



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	283066	NUTRA-LIFE ESTER-C + CHEWABLES
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	30/11/2016	
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 . NUTRA-LIFE ESTER-C + CHEWABLES

Product Type	Single Medicine Product	Effective Date	20/04/2022
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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
Helps reduce/decrease free radical damage to body cells in children over 12 years of age
Maintain/support collagen formation
Maintain/support collagen formation in children over 12 years of age
Maintain/support general health and wellbeing in children over 12 years of age
Maintain/support general health and wellbeing
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
Maintain/support healthy immune system function in children over 12 years of age
Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children over 12 years of age
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
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
Aid/assist/helps synthesis of neurotransmitters in children over 12 years of age
Maintain/support nervous system health in children over 12 years of age



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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
Decrease/reduce/relieve the severity of common cold symptoms in children over 12 years of age
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

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).

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

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

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

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

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).

(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.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1. Formulation 1

Dosage Form Tablet, chewable

Route of Administration Oral

Visual Identification

Active Ingredients

calcium ascorbate dihydrate	319.2 mg
Equivalent: ascorbic acid	250 mg
calcium carbonate	3.66 mg
calcium L-threonate	4.02 mg
Equivalent: calcium	.53 mg
sodium ascorbate	284.1 mg
Equivalent: ascorbic acid	250 mg

Other Ingredients (Excipients)

ammonium glycyrrhizinate
citric acid

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Flavour

fructose

glucose monohydrate

magnesium stearate

maize starch

maltodextrin

microcrystalline cellulose

silicon dioxide

Steviol glycosides

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