



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	209754	BLOOMS VALERIAN FORTE
ARTG entry for	Medicine Listed	
Sponsor	Phytologic Holdings Pty Ltd	
Postal Address	PO Box 6193, Alexandria, NSW, 2015 Australia	
ARTG Start Date	21/05/2013	
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 . BLOOMS VALERIAN FORTE

Product Type	Single Medicine Product	Effective Date	8/02/2021
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Permitted Indications

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia

Traditionally used in Western herbal medicine to antispasmodic/spasmodic

Decrease/reduce/relieve symptoms of stress

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress

Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest

Decrease/reduce/relieve symptoms of mild anxiety

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety

Traditionally used in Western herbal medicine to calmative/nervous system relaxant

Traditionally used in Western herbal medicine to nervine/support nervous system

Traditionally used in Western herbal medicine to soporific/induces sleep

Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness

Decrease/reduce/relieve sleeplessness

Decrease/reduce time to fall asleep

Traditionally used in Western herbal medicine to decrease/reduce time to fall asleep

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/promote/increase healthy sleep patterns

Enhance/promote/increase healthy sleep patterns

Maintain/support healthy sleeping patterns

Traditionally used in Western herbal medicine to maintain/support healthy sleeping patterns

Enhance/improve/promote/increase sleep quality/deep sleep

Traditionally used in Western herbal medicine to enhance/improve/promote/increase sleep quality/deep sleep

Decrease/reduce/relieve menstrual spasms/cramps

Indication Requirements

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

Product presentation must only refer to mild anxiety.



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

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.

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
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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Valeriana officinalis root Extract dry concentrate standardised	400 mg
Equivalent: Valeriana officinalis (Dry)	2.4 g

Other Ingredients (Excipients)

colloidal anhydrous silica

hypromellose

magnesium stearate

maltodextrin

microcrystalline cellulose

purified water

silicon dioxide

sorbitol

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