



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	340400	Nature's Sunshine Vitamin C 1000 Time Release with Bioflavonoids
ARTG entry for	Medicine Listed	
Sponsor	Nature's Sunshine Products of Australia Pty Ltd	
Postal Address	PO Box 6884, BAULKHAM HILLS BUSINESS CENTRE, NSW, 2153 Australia	
ARTG Start Date	29/07/2020	
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 . Nature's Sunshine Vitamin C 1000 Time Release with Bioflavonoids

Product Type	Single Medicine Product	Effective Date	5/08/2020
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Maintain/support collagen health
Helps enhance/promote general health and wellbeing
Maintain/support general health and wellbeing
Maintain/support healthy cardiovascular system function
Maintain/support immune system health
Helps enhance/promote/increase absorption of dietary (state vitamin/mineral/nutrient)
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
Decrease/reduce/relieve common cold duration

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).
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 cardiovascular conditions.
Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
Label statement: If symptoms persist, talk to your health professional.
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

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Warnings

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).
Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral 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**

Components

1 . Formulation 1

Dosage Form Tablet, modified release
Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	1000 mg
Citrus bioflavonoids extract	5 mg
hesperidin	5 mg
Rosa canina fruit Dry	20 mg
rutoside	5 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate
Carnauba Wax
hypromellose
macrogol 400
magnesium stearate
maltodextrin
purified water
silicon dioxide
stearic acid

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