



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	322703	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	4/09/2019	
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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . Baby & Child Teething

Product Type	Effective Date
Single Medicine Product	4/09/2019

Permitted Indications

- Traditionally used in Homoeopathic medicine to aids/assists with recovery from illness/convalescence
- Traditionally used in Homoeopathic medicine to relieve feelings of general malaise/general debility
- Traditionally used in Homoeopathic medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Homoeopathic medicine to restorative tonic
- Maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Traditionally used in Homoeopathic medicine to maintain/support general health and wellbeing
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve gum soreness/pain/discomfort
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mouth/oral mucosa mild inflammation
- Traditionally used in Homoeopathic medicine to soothe/relieve mouth/oral irritation
- Aids/assists teeth development
- Maintain/support healthy teeth
- Maintain/support teeth mineralisation
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve teething/tooth pain
- Traditionally used in Western herbal medicine to decrease/reduce/relieve teething/tooth pain
- Traditionally used in Western herbal medicine to helps reduce occurrence of teething/tooth pain
- Traditionally used in Homoeopathic medicine to helps reduce occurrence of teething/tooth pain
- Maintain/support teeth strength
- Maintain/support bone health

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Aids/assists healthy bone development/growth/building
 Maintain/support bone strength
 Help maintain/support bone mineralisation
 Maintain/support immune system health
 Maintain/support healthy immune system function
 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 when sun exposure is inadequate
 Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
 Traditionally used in Homoeopathic medicine to relieve irritability
 Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve restlessness/excess nervous energy
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve nervous tension/unrest
 Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild nerve pain/neuralgia
 Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness Temporarily
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve sleeplessness Temporarily
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve disturbed/restless sleep Temporarily
 Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep Temporarily
 Traditionally used in Western herbal medicine to enhance/improve/promote/increase sleep quality/deep sleep Temporarily
 Traditionally used in Homoeopathic medicine to decongestant/relieve nasal congestion
 Traditionally used in Homoeopathic medicine to relieve runny/dripping nose

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
 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).
 Product presentation must only refer to mild nerve pain/neuralgia.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
 Product presentation must not imply or refer to chronic fatigue syndrome.

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).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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.

Contains homoeopathic ingredients.

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



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Visual Identification

Active Ingredients

calcium phosphate (Homeopathic)	5 microlitre/mL
Citrullus colocynthis fruit flesh (Homeopathic)	5 microlitre/mL
Equivalent: Citrullus colocynthis	.0005 picogram/mL
colecalfiferol	.042 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	13.17 mg/mL
Equivalent: Matricaria chamomilla (Dry)	52.68 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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