



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 133023 NEUROCALM

ARTG entry for Medicine Listed
Sponsor Metagenics (Aust) Pty Ltd
Postal Address PO Box 675, VIRGINIA BC, QLD, 4014
Australia
ARTG Start Date 15/11/2006
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.

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. NEUROCALM

Product Type	Single Medicine Product	Effective Date	19/05/2020
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Permitted Indications

Traditionally used in Western herbal medicine to antispasmodic/spasmodic
Traditionally used in Chinese medicine to support healthy stress response in the body
Traditionally used in Western herbal medicine to support healthy stress response in the body
Traditionally used in Western herbal medicine to calms the mind
Traditionally used in Chinese medicine to calms the mind
Traditionally used in Western herbal medicine to aid/assist/helps mind relaxation
Traditionally used in Western herbal medicine to soothe/calm nerves
Traditionally used in Chinese medicine to soothe/calm nerves
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress
Linked indication - Decrease/reduce/relieve nervous tension/unrest
Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of mild anxiety
Linked indication - Decrease/reduce/relieve excessive perspiration/sweating
Linked indication - Relieve irritability
Linked indication - Decrease/reduce/relieve nervous tension/unrest
Linked indication - Decrease/reduce/relieve sleeplessness
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 - Relieve irritability
Linked indication - Decrease/reduce/relieve sleeplessness
Linked indication - Decrease/reduce/relieve nervous tension/unrest
Traditionally used in Chinese medicine to decrease/reduce/relieve headache symptoms
Linked indication - clear/cool/drain/purge/asthenic-heat/deficiency-heat
Linked indication - Maintain/support muscle relaxation
Traditionally used in Western herbal medicine to calmative/nervous system relaxant
Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness

Indication Requirements



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Product presentation must only refer to mild anxiety.

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

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

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

If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

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 Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Magnolia officinalis stem bark Extract dry concentrate	300 mg
Equivalent: Magnolia officinalis (Dry)	1.5 g
Passiflora incarnata herb Extract dry concentrate	236.364 mg
Equivalent: Passiflora incarnata (Dry)	1.3 g
Pueraria lobata root Extract dry concentrate	80 mg
Equivalent: Pueraria lobata (Dry)	2 g
Ziziphus jujuba var. spinosa seed Extract dry concentrate	166.667 mg
Equivalent: Ziziphus jujuba var. spinosa (Dry)	3 g

Other Ingredients (Excipients)

carrageenan

croscarmellose sodium

macrogol 8000

microcrystalline cellulose

powdered cellulose

silicon dioxide

stearic acid

Public Summary

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