



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	322575	Baby & Child Colic
ARTG entry for	Medicine Listed	
Sponsor	Brauer Natural Medicine Pty Ltd	
Postal Address	PO Box 234, TANUNDA, SA, 5352 Australia	
ARTG Start Date	2/09/2019	
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.

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 Colic

Product Type	Single Medicine Product	Effective Date	10/06/2020
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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 abdominal spasm
 - Linked indication - Decrease/reduce/relieve abdominal cramping
 - Linked indication - Decrease/reduce/relieve flatulence/carminative
 - Linked indication - Maintain/support digestive system health
 - Linked indication - Decrease/reduce/relieve abdominal bloating/distention
- Traditionally used in Homoeopathic medicine to helps decrease/reduce/relieve symptoms of infant colic
 - Linked indication - Decrease/reduce/relieve colic (wind/gas pain)
 - Linked indication - Decrease/reduce/relieve nausea
 - Linked indication - Reduce occurrence of nausea/vomiting
 - Linked indication - Decrease/reduce/relieve gastrointestinal pain
 - Linked indication - Decrease/reduce/relieve abdominal pain/discomfort
 - Linked indication - Decrease/reduce/relieve abdominal feeling of fullness
 - Linked indication - Decrease/reduce/relieve abdominal cramping
 - Linked indication - Decrease/reduce/relieve flatulence/carminative
 - Linked indication - Maintain/support healthy digestion
 - Linked indication - Decrease/reduce/relieve abdominal bloating/distention
- 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 Western herbal medicine to relieve irritability
- Traditionally used in Homoeopathic medicine to relieve irritability
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve restlessness/excess nervous energy
- Traditionally used in Western herbal 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



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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

Indication Requirements

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

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

Visual Identification

Active Ingredients

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

Other Ingredients (Excipients)

ethanol
 glycerol
 methyl hydroxybenzoate
 propyl hydroxybenzoate
 purified water

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