Public Summary

Summary for ARTG Entry:	321970 SomniSupport
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	19/08/2019
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 . SomniSupport

Product Type Single Medicine Product **Effective Date** 17/06/2021

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 if pregnant or likely to become pregnant (or words to that effect)

Do not use while breastfeeding.

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	**85 mg**
Equivalent: Medicago sativa (Dry)	7.65 g
Oryza sativa flower Extract dry concentrate	**5 mg**
Equivalent: Oryza sativa (Fresh)	450 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