



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	340003	Liquid Zinc
ARTG entry for	Medicine Listed	
Sponsor	BNutrition Pty Ltd	
Postal Address	PO Box 234, Tanunda, SA, 5352 Australia	
ARTG Start Date	23/07/2020	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 Zinc

Product Type	Single Medicine Product	Effective Date	23/07/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body in children
- Antioxidant/Reduce free radicals formed in the body in healthy infants
- Maintain/support collagen formation in children
- Maintain/support collagen formation in healthy infants
- Maintain/support healthy eye function in healthy infants
- Maintain/support healthy eye function in children
- Maintain/support eye health in healthy infants
- Maintain/support eye health in children
- Maintain/support healthy eyesight/vision in healthy infants
- Maintain/support healthy eyesight/vision in children
- Maintain/support healthy growth and development in healthy infants
- Maintain/support healthy growth and development in children
- Maintain/support general health and wellbeing in children
- Maintain/support general health and wellbeing in healthy infants
- Maintain/support hair health in children
- Maintain/support hair health in healthy infants
- Aids/assists teeth development in children
- Aids/assists teeth development in healthy infants
- Maintain/support healthy teeth in healthy infants
- Maintain/support healthy teeth in children
- Maintain/support teeth mineralisation in children
- Maintain/support nail health/strength/thickness in children
- Maintain/support nail health/strength/thickness in healthy infants

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Maintain/support connective tissue health in healthy infants
Maintain/support connective tissue health in children
Aid/assist/helps connective tissue production/formation in healthy infants
Aid/assist/helps connective tissue production/formation in children
Maintain/support bone health in children
Maintain/support bone health in healthy infants
Aids/assists healthy bone development/growth/building in children
Aids/assists healthy bone development/growth/building in healthy infants
Maintain/support bone strength in children
Help maintain/support bone mineralisation in children
Help maintain/support bone mineralisation in healthy infants
Maintain/support immune system health in children
Maintain/support immune system health in healthy infants
Maintain/support healthy immune system function in healthy infants
Maintain/support healthy immune system function in children
Maintain/support muscle function in children
Maintain/support healthy neuromuscular system/function in children
Aid/assist/helps protein synthesis in the body in children
Aid/assist/helps protein synthesis in the body in healthy infants
Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children
Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in healthy infants
Maintain/support (state vitamin/mineral/nutrient) levels in the body in breast fed healthy infants
Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate in children
Maintain/support (state vitamin/mineral/nutrient) levels in the body in healthy infants
Maintain/support (state vitamin/mineral/nutrient) levels in the body in children
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in healthy infants
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in breast fed healthy infants
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in children
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient) in children
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient) in healthy infants
Maintain/support cognitive function/mental function in healthy infants
Maintain/support cognitive function/mental function in children
Maintain/support nerve conduction in children
Maintain/support nerve conduction in healthy infants
Aid/assist/helps synthesis of neurotransmitters in children
Aid/assist/helps synthesis of neurotransmitters in healthy infants
Maintain/support nervous system health in children
Maintain/support nervous system health in healthy infants
Maintain/support nervous system function in children
Maintain/support nervous system function in healthy infants
Maintain/support skin health in children
Maintain/support skin health in healthy infants
Maintain/support skin integrity/structure in children
Maintain/support skin integrity/structure in healthy infants
Maintain/support skin regeneration in children
Maintain/support skin regeneration in healthy infants
Maintain/support wound healing in healthy infants
Maintain/support wound healing in children

Indication Requirements

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

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: If symptoms persist, talk to your health professional.

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



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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 serious musculoskeletal or neurological conditions.

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
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Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

betacarotene	.08 mg/mL
colecalfiferol	.35 microgram/mL
sodium ascorbate	7.88 mg/mL
Equivalent: ascorbic acid	7 mg/mL
Equivalent: sodium	.87 mg/mL
zinc glycinate	3.2648 mg/mL
Equivalent: zinc	1 mg/mL

Other Ingredients (Excipients)

- ascorbic acid
- ascorbyl palmitate
- citric acid
- dl-alpha-tocopherol
- Flavour
- Gelatin
- glycerol
- Maize Oil
- maize starch
- potassium sorbate
- purified water
- sucrose
- vegetable oil
- xanthan gum

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