



**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

<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 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 children  
Maintain/support bone health in healthy infants over 6 months of age  
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 children  
Help maintain/support bone mineralisation in healthy infants over 6 months of age  
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 when sun exposure is inadequate in children  
Maintain/support (state vitamin/mineral/nutrient) levels in the body in children  
Maintain/support (state vitamin/mineral/nutrient) levels in the body in healthy infants over 6 months of age  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in healthy infants over 6 months of age  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in children  
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).

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.

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>colecalciferol</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 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 children  
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Maintain/support bone strength in children  
Help maintain/support bone mineralisation in children  
Help maintain/support bone mineralisation in healthy infants over 6 months of age  
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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  
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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  
Maintain/support (state vitamin/mineral/nutrient) levels in the body in healthy infants over 6 months of age



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Maintain/support neuromuscular function in children  
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**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Oral Liquid

**Route of Administration** Oral

**Visual Identification**

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