



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	350819	Manuka-C
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Natural Bio Pty Limited	
<b>Postal Address</b>	PO Box 384, MONA VALE, NSW, 1660 Australia	
<b>ARTG Start Date</b>	4/12/2020	
<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 . Manuka-C

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	13/05/2022
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### Permitted Indications

Maintain/support general health and wellbeing  
Maintain/support healthy immune system function  
Enhance/improve/promote/increase (state vitamin/mineral/nutrient) levels in the body  
Decrease/reduce/relieve common cold duration  
Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections  
Decrease/reduce/relieve the severity of common cold symptoms  
Helps reduce occurrence of symptoms of upper respiratory tract infections

### Indication Requirements

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: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).  
Respiratory tract infections must be qualified by 'mild'.  
  
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 serious immunological diseases.

### 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].  
WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).  
Not suitable for infants under the age of twelve months (or words to that effect).  
Adults only.



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Not recommended for use by pregnant and lactating women (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).

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

**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**

ascorbic acid	73.89 mg/g
glutathione	25 mg/g
Honey	250 mg/g
sodium ascorbate	11.32 mg/g
Equivalent: sodium	1.32 mg/g
Equivalent: ascorbic acid	10 mg/g
zinc ascorbate	19.11 mg/g
Equivalent: zinc	3 mg/g
Equivalent: ascorbic acid	16.11 mg/g

**Other Ingredients (Excipients)**

citric acid  
colloidal anhydrous silica  
Flavour  
maltodextrin  
silicon dioxide  
sodium bicarbonate  
sodium carbonate  
Stevia rebaudiana  
tartaric acid

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Public Summary