Summary for ARTG Entry:

149005

Pregcel Benefishoil Omega 3 Softgel Capsule

ARTG entry for

Medicine Listed

Sponsor

Swisse Wellness Ptv Ltd

Postal Address

36-38 Gipps Street, COLLINGWOOD, VIC, 3066

Australia

**ARTG Start Date** Product category 10/01/2008 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. sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture snall be

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 in the dictary 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 assissin 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

Dosage Form

1. Medicine component

Capsule, soft

Route of Administration

Oral

Visual Identification

Active Ingredients d-alpha-Tocopherol

33.56 mg

Fish oil - natural

500 ma

Page 1 of 2

Produced at 13.03.2014 at 12:21:53 EST

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# **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 Status Medicine 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

## Warning

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).,

Aidş, 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.,

## Page 1 of 3

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 Equivalent: Arctostaphylos uva-ursi (Dry) 50 mg 10 mg Bacopa monnieri Bifidobacterium longum Biotin 20 microgram Calcium ascorbate dihydrate 41.24 mg Calcium orotate 70 mg Calcium pantothenate 4 mg Cholecalciferol .005 ma Choline bitartrate 120 mg Chromium picolinate 169 microgram Citrus bioflavonoids extract 100 mg Copper gluconate 7.86 ma Cyanocobalamin 1.8 microgram d-alpha-Tocopheryl acid succina 7.9968 mg Dunaliella salina Ferrous fumarate 16.01 mg Folic acid 400 microgram 3 mg Ginkgo biloba 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 25 mg Manganese amino acid chelate 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

# Page 2 of 3

Phytomenadione

Potassium iodide

45 microgram

196 microgram

# TGA eBS

Pyridoxine hydrochloride

Riboflavine

Silica - colloidal anhydrous

Silybum marianum

Equivalent: Silybum marianum (Dry)

Thiamine hydrochloride

Vaccinium macrocarpon

Equivalent: Vaccinium macrocarpon (Fresh)

Vitex agnus-castus

Equivalent: Vitex agnus-castus (Dry)

Withania somnifera

Equivalent: Withania somnifera (Dry)

Zinc amino acid chelate

10 mg

900 microgram

100 mg

8.57 mg 600 mg

900 microgram

10 mg

500 mg

5 mg

50 mg

100 mg

55 mg

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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 shell 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.,

# Page 1 of 3

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

# Components

Dosage Form

Pack Size

# 1. Medicine component

Route of Administration

Visual Identification

# Active Ingredients

#### Armoracia rusticana

Equivalent: Armoracia rusticana (Dry)

Bifidobacterium longum

Calcium ascorbate dihydrate

Calcium orotate

Calcium pantothenate

Cholecalciferol

Choline bitartrate

Chromium picolinate Citrus bioflavonoids extract

Copper gluconate

Cyanocobalamin

Cynara scolymus

Equivalent: Cynara scolymus (Fresh)

d-alpha-Tocopheryl acid succinate

Ferrous fumarate

Folic acid

Ginkgo biloba

Equivalent: Ginkgo biloba (Dry)

Inositol

Lactobacillus acidophilus

Lactobacillus rhamnosus

Magnesium aspartate dihydrate Manganese amino acid chelate

Molybdenum trioxide

Nicotinamide Passiflora incarnata

Equivalent: Passiflora incarnata (Dry)

**Phytomenadione** 

Pyridoxine hydrochloride

Riboflavine

Selenomethionine

Poison Schedule

Tablet, film coated

Oral

10 mg

50 mg

200 microgram

170 mg

100 ma 80 mg

.005 mg

20 mg

402 microgram

50 mg

28.57 mg

150 microgram

25 mg

100 mg

19.9968 ma

16.01 ma

500 microgram

30 mg

1.5 g

20 mg

100 mg

50 mg

165 microgram

55 mg

12.5 mg 50 mg

90 microgram

50 mg

30 mg

65 microgram

Page 2 of 3

This is not an ARTG Certificate document.

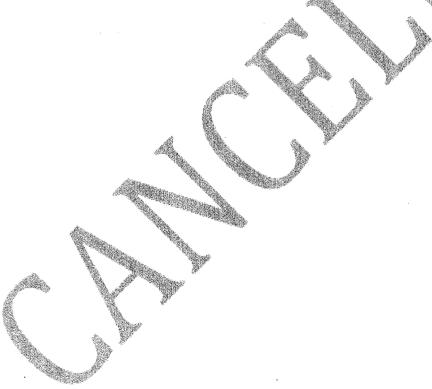
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# TGA eBS

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	ģ 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	

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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 sporsor.

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 Produc

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.,

# Page 1 of 3

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.]

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

Type	Material	Life Time	Temperature	Closure	Cond
Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not re
k Size/Poison ir	nformation				
Pack Size			Poison Sche	dule	
Components					
1. COMPONE	INT ONE				
Dosage Form	1		Capsule, hard		
Route of Adm	ninistration	*	Oral		
Visual Identifi	ication				
Active Ingred					
Apium graved				* 1 m	
Arctostaphylo					iy 2 mg
	embranaceus				mg
Avena sativa	Sindianaocas			25	_
Betacarotene					mg
Biotin	A State w				microgram
Calcium asco	rbate dihydrate			100	mg
Calcium citrat	te			50 (	mg
Calcium pante	othenate			37.	5 mg
Camellia sine	nsis			1.6	7 mg
Carica papaya	a			5 m	ıg ·
Centella asiat	ica	en de la companya de		1.2	5 mg
Cholecalcifere	10000			.00:	25 mg
Choline bitart					5 mg
Chromium pic					microgram
	onoids extract	•	•	20 :	=
Copper gluco					.5 microgram
Crataegus mo					5 mg
Cyanocobalar					microgram
Cynara scolyr					5 mg Se ma
	oheryl acid succinate			·	66 mg
Equisetum arv					5 mg 5 mg
Ferrous fumai					4 mg
Foeniculum vi				1.7	_
Folic acid					microgram
. 5,,0 0010				230	

# Page 2 of 3

Ginkgo biloba

Glycyrrhiza glabra

50 microgram

1.25 mg

Inositol Lutein Lycopersicon esculentum Lysine hydrochloride Magnesium oxide Manganese amino acid chelate Matricaria chamomilla Nicotinamide Petroselinum crispum Potassium iodide Potassium sulfate Pyridoxine hydrochloride Riboflavine Selenomethionine Silybum marianum Spearmint Oil Thiamine hydrochloride Ubidecarenone Vaccinium myrtillus Vitis vinifera

Zinc amino acid chelate

Zingiber officinale

12.5 mg 100 microgram 1 mg 25 mg 42.5 mg 8 mg 1.88 mg 25 mg 5 mg 32.7 microgram 2.23 mg 25 mg 25 mg 32.5 microgram 357 microgram 750 microgram 25 mg 500 microgram 125 microgram 4.17 mg 12.5 mg 1.5 mg

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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

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 of 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.

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

**Product Type** 

Single Medicine Product

Effective date

29/06/2012

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

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.],

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 Tablet, film coated Dosage Form Route of Administration Oral Visual Identification **Active Ingredients** Betacarotene Biotin 30 microgram 72.62 mg Calcium ascorbate dihydrate 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 Cvanocobalamin 2.6 microgram 49.9968 mg d-alpha-Tocopheryl acid succinate Folic acid 500 microgram Iron amino acid chelate 50 mg Magnesium aspartate dihydrate 100 mg Manganese amino acid chelate 50 ma 25 mg Matricaria chamomilla Molybdenum trioxide 75 microgram Nicotinamide 18 mg Phytomenadione 60 microgram Potassium iodide 327 microgram Pyridoxine hydrochlorid 20 mg Riboflavin 1.4 mg Selenomethionine 65 microgram Silybum marianum 3.57 ma Spearmint Oil 1 mg Thiamine hydrochloride 1.4 mg Vitis vinifera 833 microgram

Zinc amino acid chelate

100 ma

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# **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 Ptv Ltd

Postal Address

36-38 Gipps Street, COLLINGWOOD, VIC, 3066

Australia

**ARTG Start Date** 

29/10/2008

Product category Status Medicine 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 patch 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 exportionly 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 redicine 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 waifarin 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.,

# Page 1 of 3

# This is not an ARTG Certificate document.

The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown. Visit www.tga.gov.au for contact information

Produced at 13.03.2014 at 02:08:26 EST

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

# 1. Formulation 1

**Dosage Form** 

**Route of Administration** 

Visual Identification

# **Active Ingredients**

Apium graveolens

Equivalent: Apium graveolens (Dry)

Arctostaphylos uva-ursi

Equivalent: Arctostaphylos uva-ursi (Dry

Astragalus membranaceus

Equivalent: Astragalus membranaceus (Di

Avena sativa

Equivalent: Avena sativa (Fresh)

Betacarotene

Biotin

Calcium ascorbate dihydrate

Calcium citrate

Calcium pantothenate

amellia sinensis

Equivalent: Camellia sinensis (Dry)

Carica papaya

Centella asiatica

Equivalent: Centella asiatica (Dry)

Cholecalciferol

Choline bitartrate

Chromium picolinate

Citrus bioflavonoids extract

Copper gluconate Crataegus monogyna

Equivalent: Crataegus monogyna (Dry)

Cyanocobalamin

Cynara scolymus

Equivalent: Cynara scolymus (Fresh)

# Poison Schedule

Tablet, film coated

Oral

2 mg 20 mg

6.25 mg

25 ma

5 ma

50 ma

50 mg

500 mg

5.0002 mg

50 microgram

50 mg

200 mg

75 mg

3.34 mg

20 ma

5 mg

2.5 mg

10 mg

.005 mg

25 ma

50 microgram

417 microgram

7.5 mg

30 mg

Produced at 13.03.2014 at 02:08:26 EST

50 microgram 12.5 mg

50 mg

Page 2 of 3

This is not an ARTG Certificate document.

	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	ĺa.
	Lutein				.2 mg	
	Lycopersicon esculentum				2 mg	
	Magnesium oxide			a f	88.1 mg	
	Manganese amino acid chelate				16 mg	
	Matricaria chamomilla				3.75 mg	
	Equivalent: Matricaria chamomilla (Dry)			A.	15 mg	
	Nicotinamide				50 mg	
	Petroselinum crispum				5 mg	
	Potassium sulfate				4.45 mg	
	Pyridoxine hydrochloride				50 mg	
	Riboflavine			<b>*</b>	50 mg	
	Selenomethionine				65 microgram	
	Silybum marianum				14.29 mg	
	Spearmint Oil	الكيد			1.5 mg	
,	Thiamine hydrochloride	gsrs			50 mg	
	Ubidecarenone				1 mg	
	Vaccinium myrtillus				250 microgram	
	Vitis vinifera				8.34 mg	
	Zinc amino acid chelate				25 mg	
	Zingiber officinale		. 1		3 mg	
	Facility of the Control of the Contr				45	

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15 mg

Equivalent: Zingiber officinale (Dry)

# **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

Status

Medicine 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, efferyescent or dispersible tablets or sustained release tablets.

# Products

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

# Page 1 of 3

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.

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 lodine.

# Additional Product information

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Pack Size/Poisc	on information				
Pack Size		WITH THE TAXABLE PARTY OF TAXABLE PARTY	Poiso	on Schedule	
Compone	ents				
1. Medici	ne component				
Dosage F	orm		Table	t film coated	
Route of A	Administration		Oral		
Visual Ide	entification				
Active Ing	gredients				
Bifidobac	terium longum				
Biotin					50 microgram
Calcium a	scorbate dihydrate				50 mg
Calcium o	orotate				100 mg
Calcium p	antothenate				70 mg
Cholecalo	iferol				.005 mg
Choline b	itartrate				30 mg
Chromiun	n picolinate				402 microgram
Citrus bio	flavonoids extract				80 mg
Copper gi	uconate				14.29 mg
Çyanocob	alamin				30 microgram
Cynara sc	olymus				25 mg
Equivaler	nt: Cynara scolymus (Fi	resh)			100 mg
d-alpha-To	ocopheryl acid succin	nate			41.328 mg
Folic acid		<i>₩</i>			500 microgram
Ginkgo bil	loba				10 mg
Eguivaler	nt: Ginkgo biloba (Dry)				500 mg
Inositol					30 mg
Lactobaci	llus acidophilus				
Lactobaci	llus rhamnosus				
Magnesiu	m aspartate dihydrate	•			100 mg
Manganes	e amino acid chelate				50 mg
Molybdeni	um trioxide				67.5 microgram
Nicotinam	ide				30 mg
Phytomen	adione				80 microgram
Pyridoxine	hydrochloride				30 mg
Retinyl ace	etate				.8625 mg
Riboflavin	е				30 mg

Page 2 of 3

Selenomethionine

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Produced at 13.03.2014 at 12:17:06 EST

65 microgram

# TGA eBS

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

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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 Ptv Ltd

Postal Address

36-38 Gipps Street, COLLINGWOOD, VIC, 3066

Australia

ARTG Start Date

6/06/2007 Medicine

Product category Approval area

Revoked

Status

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 sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be

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

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 is 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, effervescentor dispersible tablets or sustained release tablets.

# 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

(ffmedicine contains one sigar) 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

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).,

## Page 1 of 3

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

# Components

## 1. Medicine component

# Dosage Form

#### **Route of Administration**

# Visual Identification

# Active Ingredients

# Bifidobacterium longum

#### Biotin

Calcium ascorbate dihydrate

# Calcium orotate

Calcium pantothenate

# Cholecalciferol Choline bitartrate

Chromium picolinate

# Cinnamomum cassia

Equivalent: Cinnamomum cassia (Dry)

# Citrus bioflavonoids extract

Copper gluconate

Crataegus monogyna

Equivalent: Crataegus monogyna (Dry)

# Cyanocobalamin

# Cynara scolymus

Equivalent: Cynara scolymus (Fresh)

# d-alpha-Tocopheryl acid succinate

Folic acid

Ginkgo biloba

Equivalent: Ginkgo biloba (Dry)

Gymnema sylvestre

Inositol

# Lactobacillus acidophilus

Lactobacillus rhamnosus

Magnesium aspartate dihydrate

Manganese amino acid chelate

Molybdenum trioxide Nicotinamide

**Phytomenadione** 

Potassium iodide

Pyridoxine hydrochloride

Retinyl acetate

## Poison Schedule

#### Tablet film coated

Oral

200 microgram

200 mg

30 mg

55 ma .005 ma

15 mg

402 microgram

6.67 mg

100 mg

20 mg

14.29 mg

12.5 mg

50 mg

120 microgram

12.5 ma

50 mg

20.0064 mg 500 microgram

20 mg

1 g

6.25 mg

15 mg

110 mg

40 mg

67.5 microgram

50 mg

60 microgram 52.32 microgram

30 mg

.8625 mg

Page 2 of 3

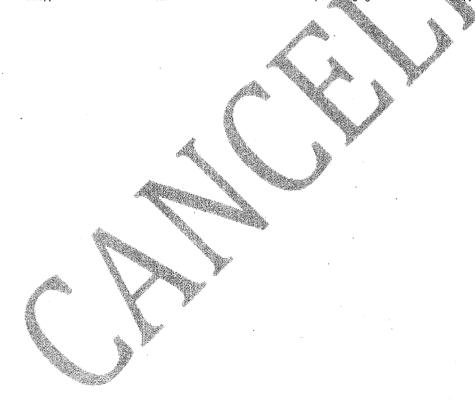
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Riboflavine	30 mg
Selenomethionine	65 microgram
Silybum marianum	14.29 mg
Equivalent: Silybum marianum (Dry)	1 g
Spearmint Oil	2 mg
Thiamine hydrochloride	55 mg
Trigonella foenum-graecum	150 mg
Equivalent: Trigonella foenum-graecum (Dry)	18.75 g
Ubidecarenone	1.0005 mg
Urtica diolca	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)	a g
Withania somnifera	<b>20</b> mg
Equivalent: Withania somnifera (Dry)	200 mg
Zinc amino acid chelate	85 mg

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# **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 Medicine

Product category

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 folicacid 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 of 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.,

## Page 1 of 3

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

# Components

1. Medicine component

**Dosage Form** 

Route of Administration

Visual Identification

# Active Ingredients

Bifidobacterium longum Biotin

Calcium ascorbate dihydrate

Calcium orotate

Calcium pantothenate

Cholecalciferol

Choline bitartrate

Chromium picolinate Cinnamomum cassia

Equivalent: Cinnamomum cassia (Dry)

Citrus bioflavonoids extract

Copper gluconate

Crataegus monogyna

Equivalent: Crataegus monogyna (Dry)

Cyanocobalamin Cynara scolymus

Equivalent: Cynara scolymus (Fresh)

d-alpha-Tocopheryl acid succinate

Folic acid

Ginkgo biloba

Equivalent: Ginkgo biloba (Dry)

Gymnema sylvestre

Inositol

Lactobacillus acidophilus

Lactobacillus rhamnosus

Magnesium aspartate dihydrate Manganese amino acid chelate

Molybdenum trioxide

Nicotinamide Phytomenadione

Potassium iodide

Pyridoxine hydrochloride

Retinyl acetate

Riboflavine

Poison Schedule

Tablet, film coate

200 microgram

200 mg

20 mg

60 mg .005 mg

20 ma

402 microgram

6.67 mg

100 mg

100 mg

21.43 mg

25 mg

100 mg

120 microgram

12.5 mg

50 mg

24.9984 mg

500 microgram

20 mg

1 g 6.25 mg

20 mg

110 mg

50 ma

67.5 microgram

55 mg

70 microgram

52.32 microgram

20 mg

.8625 mg

35 mg

Page 2 of 3

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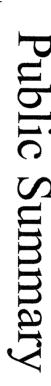
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# TGA eBS

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)	∋e 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)	1g 🐪
Vaccinium myrtillus	
Vitis vinifera	8.33 mg
Equivalent: Vitis vinifera (Dry)	1g
Zinc amino acid chelate	100 mg

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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** 

Product category

Medicine Revoked

Status 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

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 dood

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 of a 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 mingral [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

Poison Schedule

Components 1. Medicine component

Dosage Form

Powder, oral

Route of Administration

Pyridoxine hydrochloride

Visual Identification

Active Ingredients

2.27 mg/g

Produced at 13.03.2014 at 12:14:59 EST

Zingiber officinale

3.41 mg/g

Page 1 of 2

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ublic Summary

# umma

**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 **Product category**  6/06/2007 Medicine

Status

Revoked

Approval area

Listed Medicines

# **Products**

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

**Product Type** 

Single Medicine Product

Effective date

28/08/2009 9:44:39 AM

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

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 dietally 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 for 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].

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 [YX]; 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 Way 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

Page 1 of 3

Produced at 13.03.2014 at 12:16:30 EST

Pasana mauniaui	0 F ···
Bacopa monnieri Bifidobacterium longum	2.5 mg
Biotin	150 microgra
Calcium ascorbate dihydrate	200 mg
Calcium orotate	100 mg
Calcium pantothenate	, 70 mg
Cholecalciferol	.005 mg
Chromium picolinate	402 microgra
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 microgra
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 microgra
Ginkgo biloba	20 mg
Equivalent: Ginkgo biloba (Dry)	1000 mg
actobacillus acidophilus	
actobacillus rhamnosus	
ecithin powder - soy phosphatidylserine-enriched soy.	10 mg
utein	1 mg
flagnesium aspartate dihydrate	100 mg
langanese amino acid chelate	30 mg
Nolybdenum trioxide	67.5 microgra
licotinamide	20 mg
Phytomenadione	60 microgran
otassium iodide	196 microgra
yridoxine hydrochloride	30 mg
tetinyl acetate	.8625 mg
Riboflavine	30 mg
cutellaria lateriflora	12.5 mg
Equivalent: Scutellaria lateriflora (Diy)	50 mg
elenomethionine	65 microgran
ilica - colloidal anhydrous	20 mg
ilybum marianum	21.43 mg
Equivalent: Silybum marianum (Dry)	1.5 g
pearmint Oil	2 mg
hiamine hydrochloride	30 mg
urnera diffusa	50 mg
Equivalent: Turnera diffusa (Dry)	500 mg
• • • • • • • • • • • • • • • • • • • •	1.9995 mg
bidecarenone	
bidecarenone rtica dioica	20 mg
	<b>20 mg</b> 100 mg
rtica dioica	_
rtica dioica Equivalent: Urtica dioica (Dry)	100 mg

Equivalent: Vitis vinifera (Dry)

Withania somnifera

Equivalent: Withania somnifera (Dry)

Zinc amino acid chelate

1 g

50 mg

500 mg **75 mg** 

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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 Medicine

Product category 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

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 of a use 'available at http://www.tga.gov.au/industry/cm-colourings-oral-use htm as amended from time to time

# 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 hear 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

Dosage Form

Capsule, soft

Route of Administration

Oral

Visual Identification

Active Ingredients Alpha tocopherol

33.56 mg

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Page 1 of 2

# This is not an ARTG Certificate document.



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 **Product category**  6/06/2007 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

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

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 and/or nutritional deficiencies (This indication is not be to used for the treatment of iron

May assist in the management of dietary foliate deficiency

Vitamin D helps calcium absorption for 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.

Provides support for memory function and stamina

Assists in enhancing mental alertness and improving short term memory.

May assist in supporting a 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 newous 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

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 lateriffora (Dry)	50 mg
Selenomethionine Serenoa repens Equivalent: Serenoa repens (Dry)	65 microgram
Serenoa repens	30 mg
	300 mg
Silybum marianum Equivalent: Silybum marianum (Đry)	24.29 mg
Spearmint Oil	1.7 g 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
Ubidecarenoie	3 mg
Urtica dioica	10 mg
Equivalent: Urtica dioica (Dry)	50 mg
Vaccinium macrocarpon	20 mg
Equivalent: Vaccinium macrocarpon (Fresh)	1000 mg
Vaccinium myrtillus	1119
Vitis vinifera	8.33 mg
Equivalent: Vitis vinifera (Dry)	1 g
Zinc amino acid chelate	100 mg
	J

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Summary for ARTG Entry:

137244

Pregcel Calcium Magnesium

ARTG entry for

Medicine Listed

Sponsor

Swisse Wellness Ptv Ltd

Postal Address

36-38 Gipps Street, COLLINGWOOD, VIC, 3066

Australia

ARTG Start Date

5/04/2007

Product category

Approval area

Medicine

Status

Revoked

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. sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be

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 intim as amended from time to time.

# 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.

Page 1 of 2

Produced at 13.03,2014 at 12:14:35 EST

Dosage Form

Powder, oral

Route of Administration

Oral

Visual Identification

Active Ingredients

Calcium orotate

Magnesium aspartate dihydrate

172.89 mg/g

120.89 mg/g

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## TGA eBS

### **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 Approval area

Madicine

Status

Revoked

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 sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture small be

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

### 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.

an assist in maintaining allealthy 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

**Dosage Form** 

Capsule, soft

**Route of Administration** 

Oral

Visual Identification

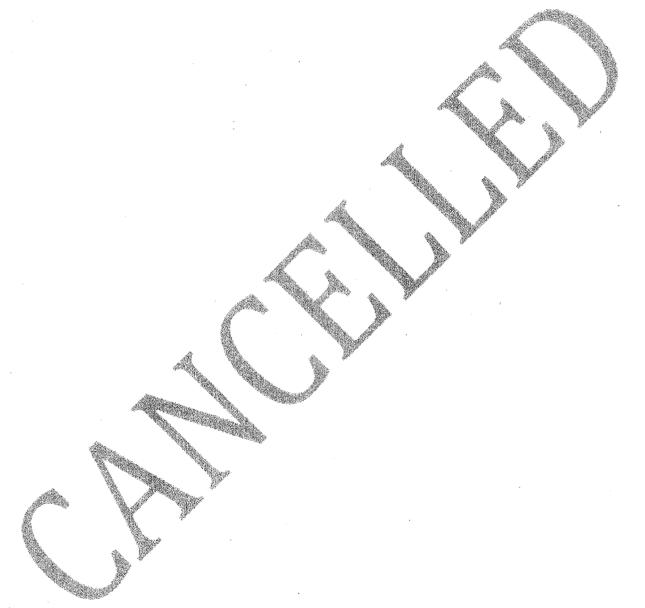
Page 1 of 2

Produced at 13.03.2014 at 12:14:12 EST

**Active Ingredients** 

Alpha tocopherol Fish oil - natural 33.56 mg 1000 mg

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### **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 Ptv Ltd

Postal Address

36-38 Gipps Street, COLLINGWOOD, VIC. 3066

Australia

ARTG Start Date

6/06/2007

Product category

Medicine 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/intrijas 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

### Warning

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

### Page 1 of 3

deficiency conditions).,

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

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

### Components

### 1. Medicine component

Dosage Form

**Route of Administration** 

Visual Identification

### **Active Ingredients**

Bacopa monnieri

Bifidobacterium longum

Biotin

Calcium ascorbate dihydrate

Calcium orotate

Calcium pantothenate

Cholecalciferol

Choline bitartrate Chromium picolinate

Citrus bioflavonoids extract

Copper gluconate

Cyanocobalamin

d-alpha-Tocopheryl acid succinate

Dunaliella salina

Ferrous fumarate Folic acid

Ginkgo biloba

Equivalent: Ginkgo biloba (Dry)

Glycyrrhiza glabra

Inositol

Lactobacillus acidophilus

Lactobacillus rhamnosus

Lemon Oil Lutein

Magnesium aspartate dihydrate

Manganese amino acid chelate

Molybdenum trioxide

Nicotinamide

Olea europaea

Equivalent: Olea europaea (Dry) Passiflora incarnata

Equivalent: Passiflora incarnata (Dry)

Phytomenadione

Potassium iodide

Pyridoxine hydrochloride

Riboflavine

Poison Schedule

Tablet, film coated

Oral

20 microgram

41.24 mg 50 mg

5 mg

.005 mg

120 mg

201 microgram

100 ma

10.72 mg

1.8 microgram

10.0032 mg

12.81 mg

400 microgram

3 mg 150 mg

35 mg

2 mg

1.13 mg

50 mg

30 mg

67.5 microgram

18 mg

8.33 ma

50 mg 25 mg

100 mg

45 microgram

196 microgram

1 mg

900 microgram

Produced at 13.03.2014 at 12:18:44 EST

## TGA eBS

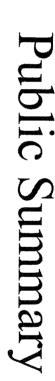
Scutellaria lateriflora 12.5 mg Equivalent: Scutellaria lateriflora (Dry) 50 mg Silica - colloidal anhydrous 50 mg 10.71 mg Silybum marianum

Equivalent: Silybum marianum (Dry) 750 mg

Thiamine hydrochloride 900 microgram 10 mg Vaccinium macrocarpon

Equivalent: Vaccinium macrocarpon (Fresh) 500 mg Zinc amino acid chelate 75 mg

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Summary for ARTG Entry:

137097

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

ARTG entry for

Medicine Listed

Sponsor

Swisse Wellness Ptv Ltd

Postal Address

36-38 Gipps Street, COLLINGWOOD, VIC, 3066

Australia

ARTG Start Date Product category 3/04/2007 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.

### Droducte

### 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 accepted.

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

### Page 1 of 2

deficiency conditions).,

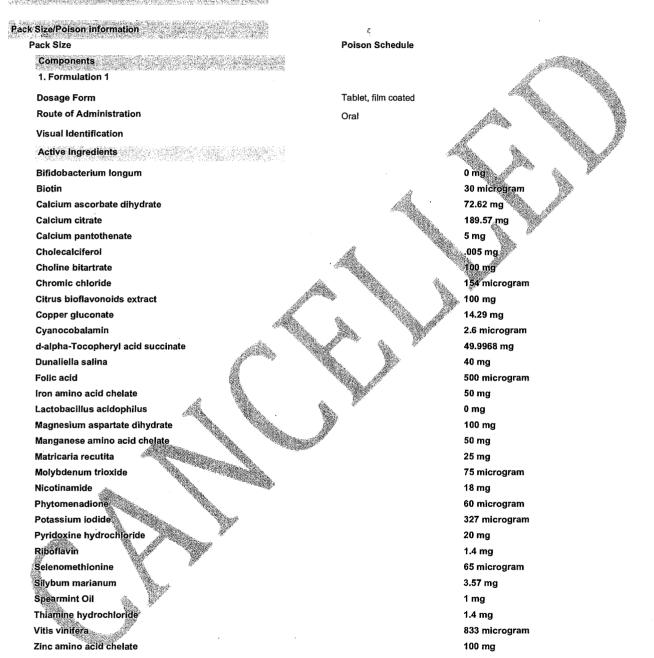
May assist in the management of dietary folate deficiency.,

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

### Specific Indications

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

## Additional Product Information



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Summary for ARTG Entry:

136511

Swisse Ultiboost Fish Oil

ARTG entry for

Medicine Listed

Sponsor

Swisse Wellness Ptv 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

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 intim, 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 (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 QIL 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

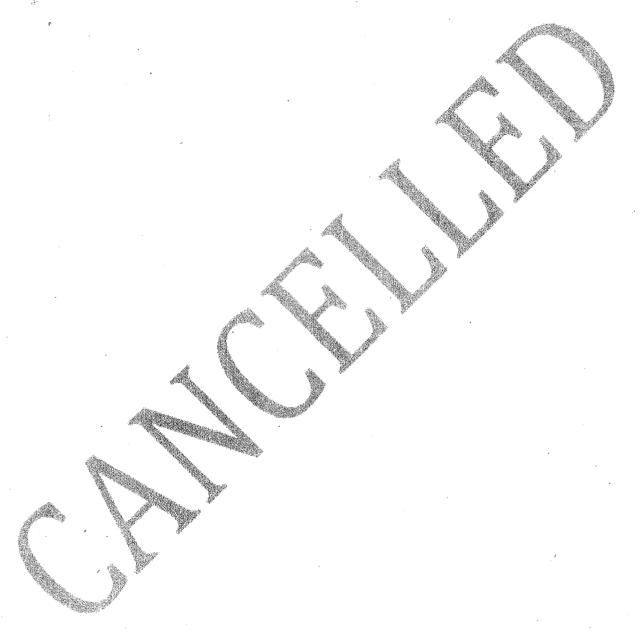
Visual Identification

Active Ingredients Alpha tocopherol

33.56 mg

Produced at 13.03.2014 at 12:12:01 EST

Page 1 of 2



### **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 Revoked

Approval area

Export only Medicines

### Conditions

Status

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.

### Dradiiata

### 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.

### Page 1 of 3

### Additional Product Information Container Information Туре 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 Tablet, film coated Dosage Form Route of Administration Oral Visual Identification Active Ingredients Apium graveolens Astragalus membranaceus 5 ma 50 mg Avena sativa Barosma betulina 2.5 mg Berberis vulgaris 2.5 mg Betacarotene 5.0002 mg 50 microgram Biotin 200 mg Calcium ascorbate dihydrate Calcium citrate 100 mg 70 mg Calcium pantothenate Camellia sinensis 3.34 mg 10 mg Carica papaya Centella asiatica 12.5 mg Cholecalciferol .005 mg Choline bitartrate 25 mg Chromium picolinate 50 microgram Citrus bioflavonoids extract 40 mg 200 microgram Copper gluconate 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 ma Lysine hydrochloride 50 mg Magnesium oxide - heavy 100 mg Manganese amino acid chelate 12 mg Nicotinamide 30 mg 16.67 mg Panax ginseng 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 30 mg Zinc amino acid chelate Zingiber officinale 1 mg

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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 Ptv 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.,

### Page 1 of 3

### This is not an ARTG Certificate document.

Produced at 13.03.2014 at 12:19:18 EST

The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown. Visit www.tga.gov.au for contact information

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

Components

1. Medicine component

Dosage Form

Route of Administration

Visual Identification

Active Ingredients

Armoracia rusticana

Equivalent: Armoracia rusticana (Dry)

Bifidobacterium longum

Biotin

Calcium ascorbate dihydrate

Calcium orotate

Calcium pantothenate

Cholecalciferol

Choline bitartrate

Chromium picolinate

Citrus bioflavonoids extract
Copper gluconate

Cvanocobalamin

Cynara scolymus

Equivalent: Cynara scolymus (Fresh)

d-alpha-Tocopheryl acid succinate

Ferrous fumarate

Folic acid

Ginkgo biloba

Equivalent: Ginkgo biloba (Dry)

lnositol

Lactobacillus acidophilus

Lactobacillus rhamnosus

Magnesium aspartate dihydrate

Manganese amino acid chelate

Molybdenum trioxide

Nicotinamide

Phytomenadione

Pyridoxine hydrochloride

Riboflavine

Selenomethionine

Silica - colloidal anhydrous

Silybum marianum

Equivalent: Silybum marianum (Dry)

### Poison Schedule

Tablet, film coated

Oral

10 mg

150 microgram

170 mg 110 mg

80 mg

.005 mg 10 mg

402 microgram

50 mg

21.43 mg

150 microgram

25 mg

100 mg

15.0048 mg

16.01 mg

500 microgram

**30 mg** 1.5 g

10 mg

io mg

110 mg 40 mg

165 microgram

50 mg

90 microgram

50 mg

25 ma

65 microgram

Produced at 13.03.2014 at 12:19:18 EST

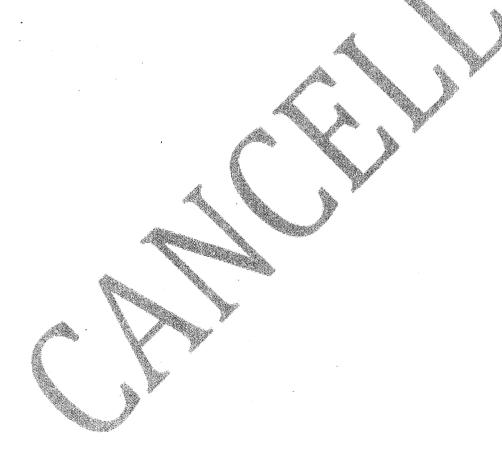
20 mg 14.29 mg

1 g

Page 2 of 3

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

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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

Approval area

Medicine Revoked

Status

**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

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 of 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 fittings a mended 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, 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 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 in this medicine must comply with the USP24 dissolution criteria. This condition does not apply to chewable, effervescent or dispersible tablets or sustained release tablets.

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

**Product Type** 

Single Medicine Produ

Effective date

31/05/2011 12:08:48 PM

### Warnings

(figmedicine 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

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.

Page 1 of 3

Produced at 13.03.2014 at 12:11:01 EST

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 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 200 mg Calcium citrate 75 mg Calcium pantothenate Camellia sinensis 3.34 mg Carica papaya 10 mg Centella asiatica 2.5 mg .005 mg Cholecalciferol Choline bitartrate 25 mg 50 microgram **Chromium picolinate** 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 vulga 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 50 mg Pyridoxine hydrochloride Riboflavine 50 mg

Page 2 of 3

## TGA eBS

Selenomethionine Silybum marianum Spearmint Oil

Thiamine hydrochloride

Ubidecarenone

Vaccinium myrtillus Vitis vinifera

Zinc amino acid chelate

Zingiber officinale

65 microgram

715 microgram

1.5 mg

50 mg 1 mg

250 microgram

8.34 mg

25 mg

3 mg

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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
Postal Address

Swisse Wellness Pty Ltd

36-38 Gipps Street, COLLINGWOOD, VIC, 3066 Australia

ARTG Start Date

31/07/2006 Medicine

Product category 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 to 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

### Warning

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),

It 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

### Page 1 of 3

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 Schedule	
Components 1. COMPONENT ONE		
Dosage Form	Capsule, hard	
Route of Administration	Oral	
Visual Identification	•	તર્સ
Active Ingredients		al de
Apium graveolens	1 mg 🦓	r.
Equivalent: Apium graveolens (Dry)	10 mg	
Astragalus membranaceus	2.5 mg	, Sec.
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	di.
Berberis vulgaris	1.25 mg	
Equivalent: Berberis vulgaris (Dry)	7.5 mg	
Biotin	25 micro	gram
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 asiática (Dry)	. 25 mg	
Challes Mentanta	.0025 mg	_
Changing placings	12.5 mg	
Chromium picolinate Citrus bioflavonoids extract	. 25 micro 20 mg	)grain
Copper gluconate	20 mg	roaran
Crataegus monogyna	12.5 mg	_
Equivalent: Crataegus monogyna (Dry)	50 mg	
Cyanocobalamin	15 micro	naram
Cynara scolymus	6.25 mg	
Equivalent: Cynara scolymus (Fresh)	25 mg	
d-alpha-Tocopheryl acid succinate	20.256 n	ng
Dunaliella salina		
Eguisetum arvense	3.75 mg	
Equivalent: Equisetum arvense (Dry)		
Ferrous fumarate	4.8 mg	
Foeniculum vulgare	1.7 mg	
Equivalent: Foeniculum vulgare (Dry)	7.5 mg	
Folic acid	250 mic	rogram
Ginkgo biloba	1 mg	
Equivalent: Ginkgo biloba (Dry)	50 mg	
Inositol	12.5 mg	
Lutein	100 mic	rogram
Lycopersicon esculentum		
Lysine hydrochloride	25 mg	
Magnesium oxide - heavy	50 mg	

Page 2 of 3
This is not an ARTG Certificate document.

## TGA eBS

Manganese	amino	acid	che	late
-----------	-------	------	-----	------

Nicotinamide

Panax ginseng

Equivalent: Panax ginseng (Dry)

Petroselinum crispum

Potassium iodide

Potassium sulfate

Pyridoxine hydrochloride

Riboflavine

Selenomethionine

Serenoa repens

Equivalent: Serenoa repens (Dry)

Silybum marianum

Smilax officinalis

Equivalent: Smilax officinalis (Dry)

Spearmint Oil

Thiamine hydrochloride

Turnera diffusa

Equivalent: Turnera diffusa (Dry)

Tyrosine

Ubidecarenone

Vaccinium myrtillus

Vitis vinifera

Zinc amino acid chelate

Zingiber officinale

Equivalent: Zingiber officinale (Dry)

6 mg

15 mg

8.33 mg

25 mg

5 mg

33 microgram

4.46 mg

15 mg

15 mg

32.5 microgram

10 mg

100 mg

357 microgran

6.25 mg

25 mg

750 microgram

15 mg

12 mg

60 mg

500 microgram

500 microgram

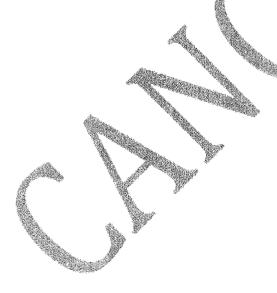
4.17 mg

15 mg

500 microgram

2.5 mg

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### **Public Summary**

Summary for ARTG Entry:

122501

Cerexi

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 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. CerexI

**Product Type** 

Single Medicine Product

Effective date

3/04/2009 8:39:00 AM

### Warning

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

Page 1 of 2

Produced at 13.03.2014 at 12:04:50 EST

circulation. Relieves symptoms of cold hands and feet.

### Additional Product Information

Zinc amino acid chelate

### Pack Size/Poison information Poison Schedule Components 1. Medicine Component Dosage Form Tablet, film coated **Route of Administration** Oral Visual Identification **Active Ingredients** Calcium ascorbate dihydrate 60 mg 20 mg Citrus bioflavonoids extract 25 microgram Cyanocobalamin Folic acid 250 microgram 30 mg Ginkgo biloba Equivalent: Ginkgo biloba (Dry) 1.5 g Glutamine 125 mg 75 mg Lecithin powder - soy phosphatidylserine-enriched soy Levocarnitine 50 mg Magnesium aspartate dihydrate 250 mg R,S-alpha Lipoic acid 50 mg Thiamine hydrochloride Tyrosine 50 mg

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12.5 mg

## ublic S

### **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** Product category 26/10/2005

Status

Medicine 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 lead to the sponsor.

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 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 intentionally or recklessly advertise the medicine for an intentional or recklessly advertise the medicine for an intention of the intention o 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 polified 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 it 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

#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 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

Capsule, hard

Dosage Form **Route of Administration** 

Oral

Visual Identification

**Active Ingredients** 

Biotin

200 microgram

Produced at 13.03.2014 at 12:07:26 EST

Page 1 of 2

## TGA eBS

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 migrogram
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

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Riboflavine

Salvia officinalis
Thiamine hydrochloride

Zingiber officinale

Zinc amino acid chelate

10 mg

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 4/08/2006

ARTG Start Date
Product category

Medicine

Status
Approval area

Revoked 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 exportantly 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 single 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.,

### Page 1 of 3

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The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown. Visit www.tqa.gov.au for contact information

Produced at 13.03.2014 at 12:10:23 EST

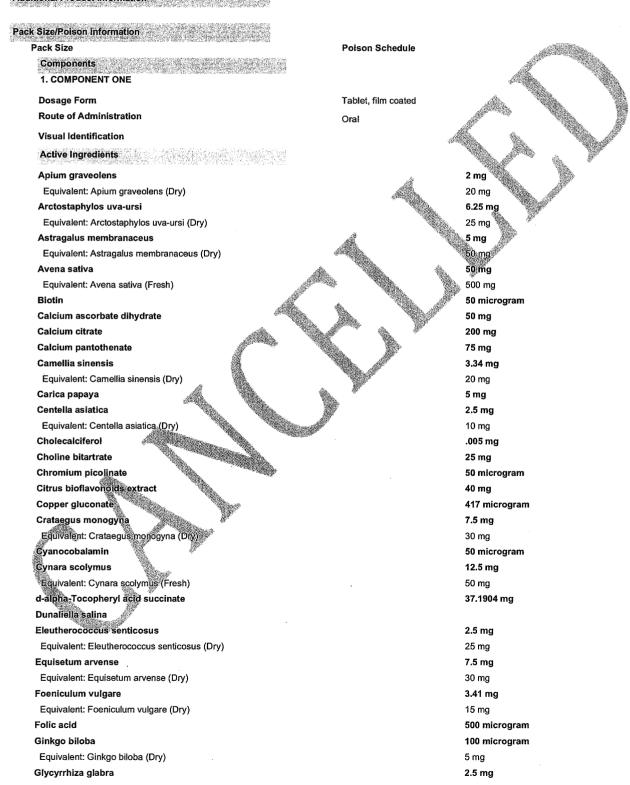
Source of folic acid. Can assist in maintaining normal blood. Blood tonic.,

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 lodine. Assists with the relief of pre-menstrual symptoms/syndrome.

### Additional Product information



### Page 2 of 3

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	Sec.
Pyridoxine hydrochloride		50 mg	
Riboflavine		50 mg	
Selenomethionine		65 microgram	¥
Silybum marianum		14,29 mg	200
Spearmint Oil		1.5 mg	k. I
Thiamine hydrochloride	TO THE	50 mg	
Tocopherols concentrate - mixed (low-alpha type)		3.353 mg/	
Ubidecarenone	Á	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	

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## TGA eBS

### **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 Status Medicine 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 folio acid supplement preparations in tablet form, of strength of 100 micrograms or more per dosage unit, the additional conditions are as follows: Where the medicine contains folio acid as a single active ingredient, the dissolution characteristics for folio acid in this medicine must comply with the dissolution requirements in the United States Pharmacopoeia 24th Edition (USP24) monograph for Folio Acid Tablets. Where the medicine contains multiple active ingredients, the dissolution characteristics for folio 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 of 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 folio 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.

### Product

### 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

Produced at 13.03.2014 at 12:05:29 EST

### 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.,

### Page 1 of 3

### This is not an ARTG Certificate document.

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## Public Summary

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.,

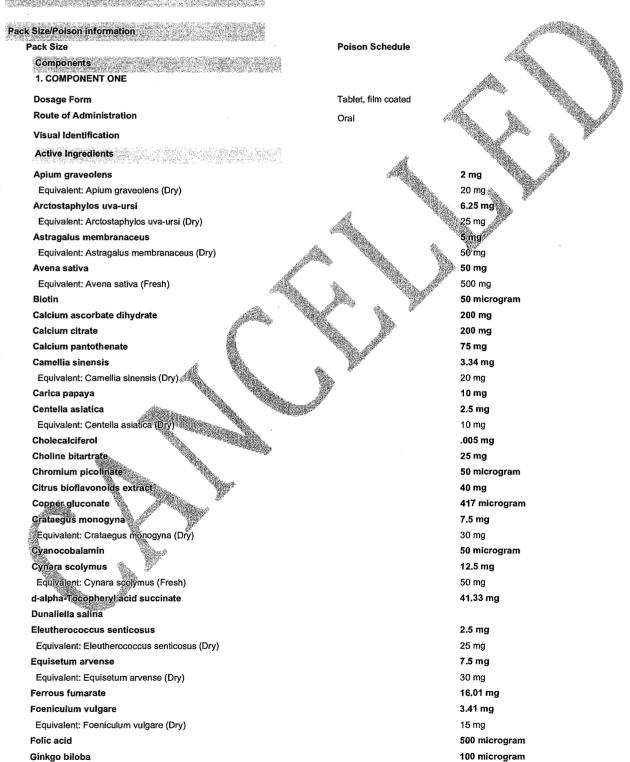
Helps relieve nervous tension, stress and mild anxiety. [Warning S required]

### 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



### Page 2 of 3

Equivalent: Ginkgo biloba (Dry)	5 mg	
Glycyrrhiza glabra	2.5 mg	3
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		
Matricaria recutita	3.75 m	ıg
Equivalent: Matricaria recutita (Dry)	15 mg	
Nicotinamide	50 mg	
Petroselinum crispum	10 mg	
Potassium iodide	66 mig	rogram
Potassium sulfate	4.45 m	ıg
Pyridoxine hydrochloride	50 mg	ith.
Riboflavine	50 mg	
Selenomethionine	65 mig	rogram
Silybum marianum	715 mi	icrogram
Spearmint Oil	1.7 mg	J
Thiamìne hydrochloride	. 50 mg	e. 1
Tocopherols concentrate - mixed (low-alpha type)	466.2 ı	microgram
Ubidecarenone		
Vaccinium myrtillus		
Vitis vinifera	8,34 m	g
Zinc amino acid chelate	25 mg	

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Zingiber officinale

Equivalent: Zingiber officinale (Dry)

3 mg

15 mg

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** 

19/12/200

Product category

Medicine Revoked

Status 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 patch 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.,

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### 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's 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
Jar/Can Not recorded

Life Time
Not recorded

Temperature
Not recorded

Closure Not recorded Conditions
Not recorded

Produced at 13.03.2014 at 12:07:53 EST

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1. Formulation 1

Dosage Form

Tablet, film coated

Route of Administration

Oral

### Page 1 of 2

Visual Identification

Active Ingredients

Calcium ascorbate dihydrate

Calcium carbonate

Cholecalciferol

Chromic chloride

Copper gluconate

Magnesium aspartate
Magnesium oxide - heavy

Magnesium phosphate

Manganese amino acid chelate

Potassium aspartate

Potassium iodide

Zinc sulfate monohydrate

50 mg

750 mg

.012 mg

51 microgram

250 microgram

80 mg

461.95 mg

150 mg

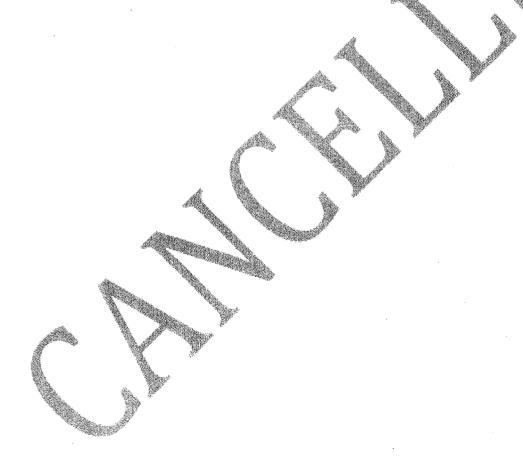
25 mg

27.28 mg

66 microgram

33.34 mg

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### **Public Summary**

Summary for ARTG Entry:

126720

SWISSE CHILDVITE 2

ARTG entry for

Medicine Listed

Sponsor

Swisse Wellness Ptv Ltd

Postal Address

36-38 Gipps Street, COLLINGWOOD, VIC. 3066

Australia

ARTG Start Date Product category

Approval area

6/04/2006

Statue

Medicine

Status

Revoked

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 ofal use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use intmas 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 sonditions (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 Gnildren'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 table with natural colours and flavours, and no preservatives.

### Additional Product information

### Pack Size/Poison information

Pack Size

Poison Schedule

Components

Dosage Form

1. COMPONENT ONE

Tablet, chewable

Route of Administration

Oral

Visual Identification

Active Ingredients
Ascorbic acid

50 mg

Produced at 13.03.2014 at 12:08:21 EST

### Page 1 of 2

Betacarotene .2 mg 30 microgram Biotin 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

Equivalent: Eleutherococcus senticosus (Dry) Ferrous fumarate

Folic acid Magnesium phosphate

Manganese sulfate monohydrate

Nicotinamide

Pyridoxine hydrochloride

Riboflavine Rosa canina

Equivalent: Rosa canina (Dry)

Thiamine nitrate Urtica dioica

Equivalent: Urtica dioica (Dry) Zinc sulfate monohydrate

650 microgram

6.5 mg 7.36 mg 15 microgram 8 mg 500 microgram

9.99 mg 1,998 mg 1.002 mg 2.5 mg 10 mg .999 mg

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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

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

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

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 exportionly 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.

# 1. Swisse Ultiboost Student Focus

**Product Type** 

Effective date

31/05/2011 12:08:48 PM

Vitamins can only be a 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 loday's demanding, competitive environment. The herbs in Swisse Student HD may be of benefit in times of stress, or when peak condition and stainina 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

Dosage Form

1. Formulation 1

Capsule, hard

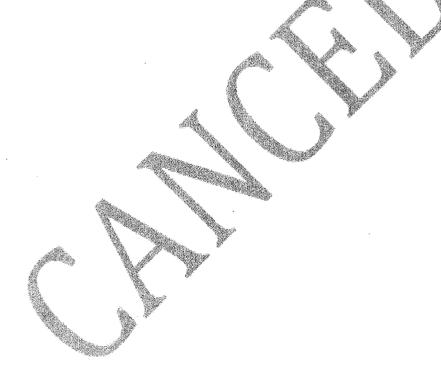
**Route of Administration** 

Oral

# Page 1 of 2

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	.ç 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

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# **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 intin as amended from time to time.

### Product

# 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 gletary 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 sidemanding, competitive environment. The herbs in Swisse Student HD may be of benefit in times of stress, or when peak condition and staming 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

Zenikonenia.

Dosage Form

1. COMPONENT ONE

Capsule, hard

Route of Administration

Oral

Visual Identification

Active Ingredients

## Page 1 of 2

# Produced at 13.03.2014 at 12:04:18 EST

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	
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

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**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 fittings amended from time to time

### Products

# 1. SWISSE CHILDVITE 1

**Product Type** 

Single Medicine Product

Effective date

28/08/2009 9:44:39 AM

Produced at 13.03.2014 at 12:08:49 EST

# Warnings

Vitamins can only be of assistance in 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

**Dosage Form** 

1. COMPONENT ONE

Tablet, chewable

Route of Administration

Oral

# Page 1 of 2

# This is not an ARTG Certificate document.

Visual Identification

**Active Ingredients** 

Ascorbic acid
Betacarotene

Biotin

Calcium citrate

Calcium pantothenate

Cholecalciferol

Citrus bioflavonoids extract

Cyanocobalamin

d-alpha-Tocopheryl acid succinate

Dunaliella salina

Ferrous fumarate

Folic acid

Humulus Iupulus

Equivalent: Humulus lupulus (Dry)

Magnesium phosphate

Manganese sulfate monohydrate

Matricaria recutita

Equivalent: Matricaria recutita (Dry)

Nicotinamide

Pyridoxine hydrochloride

Riboflavine

Thiamine nitrate

Zinc sulfate monohydrate

50 mg

.2 mg

30 microgram

100 mg

2 mg

.5 microgram

2 mg

2 microgram

4.9632 mg

3.16 mg

10 microgram

267 microgram

2 mg

8 mg

500 microgram

3.75 mg

15 mg

9.99 mg

2.9903 mg 1.2024 mg

1.4985 mg

1 mg

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# **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 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

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 intro a 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 is 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.

### Product:

# 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],

## Page 1 of 3

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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.,

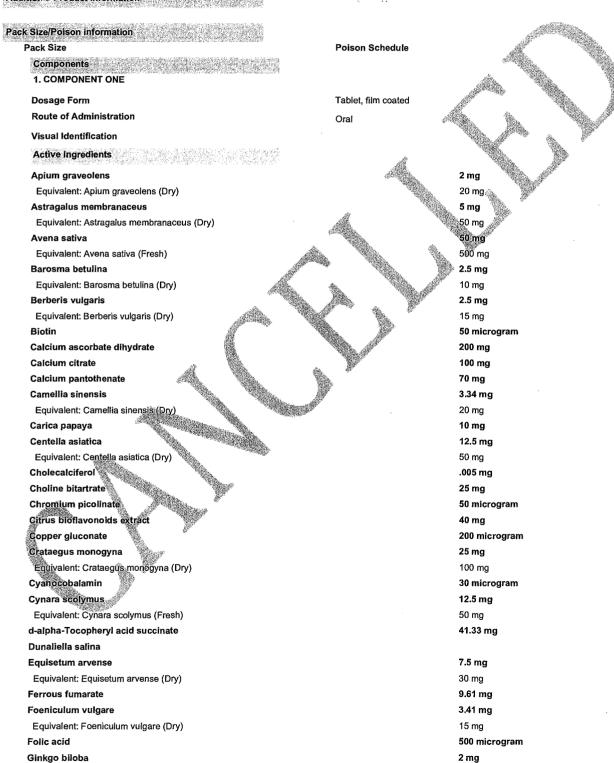
For mineral (may state the mineral) supplementation.,

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



# Page 2 of 3

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		A	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	al de la companya de		30 mg
Tocopherols concentrate - mixed (low-alpha t	ype)		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

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# ublic S

# 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

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. sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be

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 ofal use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use intrinas amended from time to time

# 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).

# 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.
Heips 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

Omega-3 fatty acids are peneficial 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

Poison Schedule

Components

1. Formulation 1

Capsule, soft

**Dosage Form Route of Administration** 

Oral

## Page 1 of 2

# This is not an ARTG Certificate document.

The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.

Produced at 13.03.2014 at 02:36:34 EST

Visit www.tga.gov.au for contact information

Visual Identification

**Active Ingredients** 

Concentrated Omega-3 triglycerides - fish

1.036 g

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# ublic S

**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 Ala

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 of 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 manufacture (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

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 sporsor.

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 of a use' available at http://www.tga.gov.au/industry/cm-colourings-oral-use introduced from time to time.

# 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).

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 source

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

Poison Schedule

Components

1. Formulation 1

## Page 1 of 2

**Dosage Form** 

Route of Administration

Capsule, soft

Oral

Visual Identification

Active Ingredients

Fish oil - natural

1.5 g

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# TGA eBS

## 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** Status

Medicine 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 Flead, 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

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

No Warnings included on Record

# Standard Indications

# Specific Indications

Swisse Professional Age Protect is a concertificated formulation that helps profest 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 Circumis melo juice concentrate and a standardised extract of blueberry to ensure potency. Cucumis melo juice is also beneficial during times of stress and fatirule. 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

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The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown. Visit www.tga.gov.au for contact information

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

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