



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	323471	Baby & Child Stomach Calm
<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>	16/09/2019	
<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.

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 Stomach Calm**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	8/04/2020
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**Permitted Indications**

- 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
- 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
- Aids/assists teeth development
- Maintain/support healthy teeth
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Maintain/support bone mass/density/integrity
- Maintain/support bone strength
- Help maintain/support bone mineralisation
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve colic (wind/gas pain)
- Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve excess intestinal gas
- Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve flatulence/carminative
- Maintain/support healthy digestive system function
- Traditionally used in Homoeopathic medicine to maintain/support healthy digestion
- Traditionally used in Western herbal medicine to maintain/support digestive system health
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve abdominal bloating/distention
- Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve abdominal cramping

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Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal cramping  
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve abdominal feeling of fullness  
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve abdominal griping pain  
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve abdominal pain/discomfort  
 Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal spasm  
 Traditionally used in Homoeopathic medicine to relieve excessive belching  
 Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia  
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia  
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of heartburn  
 Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of nervous indigestion  
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of stomach upsets  
 Traditionally used in Homoeopathic medicine to reduce occurrence of nausea/vomiting  
 Traditionally used in Homoeopathic medicine to antiemetic/Decrease/reduce/relieve vomiting  
 Traditionally used in Western herbal medicine to decrease/reduce/relieve nausea  
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve nausea  
 Maintain/support healthy muscle contraction function  
 Maintain/support muscle function  
 Maintain/support healthy neuromuscular system/function  
 Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
 Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy  
 Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest  
 Maintain/support nerve conduction  
 Maintain/support nervous system function  
 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 Western herbal medicine to enhance/improve/promote/increase sleep quality/deep sleep Temporarily

**Indication Requirements**

Label statement: If symptoms persist, talk to your health professional.  
 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 gastro oesophageal reflux disease.  
 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 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 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
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**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>calcium phosphate</b>	<b>28.6732 mg/mL</b>
<b>Cinchona officinalis stem bark (Homeopathic)</b>	<b>5 microlitre/mL</b>
Equivalent: Quinidine	0 microgram/mL
Equivalent: quinine	0 microgram/mL
<b>colloidal anhydrous silica (Homeopathic)</b>	<b>5 microlitre/mL</b>
<b>dibasic sodium phosphate dodecahydrate (Homeopathic)</b>	<b>5 microlitre/mL</b>
<b>Lycopodium clavatum spore (Homeopathic)</b>	<b>5 microlitre/mL</b>
<b>Matricaria chamomilla flower Extract dry concentrate</b>	<b>5.33 mg/mL</b>
Equivalent: Matricaria chamomilla (Dry)	21.32 mg/mL
<b>phosphorus (Homeopathic)</b>	<b>5 microlitre/mL</b>

**Other Ingredients (Excipients)**

citric acid  
ethanol  
Flavour  
glycerol  
lecithin  
methyl hydroxybenzoate  
propyl hydroxybenzoate  
purified water  
xanthan gum

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