



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 336589 NUTRA-LIFE COLD & FLU IMMUNE SUPPORT

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	18/05/2020
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.

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 COLD & FLU IMMUNE SUPPORT

Product Type	Single Medicine Product	Effective Date	18/05/2020
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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 healthy eye function
- Maintain/support eye health
- Maintain/support healthy eyesight/vision
- Maintain/support general health and wellbeing
- Traditionally used in Chinese medicine to maintain/support general health and wellbeing
- Maintain/support hair health
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of mild mouth ulcers
- Maintain/support healthy teeth
- Maintain/support nail health/strength/thickness
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support bone health
- 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)

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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 female reproductive system health
 Maintain/support reproductive system health in males
 Maintain/support healthy reproductive hormones
 Maintain/support sperm health in healthy males
 Maintain/support sperm production in healthy males
 Maintain/support testosterone level
 Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of common colds and flu
 Traditionally used in Chinese medicine to decrease/reduce/relieve cough
 Traditionally used in Chinese medicine to relieve symptoms of sore throat/pharyngitis
 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 infertility.
 Label statement: If symptoms persist, talk to your health professional.
 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.
 Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to serious immunological diseases.
 Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.
 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 recurrent or persistent mouth lesions.
 Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
 Product presentation must only refer to mild mouth ulcers.
 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).
 Product presentation must not imply or refer to hormone imbalances.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).
 Andrographis may cause allergic reactions in some people. If you have a severe reaction (such as anaphylaxis), stop use and seek immediate medical attention (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



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Oral

Visual Identification

Active Ingredients

Andrographis paniculata leaf Extract dry concentrate	166.67 mg
Equivalent: Andrographis paniculata (Dry)	6 g
ascorbic acid	100 mg
Sambucus nigra fruit Extract dry concentrate	80 mg
Equivalent: Sambucus nigra (Fresh)	4 g
zinc glycinate	48.87 mg
Equivalent: zinc	15 mg

Other Ingredients (Excipients)

Gelatin
hypromellose
magnesium citrate
magnesium stearate
maltodextrin
microcrystalline cellulose
purified water
silicon dioxide
sodium lauryl sulfate

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