



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	311525	Eagle Lavandula Calm
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	14/11/2018	
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 . Eagle Lavandula Calm

Product Type	Single Medicine Product	Effective Date	30/04/2021
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Permitted Indications

Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
Traditionally used in Ayurvedic medicine to balance Vata
Traditionally used in Ayurvedic medicine to balance aggravated Vata
Traditionally used in Ayurvedic medicine to enhance/promote energy levels
Maintain/support general health and wellbeing
Traditionally used in Ayurvedic medicine to maintain/support general health and wellbeing
Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
Traditionally used in Western herbal medicine to relieve digestive discomfort
Traditionally used in Western herbal medicine to decrease/reduce/relieve digestive spasms
Traditionally used in Western herbal medicine to antispasmodic/spasmolytic
Antispasmodic/spasmolytic
Maintain/support muscle relaxation
Traditionally used in Ayurvedic medicine to calms the mind
Help maintain/support emotional wellbeing
Traditionally used in Pacific Islander medicine to aid/assist/helps mind relaxation
Aid/assist/helps mind relaxation
Decrease/reduce/relieve restlessness/excess nervous energy
Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy
Traditionally used in Ayurvedic medicine to soothe/calm nerves
Decrease/reduce/relieve symptoms of stress
Decrease/reduce/relieve nervous tension/unrest
Decrease/reduce/relieve symptoms of mild anxiety
Traditionally used in Ayurvedic medicine to nerve tonic
Traditionally used in Pacific Islander medicine to calmative/nervous system relaxant
Traditionally used in Ayurvedic medicine to calmative/nervous system relaxant
Traditionally used in Ayurvedic medicine to nervine/support nervous system
Traditionally used in Ayurvedic medicine to soporific/induces sleep



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Traditionally used in Pacific Islander medicine to soporific/induces sleep
Maintains/supports refreshing sleep
Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
Decrease/reduce/relieve sleeplessness
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve sleeplessness
Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep
Decrease/reduce/relieve disturbed/restless sleep

Indication Requirements

Product presentation must not imply or refer to chronic fatigue syndrome.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.
Product presentation must not imply or refer to gastro oesophageal reflux disease.
Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
Product presentation must only refer to mild anxiety.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist, seek the advice of a healthcare professional.
Not for prolonged use. If symptoms persist, seek advice from a health care practitioner. Not recommended for use by pregnant or lactating women (or words to that effect). May harm the liver.
For practitioner dispensing only.
Do not use if pregnant or likely to become pregnant (or words to that effect)

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

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

Lavandula angustifolia flower Extract dry concentrate	100 mg
Equivalent: Lavandula angustifolia (Dry)	400 mg
Piper methysticum root and rhizome Extract dry concentrate standardised	400 mg
Equivalent: Piper methysticum (Dry)	2.8 g
Withania somnifera root Extract dry concentrate standardised	100 mg
Equivalent: Withania somnifera (Dry)	1 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
croscarmellose sodium

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hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
sodium starch glycollate

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