product **Effective date** 29/06/2012

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Standard Indications

Specific Indications

Wild fish from sustainable sources.
Concentrated omega-3 fish oil.
Each capsule contains double the omega-3 than a standard fish oil capsule, making it a convenient one capsule a day dose. The capsules are completely free from 'fishy' taste with no unpleasant aftertaste.
Ultiboost Range is based on over 25 years of research.
Studies show that fish oils/omega 3 help to maintain general good health and development, they are especially beneficial for the heart, brain, joints and eyes.
Helps to maintain normal triglycerides in healthy people and maintain healthy cholesterol levels.
Omega-3 fatty acids play an important role in helping maintain a healthy cardiovascular system by supporting circulation, blood pressure and cholesterol levels in healthy individuals.
Omega-3 fatty acids are beneficial for eye health and play a structural role in the retina and nerve cells of the eye.
Contains DHA, needed for the maintenance of normal function of the eye, brain and nervous system
DHA is the predominant fatty acid in the central nervous system which is found in the walls of brain cells
For those not consuming enough fatty fish in their diet.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1. Formulation 1

Dosage Form	Capsule, soft
Route of Administration	Oral

Visual Identification

Active Ingredients

Concentrated Omega-3 triglycerides - fish	**1.036 g**

Public Summary

Summary for ARTG Entry: 181169 Swisse Ultiboost High Strength Wild Fish Oil

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	17/03/2011
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm as amended from time to time.

Products

1. Swisse Ultiboost High Strength Wild Fish Oil

Product Type Single Medicine Product **Effective date** 29/06/2012

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Standard Indications

May help reduce joint inflammation associated with arthritis.,

May assist in the management of osteoarthritis. [Warning S required],

May help increase joint mobility associated with arthritis.,

Symptomatic relief of osteoarthritis. [Warning S required]

Specific Indications

Wild fish from sustainable sources.
Ultiboost Range is based on over 25 years of research.
Swisse Ultiboost High Strength Wild Fish Oil is free from high levels of environmental toxins found in some sources of farmed fish.
Studies show that fish oils help to maintain general good health and are especially beneficial for the heart, brain, joints and eyes.
Omega-3 fatty acids play an important role in helping to maintain a healthy cardiovascular system, healthy blood pressure and support heart health.
Helps to reduce triglycerides in healthy people and maintain healthy cholesterol levels.
Omega-3 fatty acids provide an anti-inflammatory action and may help to reduce inflammation and joint swelling associated with arthritis.
Contains DHA, needed for the maintenance of normal function of the eye, brain and nervous system
DHA is the predominant fatty acid in the central nervous system which is found in the walls of brain cells
contains 50% more omega-3s than regular 1000mg fish oil.

Additional Product Information

Pack Size/Poison Information

Pack Size **Poison Schedule**

Components

1. Formulation 1

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients

Fish oil - natural	**1.5 g**

Public Summary

Summary for ARTG Entry: 181910 Swisse Professional Age Protect

ARTG entry for	Medicine Listed
Sponsor	Swisse Wellness Pty Ltd
Postal Address	36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia
ARTG Start Date	6/04/2011
Product category	Medicine
Status	Revoked
Approval area	Listed Medicines

Conditions

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.,

The sponsor shall not supply the listed medicine after the expiry date of the goods.,

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.,

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.,

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Office of Complementary Medicines, Therapeutic Goods Administration, upon request.,

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.,

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Therapeutic Goods Act 1989, shall be only those included in the list of 'Colourings permitted in medicines for oral use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use.htm as amended from time to time.

Products

1. Swisse Professional Age Protect

Product Type Single Medicine Product **Effective date** 29/06/2012

Warnings

No Warnings included on Record

Standard Indications

Specific Indications

Swisse Professional Age Protect is a concentrated formulation that helps protect from free radical damage, which can lead to premature ageing of cells.
The therapeutic properties of this premium quality formula can be attributed to knotweed - one of the richest botanical sources of resveratrol as well as Cucumis melo juice concentrate and a standardised extract of blueberry to ensure potency.
Cucumis melo juice is also beneficial during times of stress and fatigue.
All of these ingredients are high in antioxidants for defence against free radical damage.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1. Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Cucumis melo	**10 mg**
Equivalent: Cucumis melo (Fresh)	1.75 g
Fallopia japonica	**600 mg**
Equivalent: Fallopia japonica (Dry)	60 g
Vaccinium myrtilloides	**50 mg**
Equivalent: Vaccinium myrtilloides (Fresh)	1 g