



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	351865	Baby & Child Teething
ARTG entry for	Medicine Listed	
Sponsor	Brauer Natural Medicine Pty Ltd	
Postal Address	PO Box 234, TANUNDA, SA, 5352 Australia	
ARTG Start Date	17/12/2020	
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 . Baby & Child Teething

Product Type	Single Medicine Product	Effective Date	1/09/2021
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Permitted Indications

Traditionally used in Homoeopathic medicine to decrease/reduce ear irritation/inflammation

Maintain/support general health and wellbeing in children

Traditionally used in Western herbal medicine to maintain/support general health and wellbeing in children

Traditionally used in Homoeopathic medicine to decrease/reduce/relieve gum soreness/pain/discomfort

Traditionally used in Homoeopathic medicine to decrease/reduce/relieve toothache

Aids/assists teeth development in children

Aids/assists teeth development in healthy infants

Maintain/support healthy teeth in children

Maintain/support teeth mineralisation in children

Traditionally used in Homoeopathic medicine to decrease/reduce/relieve teething/tooth pain in healthy children

Traditionally used in Western herbal medicine to decrease/reduce/relieve teething/tooth pain in children

Traditionally used in Homoeopathic medicine to decrease/reduce/relieve teething/tooth pain in healthy infants over 6 months of age

Traditionally used in Western herbal medicine to decrease/reduce/relieve teething/tooth pain in healthy infants over 6 months of age

Maintain/support bone health in healthy infants

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

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

Help maintain/support bone mineralisation in healthy infants

Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative in children

Maintain/support immune system health in children

Maintain/support healthy immune system function in healthy infants

Maintain/support healthy immune system function in children

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

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in healthy infants

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in breast fed healthy infants

Traditionally used in Homoeopathic medicine to relieve irritability in children

Traditionally used in Western herbal medicine to relieve irritability in children

Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy in children



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Department of Health
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Traditionally used in Homoeopathic medicine to decrease/reduce/relieve restlessness/excess nervous energy in children
Traditionally used in Western herbal medicine to soporific/induces sleep in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve disturbed/restless sleep in healthy infants over 6 months of age
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve disturbed/restless sleep in children

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 mental illnesses, disorders or 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).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains homoeopathic ingredients.

Contains hydroxybenzoates (or words to this effect) if the medicines contains more than one hydroxybenzoate source OR Contains (insert the approved name of hydroxybenzoate used)(or words to this effect) if product contains one hydroxybenzoate source.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

calcium phosphate (Homeopathic)	5 microlitre/mL
Citrullus colocynthis fruit flesh (Homeopathic)	5 microlitre/mL
colecalfiferol	.3335 microgram/mL
colloidal anhydrous silica (Homeopathic)	5 microlitre/mL
creosote (Homeopathic)	5 microlitre/mL
Matricaria chamomilla whole plant (Homeopathic)	5 microlitre/mL
Matricaria chamomilla flower Extract dry concentrate	19.1 mg/mL
Equivalent: Matricaria chamomilla (Dry)	76.4 mg/mL
Oyster shell (Homeopathic)	5 microlitre/mL

Other Ingredients (Excipients)

dl-alpha-tocopherol
ethanol
Flavour
glycerol
methyl hydroxybenzoate
propyl hydroxybenzoate
purified water
vegetable oil
xanthan gum



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