



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

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| 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.

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 . Brauer Baby & Kids Liquid Calcium with Magnesium and Zinc

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|---------------------|-------------------------|-----------------------|-----------|
| Product Type | Single Medicine Product | Effective Date | 7/04/2020 |
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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 healthy infants
- Aids/assists healthy bone development/growth/building in children
- Maintain/support bone mass/density/integrity
- Maintain/support bone strength
- Help maintain/support bone mineralisation
- Maintain/support cardiovascular system health

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- Maintain/support healthy cardiovascular system function
- Maintain/support heart health
- Maintain/support blood capillary health
- Maintain/support blood vessel health
- 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

- 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. 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 circulatory disorders/diseases/conditions e.g. thrombosis.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- 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 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 chronic fatigue syndrome.
- 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



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Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

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| calcium ascorbate dihydrate | 2.85 mg/mL |
| Equivalent: calcium | 268 microgram/mL |
| Equivalent: ascorbic acid | 2.34 mg/mL |
| calcium phosphate | 22.2033 mg/mL |
| colecalfiferol | .11 microgram/mL |
| magnesium citrate | 8.65 mg/mL |
| Equivalent: magnesium | 1.34 mg/mL |
| zinc glycinate | 450 microgram/mL |
| Equivalent: zinc | 135 microgram/mL |

Other Ingredients (Excipients)

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

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