

## **Australian Government**

## Department of Health and Aged Care

Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 302979 Brauer Baby & Kids Liquid Calcium with Magnesium and Zinc

ARTG entry for Medicine Listed

Sponsor BNutrition Pty Ltd

Postal Address PO Box 234, Tanunda, SA, 5352

Australia

ARTG Start Date 14/05/2018

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 . Brauer Baby & Kids Liquid Calcium with Magnesium and Zinc

Product Type Single Medicine Product Effective Date 16/08/2024

# Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Maintain/support collagen formation

Maintain/support energy levels

Maintain/support heat/energy production/thermogenesis

Maintain/support healthy eye function

Maintain/support eye health

Maintain/support healthy eyesight/vision

Maintain/support healthy growth and development

Maintain/support general health and wellbeing

Maintain/support hair health

Aids/assists teeth development

Maintain/support healthy teeth

Maintain/support nail health/strength/thickness

Maintain/support connective tissue health

Aid/assist/helps connective tissue production/formation

Maintain/support bone health

Aids/assists healthy bone development/growth/building in children

Aids/assists healthy bone development/growth/building in healthy infants

Maintain/support bone mass/density/integrity

Maintain/support bone strength

Help maintain/support bone mineralisation

Maintain/support cardiovascular system health

Maintain/support healthy cardiovascular system function

Maintain/support heart health

Maintain/support blood capillary health

Maintain/support blood vessel health

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Maintain/support healthy digestive system function

Maintain/support immune system health

Maintain/support healthy immune system function

Maintain/support healthy muscle contraction function

Maintain/support muscle function

Maintain/support healthy neuromuscular system/function

Aid/assist/helps protein synthesis in the body

Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when sun exposure is inadequate

Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Maintain/support cognitive function/mental function in healthy children

Maintain/support nerve conduction

Maintain/support neuromuscular function

Aid/assist/helps synthesis of neurotransmitters

Maintain/support nervous system health

Maintain/support nervous system function

Maintain/support skin health

Maintain/support skin integrity/structure

Maintain/support skin regeneration

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.

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.

Label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Product presentation must not imply or refer to chronic fatigue syndrome.

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

Product presentation must not imply or refer to serious cardiovascular conditions.

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

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

## Components

1 . Formulation 1

Dosage FormOral LiquidRoute of AdministrationOral

**Visual Identification** 

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Active	Ingred	dients

calcium ascorbate dihydrate 2.85 mg/mL Equivalent: ascorbic acid 2.34 mg/mL calcium phosphate 22.2033 mg/mL Equivalent: calcium 8.4006 mg/mL colecalciferol .11 microgram/mL 8.65 mg/mL magnesium citrate Equivalent: magnesium 1.34 mg/mL zinc glycinate 450 microgram/mL

## Other Ingredients (Excipients)

citric acid

dl-alpha-tocopherol

Equivalent: zinc

Flavour glycerol lecithin

potassium sorbate purified water vegetable oil xanthan gum

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135 microgram/mL