



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

## Public Summary

<b>Summary for ARTG Entry:</b>	322575	Baby & Child Colic
<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>	2/09/2019	
<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.

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 Colic

Product Type	Single Medicine Product	Effective Date	8/08/2022
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#### Permitted Indications

- 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 Western herbal medicine to helps decrease/reduce/relieve symptoms of infant colic
  - Linked indication - Decrease/reduce/relieve colic (wind/gas pain)
  - Linked indication - Decrease/reduce/relieve flatulence/carminative
  - Linked indication - Maintain/support digestive system health
  - Linked indication - Decrease/reduce/relieve abdominal bloating/distention
  - Linked indication - Decrease/reduce/relieve abdominal cramping
  - Linked indication - Decrease/reduce/relieve abdominal spasm
- Traditionally used in Homoeopathic medicine to helps decrease/reduce/relieve symptoms of infant colic
  - Linked indication - Decrease/reduce/relieve nausea
  - Linked indication - Decrease/reduce/relieve flatulence/carminative
  - Linked indication - Maintain/support healthy digestion
  - Linked indication - Decrease/reduce/relieve abdominal bloating/distention
  - Linked indication - Decrease/reduce/relieve abdominal cramping
  - Linked indication - Decrease/reduce/relieve abdominal feeling of fullness
  - Linked indication - Decrease/reduce/relieve abdominal pain/discomfort
  - Linked indication - Decrease/reduce/relieve gastrointestinal pain
  - Linked indication - Reduce occurrence of nausea/vomiting
  - Linked indication - Decrease/reduce/relieve colic (wind/gas pain)
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of nervous indigestion
- Traditionally used in Homoeopathic medicine to relieve irritability
- Traditionally used in Western herbal 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 Western herbal medicine to decrease/reduce/relieve sleeplessness Temporarily
- Traditionally used in Homoeopathic 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

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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 gastro oesophageal reflux disease.  
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.  
 Label statement: If symptoms persist or worsen talk to your medical practitioner.

**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 homeopathic 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

**Visual Identification**

**Active Ingredients**

<b>Bryonia alba root (Homeopathic)</b>	<b>5 microlitre/mL</b>
<b>calcium phosphate (Homeopathic)</b>	<b>5 microlitre/mL</b>
<b>Cinchona officinalis stem bark (Homeopathic)</b>	<b>5 microlitre/mL</b>
Equivalent: quinine	0 picogram/mL
Equivalent: Quinidine	0 picogram/mL
<b>Citrullus colocynthis fruit flesh (Homeopathic)</b>	<b>5 microlitre/mL</b>
Equivalent: Citrullus colocynthis	.0005 picogram/mL
<b> dibasic magnesium phosphate trihydrate (Homeopathic)</b>	<b>5 microlitre/mL</b>
Equivalent: magnesium	.0007 picogram/mL
<b>Dill Seed Oil</b>	<b>400 nanolitre/mL</b>
<b>Matricaria chamomilla whole plant (Homeopathic)</b>	<b>5 microlitre/mL</b>
<b>Matricaria chamomilla flower Extract dry concentrate</b>	<b>13.67 mg/mL</b>
Equivalent: Matricaria chamomilla (Dry)	54.68 mg/mL

**Other Ingredients (Excipients)**

ethanol  
 glycerol  
 methyl hydroxybenzoate  
 propyl hydroxybenzoate  
 purified water

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