



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	378296	METAGENICS NEUROCALM SOOTHE
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	19/11/2021	
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 NEUROCALM SOOTHE

Product Type	Single Medicine Product	Effective Date	19/11/2021
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Permitted Indications

Maintain/support general health and wellbeing
Traditionally used in Western herbal medicine to relieve irritability
Traditionally used in Western herbal medicine to calms the mind
Traditionally used in Western herbal medicine to help maintain/support emotional wellbeing
Traditionally used in Western herbal medicine to aid/assist/helps mind relaxation
Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy
Traditionally used in Western herbal medicine to soothe/calm nerves
Traditionally used in Western herbal medicine to helps reduce occurrence of irritability
Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
Linked indication - Calms the mind
Linked indication - Decrease/reduce/relieve restlessness/excess nervous energy
Linked indication - Soothe/calm nerves
Linked indication - Decrease/reduce/relieve nervous tension/unrest
Linked indication - Decrease/reduce/relieve mental overactivity
Traditionally used in Western herbal medicine to helps reduce occurrence of symptoms of mild anxiety
Traditionally used in Western herbal medicine to decrease/reduce/relieve mental overactivity
Traditionally used in Western herbal medicine to maintain/support general mental wellbeing

Indication Requirements

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



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Warnings

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

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Camellia sinensis leaf Extract dry concentrate standardised	250 mg
Equivalent: Camellia sinensis (Dry)	40 g
Lavender Oil	80 mg
Equivalent: Lavender Oil ()	80 mg
Melissa officinalis leaf Extract dry concentrate	120 mg
Equivalent: Melissa officinalis (Dry)	6 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
dl-alpha-tocopheryl acetate
ethoxylated hydrogenated castor oil
glyceryl monooleate
hypromellose
lecithin
Lime Oil Coldpressed
magnesium stearate
medium chain triglycerides
microcrystalline cellulose
Olive Oil
povidone
purified water
silicon dioxide
sorbitol

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