



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

## Public Summary

<b>Summary for ARTG Entry:</b>	159838	Vitamin C with Hesperidin Complex
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Millenium Pharmaceuticals Pty Ltd	
<b>Postal Address</b>	PO Box 616, CASTLE HILL, NSW, 2154 Australia	
<b>ARTG Start Date</b>	6/03/2009	
<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.

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 . Vitamin C with Hesperidin Complex

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	14/12/2020
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#### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps enhance/promote general health and wellbeing
- Helps enhance/improve/promote blood circulation to the peripheral areas of the body (legs, hands and feet)
- Maintain/support blood circulation/flow to the peripheral areas of the body (legs, hands and feet)
- Decrease/reduce/relieve symptoms of hayfever
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Decrease/reduce/relieve common cold duration
- Decrease/reduce/relieve the severity of common cold symptoms

#### 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 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 cardiovascular conditions.
- 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

- (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].
- For practitioner dispensing only.
- Contains homoeopathic ingredients.
- This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

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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** Powder, oral

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>350 mg/g</b>
<b>calcium ascorbate dihydrate</b>	<b>176 mg/g</b>
Equivalent: ascorbic acid	145.5 mg/g
<b>hesperidin</b>	<b>112.5 mg/g</b>
<b>iron (Homeopathic)</b>	<b>1.25 mg/g</b>
<b>manganese (Homeopathic)</b>	<b>1.25 mg/g</b>
<b>selenium (Homeopathic)</b>	<b>2.5 mg/g</b>
<b>zinc (Homeopathic)</b>	<b>1.25 mg/g</b>

**Other Ingredients (Excipients)**

colloidal anhydrous silica

Flavour

glucose monohydrate

riboflavin sodium phosphate

Stevia rebaudiana

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