



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	188865	METAGENICS CALM CARE FOR KIDS
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	5/09/2011	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

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 . METAGENICS CALM CARE FOR KIDS

Product Type	Single Medicine Product	Effective Date	29/11/2021
--------------	-------------------------	----------------	------------

Permitted Indications

- Relieve irritability in children
- Traditionally used in Western herbal medicine to relieve irritability in children
- Decrease/reduce/relieve restlessness/excess nervous energy in children
- Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy in children
- Decrease/reduce/relieve symptoms of stress in children
- Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest in children
- Decrease/reduce/relieve nervous tension/unrest in children
- Decrease/reduce/relieve symptoms of mild anxiety 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
- Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness in children
- Decrease/reduce/relieve sleeplessness in children
- Traditionally used in Western herbal medicine to maintain/support healthy sleeping patterns 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 only refer to mild anxiety.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

- 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)
- If symptoms persist consult your healthcare practitioner (or words to that effect).
- Contains lactose (or words to that effect).
- (If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Contains milk/milk products.

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Powder

Route of Administration Oral

Visual Identification

Active Ingredients

alpha caseozepine enriched hydrolysed milk protein	28.57 mg/g
magnesium glycinate dihydrate	171.43 mg/g
Equivalent: magnesium	17.14 mg/g
Matricaria chamomilla flower Extract dry concentrate	35.71 mg/g
Equivalent: Matricaria chamomilla (Dry)	214.3 mg/g
Passiflora incarnata herb Extract dry concentrate	51.94 mg/g
Equivalent: Passiflora incarnata (Dry)	285.67 mg/g

Other Ingredients (Excipients)

colloidal anhydrous silica

Flavour

fructose

maltodextrin

polydextrose

Stevia rebaudiana

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary