



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	289118	NUTRA-LIFE SILICAPLEX 5000
ARTG entry for	Medicine Listed	
Sponsor	Vitaco Health Australia Pty Ltd	
Postal Address	PO Box 399, NORTH RYDE BC, NSW, 1670 Australia	
ARTG Start Date	18/05/2017	
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.

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.

Products

1 . NUTRA-LIFE SILICAPLEX 5000

Product Type	Single Medicine Product	Effective Date	22/11/2019
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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 collagen formation
- Maintain/support energy levels
- Helps convert (state food) into energy
- Maintain/support energy production
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support healthy eyesight/vision
- Maintain/support body mucous membrane health
- Maintain/support general health and wellbeing
- Maintain/support hair health
- Maintain/support healthy teeth
- Maintain/support nail health/strength/thickness
- Traditionally used in Western herbal medicine to astringent/tightens tissues
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Traditionally used in Western herbal medicine to relieve mild tissue oedema
- Maintain/support bone health

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- Aid/assist healthy red blood cell production
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support blood capillary health
- Maintain/support blood vessel health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Aid/assist/helps protein synthesis in the body
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Maintain/support cognitive function/mental function
- Maintain/support nerve conduction
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system health
- Maintain/support nervous system function
- Maintain/support skin health
- Maintain/support skin integrity/structure
- Maintain/support skin regeneration
- Maintain/support wound healing

Indication Requirements

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

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

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

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

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 serious cardiovascular conditions.

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

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).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification



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Active Ingredients

ascorbic acid	25 mg
Biotin	.02 mg
Equisetum arvense stem Extract dry concentrate	500 mg
Equivalent: Equisetum arvense (Dry)	5 g
pyridoxine hydrochloride	7.5 mg
Equivalent: pyridoxine	6.17 mg
zinc gluconate	31.01 mg
Equivalent: zinc	4 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
Gelatin
magnesium stearate
maltodextrin
manganese amino acid chelate
purified water
sodium lauryl sulfate

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