



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

## Public Summary

<b>Summary for ARTG Entry:</b>	378296	METAGENICS NEUROCALM SOOTHE
<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>	19/11/2021	
<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.

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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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  
Linked indication - Calms the mind  
Linked indication - Decrease/reduce/relieve restlessness/excess nervous energy  
Linked indication - Decrease/reduce/relieve mental overactivity  
Linked indication - Decrease/reduce/relieve nervous tension/unrest  
Linked indication - Soothe/calm nerves  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety  
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

Public Summary

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