



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	320774	Thompson's Vitamin C 1000
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd	
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
<b>ARTG Start Date</b>	25/07/2019	
<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 . Thompson's Vitamin C 1000**

Product Type	Single Medicine Product	Effective Date	16/06/2021
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support collagen formation
- Maintain/support collagen health
- Maintain/support general health and wellbeing
- Aid/assist/helps connective tissue production/formation
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral) within normal range
- Decrease/reduce/relieve common cold duration
- Decrease/reduce/relieve symptoms of common colds and flu
  - Linked indication - Decrease/reduce/relieve cough
  - Linked indication - Decrease/reduce/relieve sneezing
  - Linked indication - Relieve runny/dripping nose
- Decrease/reduce/relieve symptoms of common colds and flu
- Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
  - Linked indication - Relieve runny/dripping nose
  - Linked indication - Decrease/reduce/relieve cough
  - Linked indication - Decrease/reduce/relieve sneezing
- Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
- Decrease/reduce/relieve sneezing
- Relieve symptoms of mild upper respiratory tract infections
- Decrease/reduce/relieve cough
- Relieve runny/dripping nose
- Relieve symptoms of sore throat/pharyngitis
- Maintain/support skin health
- Enhance/improve healing of minor skin wound/cuts/scratches/abrasions

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Maintain/support wound healing  
 Maintain/support skin repair/healing/regeneration

**Indication Requirements**

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).  
 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 serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.  
 Respiratory tract infections must be qualified by 'mild'.  
 Product presentation must not imply or refer to serious immunological diseases.  
 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].  
 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**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Tablet, uncoated
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>400 mg</b>
<b>Citrus bioflavonoids extract</b>	<b>5 mg</b>
<b>Malpighia glabra fruit Extract dry concentrate</b>	<b>300 microgram</b>
Equivalent: Malpighia glabra (Fresh)	5.1 mg
<b>Rosa canina fruit Extract dry concentrate</b>	<b>.83 mg</b>
Equivalent: Rosa canina (Dry)	4.98 mg
<b>sodium ascorbate</b>	<b>675 mg</b>
Equivalent: ascorbic acid	600 mg

**Other Ingredients (Excipients)**

colloidal anhydrous silica  
 Flavour  
 glucose monohydrate  
 hypromellose  
 magnesium stearate  
 maize starch  
 maltodextrin  
 sucralose  
 sunset yellow FCF aluminium lake

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