



Australian Government
Department of Health
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.

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

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

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.

Label statement: If symptoms persist, talk to your health professional.

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

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.

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

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

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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