



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	365101	Liquid Vitamin C
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	BNutrition Pty Ltd	
<b>Postal Address</b>	PO Box 234, Tanunda, SA, 5352 Australia	
<b>ARTG Start Date</b>	10/05/2021	
<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 . Liquid Vitamin C**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	20/08/2021
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body in children
- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells in children
- Helps reduce/decrease free radical damage to body cells
- Maintain/support collagen formation in children
- Maintain/support collagen formation
- Maintain/support general health and wellbeing in children
- Maintain/support general health and wellbeing
- Aids/assists teeth development in children
- Maintain/support healthy teeth
- Maintain/support healthy teeth in children
- Maintain/support connective tissue health in children
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation in children
- Aid/assist/helps connective tissue production/formation
- Maintain/support bone health
- Maintain/support bone health in children
- Aids/assists healthy bone development/growth/building in children
- Maintain/support blood capillary health
- Maintain/support blood vessel health
- Maintain/support immune system health
- Maintain/support immune system health in children
- Maintain/support healthy immune system function in children
- Maintain/support healthy immune system function
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in children

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Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
 Aid/assist/helps synthesis of neurotransmitters in children  
 Aid/assist/helps synthesis of neurotransmitters  
 Maintain/support nervous system health  
 Maintain/support nervous system health in children  
 Maintain/support nervous system function  
 Maintain/support nervous system function in children  
 Maintain/support skin health in children  
 Maintain/support skin health  
 Maintain/support wound healing in children  
 Maintain/support wound healing

**Indication Requirements**

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 bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.  
 Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.  
 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.  
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.  
 Label statement: If symptoms persist, talk to your health professional.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

**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>	Oral Liquid
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>10 mg/mL</b>
<b>sodium ascorbate</b>	<b>45 mg/mL</b>
Equivalent: sodium	5 mg/mL
Equivalent: ascorbic acid	40 mg/mL

**Other Ingredients (Excipients)**

**Flavour**  
**glycerol**  
**potassium sorbate**  
**purified water**  
**Siraitia grosvenorii**  
**xylitol**

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