



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	322409	Baby & Child Sleep
ARTG entry for	Medicine Listed	
Sponsor	Brauer Natural Medicine Pty Ltd	
Postal Address	PO Box 234, TANUNDA, SA, 5352 Australia	
ARTG Start Date	28/08/2019	
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 Sleep

Product Type	Single Medicine Product	Effective Date	29/07/2022
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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 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 nerve/support nervous system
- 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 Homoeopathic medicine to decrease/reduce/relieve disturbed/restless sleep 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.

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.

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Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

Anemone pulsatilla whole plant (Homeopathic)	5 microlitre/mL
Coffea arabica seed (Homeopathic)	5 microlitre/mL
Matricaria chamomilla flower Extract dry concentrate	25 mg/mL
Equivalent: Matricaria chamomilla (Dry)	100 mg/mL
Matricaria chamomilla whole plant (Homeopathic)	5 microlitre/mL
Melissa officinalis leaf Extract dry concentrate	16.88 mg/mL
Equivalent: Melissa officinalis (Dry)	67.52 mg/mL
Strychnos ignatii seed (Homeopathic)	5 microlitre/mL
Equivalent: strychnine (of Strychnos spp.)	0 microlitre/mL

Other Ingredients (Excipients)

ethanol

Flavour

glycerol

methyl hydroxybenzoate

propyl hydroxybenzoate

purified water

xanthan gum

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