



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	313283	METAGENICS NEUROCALM SLEEP
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	16/01/2019	
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 SLEEP

Product Type	Single Medicine Product	Effective Date	15/12/2020
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Permitted Indications

- Traditionally used in Western herbal medicine to analgesic/Anodyne/relieve pain
- Traditionally used in Western herbal medicine to soothe/calm nerves
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of stress
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress
- Traditionally used in Chinese medicine to decrease/reduce/relieve nervous tension/unrest
- 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 Chinese medicine to decrease/reduce/relieve symptoms of mild anxiety
- Decrease/reduce/relieve symptoms of mild anxiety
- Traditionally used in Western herbal medicine to soporific/induces sleep
- Traditionally used in Chinese medicine to soporific/induces sleep
- Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Chinese medicine to decrease/reduce time to fall asleep
- Traditionally used in Western herbal medicine to decrease/reduce time to fall asleep
- Traditionally used in Chinese medicine to decrease/reduce/relieve disturbed/restless sleep
- Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep
- Traditionally used in Western herbal medicine to enhance/improve/promote/increase sleep quality/deep sleep

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.

Product presentation must only refer to mild anxiety.

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 Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Eschscholzia californica herb flowering Extract dry concentrate	125 mg
Equivalent: Eschscholzia californica (Dry)	750 mg
Lavender Oil	40 mg
Passiflora incarnata herb Extract dry concentrate	363.64 mg
Equivalent: Passiflora incarnata (Dry)	2 g
Piscidia piscipula stem bark Extract dry concentrate	187.5 mg
Equivalent: Piscidia piscipula (Dry)	750 mg
Ziziphus jujuba var. spinosa seed Extract dry concentrate	277.78 mg
Equivalent: Ziziphus jujuba var. spinosa (Dry)	5 g

Other Ingredients (Excipients)

calcium hydrogen phosphate
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose
povidone

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