Public Summary

Summary for ARTG Entry:	365751 METAGENICS CALMX RASPBERRY
ARTG entry for	Medicine Listed
Sponsor	Metagenics (Aust) Pty Ltd
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia
ARTG Start Date	13/05/2021
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 . METAGENICS CALMX RASPBERRY

Product Type Single Medicine Product **Effective Date** 29/08/2022

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

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

If symptoms persist consult your healthcare practitioner (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.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form	Powder, oral
Route of Administration	Oral
Visual Identification	

Active Ingredients	
calcium ascorbate dihydrate	**47.65 mg/g**
Equivalent: calcium	4.35 mg/g
Equivalent: ascorbic acid	39.37 mg/g
calcium citrate tetrahydrate	**55.96 mg/g**
Equivalent: calcium	11.8 mg/g
calcium pantothenate	**1.97 mg/g**
glutamine	**157.48 mg/g**
magnesium glycinate dihydrate	**275.59 mg/g**
Equivalent: magnesium	27.56 mg/g
nicotinamide	**1.97 mg/g**
potassium citrate	**21.68 mg/g**
Equivalent: potassium	7.84 mg/g
pyridoxal 5-phosphate monohydrate	**1.97 mg/g**
Equivalent: pyridoxine	1.26 mg/g
riboflavin sodium phosphate	**2.7 mg/g**
Equivalent: riboflavin	1.97 mg/g
taurine	**236.22 mg/g**
thiamine hydrochloride	**1.97 mg/g**
zinc amino acid chelate	**3.94 mg/g**
Equivalent: zinc	787.4 microgram/g

Other Ingredients (Excipients)

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

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