



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	322703	Baby & Child Teething
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Brauer Natural Medicine Pty Ltd	
<b>Postal Address</b>	PO Box 234, TANUNDA, SA, 5352 Australia	
<b>ARTG Start Date</b>	4/09/2019	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- 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 Western herbal medicine to decrease/reduce/relieve teething/tooth pain
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve teething/tooth pain
- Traditionally used in Homoeopathic medicine to helps reduce occurrence of teething/tooth pain
- Traditionally used in Western herbal 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  
 Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when sun exposure is inadequate  
 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 Western herbal medicine to decrease/reduce/relieve nervous tension/unrest  
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve nervous tension/unrest  
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild nerve pain/neuralgia  
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve sleeplessness Temporarily  
 Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness Temporarily  
 Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep Temporarily  
 Traditionally used in Homoeopathic 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**

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

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 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 mental illnesses, disorders or conditions.

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).

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**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Oral Liquid
<b>Route of Administration</b>	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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