



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	323471	Baby & Child Stomach Calm
ARTG entry for	Medicine Listed	
Sponsor	Brauer Natural Medicine Pty Ltd	
Postal Address	PO Box 234, TANUNDA, SA, 5352 Australia	
ARTG Start Date	16/09/2019	
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.

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

Product Type	Single Medicine Product	Effective Date	29/07/2022
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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
- 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
- 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 Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve colic (wind/gas pain)
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve excess intestinal gas
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve flatulence/carminative
- Traditionally used in Western herbal 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 Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve abdominal bloating/distention
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve abdominal cramping
- 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

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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 Homoeopathic medicine to decrease/reduce/relieve nausea
 Traditionally used in Western herbal 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 mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to gastro oesophageal reflux disease.
 Product presentation must not imply or refer to chronic fatigue syndrome.
 Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
 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.
 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
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Components

1 . Formulation 1

Dosage Form	Oral Liquid
Route of Administration	Oral

Visual Identification

Active Ingredients

calcium phosphate	28.6732 mg/mL
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Equivalent: calcium	10.8485 mg/mL
Cinchona officinalis stem bark (Homeopathic)	5 microlitre/mL
Equivalent: quinine	0 microgram/mL
Equivalent: Quinidine	0 microgram/mL
colloidal anhydrous silica (Homeopathic)	5 microlitre/mL
dibasic sodium phosphate dodecahydrate (Homeopathic)	5 microlitre/mL
Lycopodium clavatum spore (Homeopathic)	5 microlitre/mL
Matricaria chamomilla flower Extract dry concentrate	5.33 mg/mL
Equivalent: Matricaria chamomilla (Dry)	21.32 mg/mL
phosphorus (Homeopathic)	5 microlitre/mL
Other Ingredients (Excipients)	
citric acid	
ethanol	
Flavour	
glycerol	
lecithin	
methyl hydroxybenzoate	
propyl hydroxybenzoate	
purified water	
xanthan gum	

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