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.

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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 Sleep

Product Type	Single Medicine Product	**Effective Date**	28/08/2019

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 nervine/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

Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Label statement: If symptoms persist, talk to your health professional.

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

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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