



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

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

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

Product Type	Single Medicine Product	Effective Date	30/07/2022
---------------------	-------------------------	-----------------------	------------

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
- Maintain/support connective tissue health in children
- Aid/assist/helps connective tissue production/formation
- Aid/assist/helps connective tissue production/formation in children
- Maintain/support bone health in children
- Maintain/support bone health
- 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
- Maintain/support healthy immune system function in children
- 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

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps synthesis of neurotransmitters
Aid/assist/helps synthesis of neurotransmitters in children
Maintain/support nervous system health
Maintain/support nervous system health in children
Maintain/support nervous system function in children
Maintain/support nervous system function
Maintain/support skin health
Maintain/support skin health in children
Maintain/support wound healing in children
Maintain/support wound healing
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
Aid/assist/helps connective tissue production/formation in children
Maintain/support bone health in children
Maintain/support bone health
Aids/assists healthy bone development/growth/building in children
Maintain/support blood capillary health
Maintain/support blood vessel health
Maintain/support immune system health in children
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support healthy immune system function in children
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
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 in children
Maintain/support nervous system health
Maintain/support nervous system function in children
Maintain/support nervous system function
Maintain/support skin health
Maintain/support skin health in children
Maintain/support wound healing in children
Maintain/support wound healing

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.



Australian Government
Department of Health
 Therapeutic Goods Administration

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.

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: 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

Pack Size	Poison Schedule
-----------	-----------------

Components

1 . Formulation 1

Dosage Form Oral Liquid
Route of Administration Oral

Visual Identification

Active Ingredients

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

Other Ingredients (Excipients)

Flavour
 glycerol
 potassium sorbate
 purified water
 Siraitia grosvenorii
 xylitol

2 . Liquid Vitamin C

Product Type	Single Medicine Product	Effective Date	30/07/2022
---------------------	-------------------------	-----------------------	------------

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
 Maintain/support connective tissue health in children

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Aid/assist/helps connective tissue production/formation
Aid/assist/helps connective tissue production/formation in children
Maintain/support bone health in children
Maintain/support bone health
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
Maintain/support healthy immune system function in children
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
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps synthesis of neurotransmitters
Aid/assist/helps synthesis of neurotransmitters in children
Maintain/support nervous system health
Maintain/support nervous system health in children
Maintain/support nervous system function in children
Maintain/support nervous system function
Maintain/support skin health
Maintain/support skin health in children
Maintain/support wound healing in children
Maintain/support wound healing
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
Aid/assist/helps connective tissue production/formation in children
Maintain/support bone health in children
Maintain/support bone health
Aids/assists healthy bone development/growth/building in children
Maintain/support blood capillary health
Maintain/support blood vessel health
Maintain/support immune system health in children
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support healthy immune system function in children
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
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps synthesis of neurotransmitters in children
Aid/assist/helps synthesis of neurotransmitters

Public Summary



Australian Government
Department of Health
 Therapeutic Goods Administration

Maintain/support nervous system health in children
 Maintain/support nervous system health
 Maintain/support nervous system function in children
 Maintain/support nervous system function
 Maintain/support skin health
 Maintain/support skin health in children
 Maintain/support wound healing in children
 Maintain/support wound healing

Indication Requirements

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 mental illnesses, disorders or conditions.

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).

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

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

Pack Size	Poison Schedule
------------------	------------------------

Components

1 . Formulation 1

Dosage Form	Oral Liquid
Route of Administration	Oral

Visual Identification

Active Ingredients

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

Other Ingredients (Excipients)

Flavour
glycerol
potassium sorbate
purified water
Siraitia grosvenorii
xylitol

Public Summary