



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	322579	Baby & Child Calm
<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.

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 Calm**

Product Type	Single Medicine Product	Effective Date	2/09/2019
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**Permitted Indications**

- Traditionally used in Homoeopathic medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Homoeopathic medicine to maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Traditionally used in Homoeopathic medicine to relieve irritability
- Traditionally used in Western herbal medicine to calms the mind
- 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 Western herbal medicine to soothe/calm nerves
- 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 calmative/nervous system relaxant
- Traditionally used in Homoeopathic medicine to support healthy emotional/mood balance
- 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, talk to your health professional.



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Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to chronic fatigue syndrome.

**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 milk/milk products.

Contains homeopathic ingredients.

Not suitable for use in children under the age of 12 months except on the advice of a health professional. (or words to that effect)

**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**

alpha casozepine enriched hydrolysed milk protein	2.78 mg/mL
dibasic magnesium phosphate trihydrate (Homeopathic)	5 microlitre/mL
dibasic potassium phosphate (Homeopathic)	5 microlitre/mL
Matricaria chamomilla flower Extract dry concentrate	13.333 mg/mL
Equivalent: Matricaria chamomilla (Dry)	53.333 mg/mL
Matricaria chamomilla whole plant (Homeopathic)	5 microlitre/mL
Passiflora incarnata herb flowering (Homeopathic)	5 microlitre/mL

**Other Ingredients (Excipients)**

ethanol

Flavour

glycerol

methyl hydroxybenzoate

propyl hydroxybenzoate

purified water

xanthan gum

Public Summary

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