



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

## Public Summary

<b>Summary for ARTG Entry:</b>	188865	METAGENICS CALM CARE FOR KIDS
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	5/09/2011	
<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.

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 . METAGENICS CALM CARE FOR KIDS

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	27/02/2020
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### Permitted Indications

- Relieve irritability 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
- 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
- Decrease/reduce/relieve sleeplessness in children
- Traditionally used in Western herbal medicine to 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 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



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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 the advice of a health professional. (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].  
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.  
Contains milk/milk products.  
If symptoms persist consult your healthcare practitioner (or words to that effect).  
Contains lactose (or words to that effect).

#### 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

<b>alpha casozepine enriched hydrolysed milk protein</b>	<b>28.57 mg/g</b>
<b>magnesium amino acid chelate</b>	<b>171.43 mg/g</b>
Equivalent: magnesium	17.14 mg/g
<b>Matricaria chamomilla flower Extract dry concentrate</b>	<b>35.71 mg/g</b>
Equivalent: Matricaria chamomilla (Dry)	214.3 mg/g
<b>Passiflora incarnata herb Extract dry concentrate</b>	<b>51.94 mg/g</b>
Equivalent: Passiflora incarnata (Dry)	285.67 mg/g

#### Other Ingredients (Excipients)

colloidal anhydrous silica

Flavour

fructose

maltodextrin

polydextrose

Stevia rebaudiana

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