



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	350630	Liquid Milk Calcium
ARTG entry for	Medicine Listed	
Sponsor	BNutrition Pty Ltd	
Postal Address	PO Box 234, Tanunda, SA, 5352 Australia	
ARTG Start Date	3/12/2020	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

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 Milk Calcium

Product Type	Single Medicine Product	Effective Date	30/07/2022
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Permitted Indications

- Maintain/support general health and wellbeing in children
- Maintain/support general health and wellbeing in healthy infants over 6 months of age
- Aids/assists teeth development in children
- Maintain/support healthy teeth in children
- Maintain/support teeth mineralisation in children
- Maintain/support bone health in healthy infants over 6 months of age
- Maintain/support bone health in children
- Aids/assists healthy bone development/growth/building in healthy infants over 6 months of age
- Aids/assists healthy bone development/growth/building in children
- Maintain/support bone mass/density/integrity in children
- Maintain/support bone strength in children
- Help maintain/support bone mineralisation in healthy infants over 6 months of age
- Help maintain/support bone mineralisation in children
- Maintain/support healthy digestive system function in children
- Maintain/support immune system health in children
- Maintain/support healthy immune system function in children
- Maintain/support healthy immune system function in healthy infants over 6 months of age
- Maintain/support healthy muscle contraction function in children
- Maintain/support muscle function in children
- Maintain/support healthy neuromuscular system/function in children
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in healthy infants over 6 months of age
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in healthy infants over 6 months of age
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in children
- Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate in children
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in children
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in healthy infants over 6 months of age
- Maintain/support nerve conduction in children
- Maintain/support neuromuscular function in children

Public Summary



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

- Maintain/support nervous system function in children
- Maintain/support general health and wellbeing in children
- Maintain/support general health and wellbeing in healthy infants over 6 months of age
- Aids/assists teeth development in children
- Maintain/support healthy teeth in children
- Maintain/support teeth mineralisation in children
- Maintain/support bone health in healthy infants over 6 months of age
- Maintain/support bone health in children
- Aids/assists healthy bone development/growth/building in healthy infants over 6 months of age
- Aids/assists healthy bone development/growth/building in children
- Maintain/support bone mass/density/integrity in children
- Maintain/support bone strength in children
- Help maintain/support bone mineralisation in healthy infants over 6 months of age
- Help maintain/support bone mineralisation in children
- Maintain/support healthy digestive system function in children
- Maintain/support immune system health in children
- Maintain/support healthy immune system function in children
- Maintain/support healthy immune system function in healthy infants over 6 months of age
- Maintain/support healthy muscle contraction function in children
- Maintain/support muscle function in children
- Maintain/support healthy neuromuscular system/function in children
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in healthy infants over 6 months of age
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in healthy infants over 6 months of age
- 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 children
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in children
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in healthy infants over 6 months of age
- Maintain/support nerve conduction in children
- Maintain/support neuromuscular function in children
- Maintain/support nervous system function in children

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 serious immunological diseases.

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).

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Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

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



Australian Government
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Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

calcium phosphate	37.6942 mg/mL
Equivalent: calcium	14.2616 mg/mL
coleciferol	.3125 microgram/mL
hydroxyapatite	2.68 mg/mL
Equivalent: calcium	750 microgram/mL

Other Ingredients (Excipients)

- citric acid
- dl-alpha-tocopherol
- Flavour
- glycerol
- inulin
- lecithin
- potassium sorbate
- purified water
- vegetable oil
- xanthan gum

2 . Liquid Milk Calcium

Product Type	Single Medicine Product	Effective Date	30/07/2022
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Permitted Indications

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- Help maintain/support bone mineralisation in children
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- Maintain/support immune system health in children
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- Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in healthy infants over 6 months of age
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in children
- Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate in children



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in children
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Other Ingredients (Excipients)

citric acid

dl-alpha-tocopherol

Flavour

glycerol

inulin

lecithin

potassium sorbate

purified water

vegetable oil

xanthan gum

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