



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	291398	Calmamile
ARTG entry for	Medicine Listed	
Sponsor	The Pharmaceutical Plant Company Pty Ltd	
Postal Address	3 Sigma Drive, Croydon South, VIC, 3136 Australia	
ARTG Start Date	12/07/2017	
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 . Calmamile

Product Type	Single Medicine Product	Effective Date	19/02/2021
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Permitted Indications

- Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
- Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative in children over 2 years of age
- Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy
- Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy in children over 2 years of age
- Traditionally used in Western herbal medicine to soothe/calm nerves in children over 2 years of age
- Traditionally used in Western herbal medicine to soothe/calm nerves
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety in children over 2 years of age
- Traditionally used in Western herbal medicine to nerve/support nervous system in children over 2 years of age
- Traditionally used in Western herbal medicine to nerve/support nervous system
- Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness in children over 2 years of age

Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must only refer to mild anxiety.
- 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

- If symptoms persist consult your healthcare practitioner (or words to that effect).
- Contains ethanol or contains alcohol.

Additional Product information



Australian Government
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Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

Matricaria chamomilla herb top flowering Extract liquid	.91 mL/mL
Equivalent: Matricaria chamomilla (Fresh)	450 mg/mL

Other Ingredients (Excipients)

glycerol

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