



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	387191	Swisse Ultivite Men's 65+ Multivitamin
ARTG entry for	Medicine Listed	
Sponsor	Swisse Wellness Pty Ltd	
Postal Address	L6 & 7 88 Langridge Street, Collingwood, VIC, 3066 Australia	
ARTG Start Date	19/04/2022	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

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 Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

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.

Products

1 . Swisse Ultivite Men's 65+ Multivitamin

Product Type	Single Medicine Product	Effective Date	19/04/2022
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support energy production
Maintain/support vitality
Relieve weariness/tiredness/fatigue/feeling of weakness
Maintain/support eye health
Maintain/support healthy eyesight/vision
Maintain/support general health and wellbeing
Maintain/support bone health
Maintain/support heart health
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Support healthy stress response in the body
Maintain/support cognitive function/mental function
Maintain/support brain function
Maintain/support brain health
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support wound healing

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.
Product presentation must not imply or refer to chronic fatigue syndrome.
Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Public Summary



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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

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

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

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of the table in Part 2 of Schedule 1 to this instrument are also used.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

This medicine 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).

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

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

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

Do not take while on warfarin therapy without medical advice.

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

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Biotin	200 microgram
calcium ascorbate dihydrate	200 mg
Equivalent: ascorbic acid	165.3 mg
Equivalent: calcium	18.81 mg
calcium orotate	100 mg
Equivalent: calcium	10.1 mg
calcium pantothenate	109.15 mg
Equivalent: calcium	9.15 mg
Equivalent: pantothenic acid	100 mg
chromium picolinate	402.3 microgram
Equivalent: chromium	50 microgram
Citrus bioflavonoids extract	20 mg
colecalfiferol	.025 mg
copper gluconate	12.14 mg
Equivalent: copper	1.7 mg
Crataegus monogyna fruit Extract dry concentrate	30 mg

Public Summary



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Equivalent: Crataegus monogyna (Dry)	120 mg
cyanocobalamin	200 microgram
Cynara scolymus leaf Extract dry concentrate standardised	1 mg
Equivalent: Cynara scolymus (Fresh)	50 mg
d-alpha-tocopheryl acid succinate	25 mg
Dulacia inopiflora root Extract dry concentrate	20 mg
Equivalent: Dulacia inopiflora (Dry)	200 mg
ferrous fumarate	16.01 mg
Equivalent: iron	5 mg
folic acid	500 microgram
Ginkgo biloba leaf Extract dry concentrate standardised	20 mg
Equivalent: Ginkgo biloba (Dry)	1 g
lutein	1 mg
magnesium aspartate dihydrate	100 mg
Equivalent: magnesium	7.5 mg
manganese amino acid chelate	40 mg
Equivalent: manganese	4 mg
molybdenum trioxide	67.5 microgram
Equivalent: molybdenum	45 microgram
nicotinamide	100 mg
phytomenadione	70 microgram
potassium iodide	196 microgram
Equivalent: potassium	46.2 microgram
Equivalent: iodine	149.8 microgram
pyridoxine hydrochloride	50 mg
Equivalent: pyridoxine	41.1 mg
retinol acetate	.8625 mg
Equivalent: vitamin A	.75 mg
Reynoutria japonica root Extract dry concentrate standardised	80 mg
Equivalent: Reynoutria japonica (Dry)	8 g
riboflavin	50 mg
Scutellaria lateriflora herb Extract dry concentrate	12.5 mg
Equivalent: Scutellaria lateriflora (Dry)	50 mg
selenomethionine	124.2 microgram
Equivalent: selenium	50 microgram
Serenoa repens fruit Extract dry concentrate standardised	75 mg
Equivalent: Serenoa repens (Dry)	300 mg
Silybum marianum fruit Extract dry concentrate standardised	24.29 mg
Equivalent: Silybum marianum (Dry)	1.7 g
soy phosphatidylserine-enriched soy lecithin powder	10 mg
Equivalent: soy phosphatidylserine	2 mg
Spearmint oil	2 mg
thiamine hydrochloride	50 mg
Equivalent: thiamine	39.34 mg
Tribulus terrestris fruit Extract dry concentrate standardised	10 mg
Equivalent: Tribulus terrestris (Dry)	500 mg
Tribulus terrestris root Extract dry concentrate standardised	10 mg
Equivalent: Tribulus terrestris (Dry)	500 mg
ubidecarenone	3 mg
Urtica dioica leaf Extract dry concentrate	5 mg



Australian Government
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Therapeutic Goods Administration

Equivalent: Urtica dioica (Dry)	50 mg
Vaccinium macrocarpon fruit Extract dry concentrate	2 mg
Equivalent: Vaccinium macrocarpon (Fresh)	1 g
Vaccinium myrtillus fruit Extract dry concentrate standardised	1 mg
Equivalent: Vaccinium myrtillus (Fresh)	100 mg
Vitis vinifera seed Extract dry concentrate standardised	8.33 mg
Equivalent: Vitis vinifera (Dry)	1 g
zinc amino acid chelate	100 mg
Equivalent: zinc	20 mg

Other Ingredients (Excipients)

Acacia
butylated hydroxytoluene
calcium hydrogen phosphate dihydrate
calcium phosphate
Carnauba Wax
croscarmellose sodium
crospovidone
dl-alpha-tocopherol
Gelatin
hypromellose
iron oxide red
macrogol 400
magnesium hydroxide
magnesium stearate
maize starch
maltodextrin
medium chain triglycerides
microcrystalline cellulose
povidone
powdered cellulose
Safflower Oil
silicon dioxide
Spearmint oil
sucrose
tartaric acid

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Public Summary