



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	375934	Somni Support
ARTG entry for	Medicine Listed	
Sponsor	Factors Group Australia Pty Ltd	
Postal Address	Unit B 10-16 South Street, Rydalmere, NSW, 2116 Australia	
ARTG Start Date	7/10/2021	
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 . Somni Support

Product Type	Single Medicine Product	Effective Date	3/11/2021 9:36:52 AM
---------------------	-------------------------	-----------------------	----------------------

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Maintain/support general health and wellbeing
Decrease/reduce/relieve restlessness/excess nervous energy
Decrease/reduce/relieve nervous tension/unrest
Decrease/reduce/relieve symptoms of mild anxiety
Traditionally used in Western herbal medicine to calmative/nervous system relaxant
Enhance/promote/increase refreshing sleep
Decrease/reduce/relieve sleeplessness
Decrease/reduce time to fall asleep
Decrease/reduce/relieve disturbed/restless 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

Warnings

If symptoms persist, seek the advice of a healthcare professional.
Keep out of reach of children (or words to that effect).
If symptoms persist consult your healthcare practitioner (or words to that effect).
Do not use while breastfeeding.
Do not use if pregnant or likely to become pregnant (or words to that effect)

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

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 Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Humulus lupulus flower Extract dry concentrate 125 mg

Equivalent: Humulus lupulus (Dry) 500 mg

Medicago sativa leaf Extract dry concentrate 80 mg

Equivalent: Medicago sativa (Dry) 7.2 g

Oryza sativa seed Powder 5 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

Chlorella pyrenoidosa

colloidal anhydrous silica

croscarmellose sodium

disodium edetate

gellan gum

hypromellose

magnesium stearate

microcrystalline cellulose

potable water

potassium acetate

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary