



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	219050	NUTRA-LIFE ESTER-C HIGH STRENGTH + BIOFLAVONOIDS
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Vitaco Health Australia Pty Ltd	
<b>Postal Address</b>	PO Box 399, NORTH RYDE BC, NSW, 1670 Australia	
<b>ARTG Start Date</b>	9/01/2014	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 ESTER-C HIGH STRENGTH + BIOFLAVONOIDS**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	5/02/2020
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Antioxidant/Reduce free radicals formed in the body in children over 12 years of age
- Helps reduce/decrease free radical damage to body cells in children over 12 years of age
- Helps reduce/decrease free radical damage to body cells
- Maintain/support collagen formation in children over 12 years of age
- Maintain/support collagen formation
- Maintain/support general health and wellbeing
- Maintain/support general health and wellbeing in children over 12 years of age
- Maintain/support connective tissue health in children over 12 years of age
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation in children over 12 years of age
- Aid/assist/helps connective tissue production/formation
- Maintain/support blood capillary health
- Maintain/support blood capillary health in children over 12 years of age
- Maintain/support blood vessel health
- Maintain/support blood vessel health in children over 12 years of age
- Maintain/support immune system health
- Maintain/support immune system health in children over 12 years of age
- Maintain/support healthy immune system function in children over 12 years of age

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- Maintain/support healthy immune system function
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children over 12 years of age
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in children over 12 years of age
- Aid/assist/helps synthesis of neurotransmitters in children over 12 years of age
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system health in children over 12 years of age
- Maintain/support nervous system health
- Maintain/support nervous system function in children over 12 years of age
- Maintain/support nervous system function
- Decrease/reduce/relieve common cold duration
- Decrease/reduce/relieve common cold duration in children over 12 years of age
- Decrease/reduce/relieve the severity of common cold symptoms in children over 12 years of age
- Decrease/reduce/relieve the severity of common cold symptoms
- Maintain/support skin health in children over 12 years of age
- Maintain/support skin health
- Maintain/support wound healing
- Maintain/support wound healing in children over 12 years of age

**Indication Requirements**

- 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 not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- 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 serious immunological diseases.

**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).
- 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.

**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**

<b>calcium ascorbate dihydrate</b>	<b>1.465 g</b>
Equivalent: ascorbic acid	1.15 g
<b>calcium carbonate</b>	<b>16.8 mg</b>
<b>calcium L-threonate</b>	<b>18.45 mg</b>

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Equivalent: calcium	2.435 mg
<b>Citrus bioflavonoids extract</b>	<b>100 mg</b>
Equivalent: hesperidin	35 mg

**Other Ingredients (Excipients)**

**copovidone**

**crospovidone**

**Flavour**

**macrogol 4000**

**magnesium stearate**

**microcrystalline cellulose**

**polysorbate 80**

**polyvinyl alcohol**

**purified talc**

**silicon dioxide**

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