



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	231501	Children's Calm Care
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	5/12/2014	
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 . Children's Calm Care

Product Type	Effective Date
Single Medicine Product	2/08/2019

Permitted Indications

- Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative in children
- Maintain/support gastrointestinal system health in children
- Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention in children
- Traditionally used in Western herbal medicine to relieve digestive discomfort in children
- Traditionally used in Western herbal medicine to decrease/reduce/relieve digestive spasms in children
- Traditionally used in Western herbal medicine to relieve irritability in children
- Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy in children
- Traditionally used in Western herbal medicine to soothe/calm nerves in children
- Maintain/support nervous system health in children
- Traditionally used in Western herbal medicine to calmative/nervous system relaxant in children
- Maintain/support nervous system function in children

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.
- Product presentation must not imply or refer to gastro oesophageal reflux disease.

Standard Indications

No Standard Indications included on Record

Specific Indications



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No Specific Indications included on Record

Warnings

Not suitable for use in children under the age of 12 months, except on health professional advice.
Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea [or words to that effect].
Derived from cow's milk.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Tablet, chewable
Route of Administration Oral

Visual Identification

Active Ingredients

alpha casozepine enriched hydrolysed milk protein	25 mg
magnesium amino acid chelate	75 mg
Equivalent: magnesium	15 mg
Matricaria chamomilla	30 mg
Equivalent: Matricaria chamomilla	300 mg

Other Ingredients (Excipients)

Black currant
citric acid
colloidal anhydrous silica
magnesium stearate
povidone
thaumatin
xylitol

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