



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

## Public Summary

<b>Summary for ARTG Entry:</b>	343133	METAGENICS CALMX RASPBERRY
<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>	8/09/2020	
<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 CALMX RASPBERRY

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	8/09/2020
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#### Permitted Indications

- Support healthy stress response in the body
- Decrease/reduce/relieve symptoms of stress
- Maintain/support neuroendocrine function
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system function

#### 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.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

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. If symptoms persist consult your healthcare practitioner (or words to that effect).

#### Additional Product information

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
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#### Components



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**1 . Formulation 1**

**Dosage Form** Powder, oral  
**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>calcium ascorbate dihydrate</b>	<b>47.65 mg/g</b>
Equivalent: ascorbic acid	39.37 mg/g
<b>calcium pantothenate</b>	<b>1.97 mg/g</b>
<b>glutamine</b>	<b>157.48 mg/g</b>
<b>magnesium amino acid chelate</b>	<b>275.59 mg/g</b>
Equivalent: magnesium	27.56 mg/g
<b>nicotinamide</b>	<b>1.97 mg/g</b>
<b>potassium citrate</b>	<b>78.83 mg/g</b>
Equivalent: potassium	28.5 mg/g
<b>pyridoxal 5-phosphate monohydrate</b>	<b>1.97 mg/g</b>
Equivalent: pyridoxine	1.26 mg/g
<b>riboflavin sodium phosphate</b>	<b>2.7 mg/g</b>
Equivalent: riboflavin	1.97 mg/g
<b>taurine</b>	<b>236.22 mg/g</b>
<b>thiamine hydrochloride</b>	<b>1.97 mg/g</b>
<b>zinc amino acid chelate</b>	<b>3.94 mg/g</b>
Equivalent: zinc	787 microgram/g

**Other Ingredients (Excipients)**

**citric acid**  
**Colour**  
**Flavour**  
**hypromellose**  
**malic acid**  
**silicon dioxide**  
**Steviol glycosides**  
**tartaric acid**

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