



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	350630	Liquid Milk Calcium
<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>	3/12/2020	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 healthy infants over 6 months of age
- Maintain/support general health and wellbeing in children
- 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 children
- Aids/assists healthy bone development/growth/building in healthy infants over 6 months of age
- 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 children
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in healthy infants over 6 months of age
- 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

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- 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

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**Components**

**1 . Formulation 1**

**Dosage Form** Oral Liquid  
**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>calcium phosphate</b>	<b>37.6942 mg/mL</b>
Equivalent: calcium	14.2616 mg/mL
<b>coleciferol</b>	<b>.3125 microgram/mL</b>
<b>hydroxyapatite</b>	<b>2.68 mg/mL</b>
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**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	30/07/2022
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**Permitted Indications**

- Maintain/support general health and wellbeing in healthy infants over 6 months of age
- Maintain/support general health and wellbeing in children
- 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 children
- Aids/assists healthy bone development/growth/building in healthy infants over 6 months of age
- 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
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- Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in healthy infants over 6 months of age
- 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

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Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in children  
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**Standard Indications**

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**Additional Product information**



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**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

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**Route of Administration** Oral

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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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