



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

## Public Summary

<b>Summary for ARTG Entry:</b>	321970	SomniSupport
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Factors Group Australia Pty Ltd	
<b>Postal Address</b>	Unit B 10-16 South Street, Rydalmere, NSW, 2116 Australia	
<b>ARTG Start Date</b>	19/08/2019	
<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 . SomniSupport

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	17/06/2021
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#### 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

Label statement: If symptoms persist, talk to your health professional.  
Product presentation must only refer to mild anxiety.  
Product presentation must not imply or refer to mental illnesses, disorders or 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).  
Do not use if pregnant or likely to become pregnant (or words to that effect)  
If symptoms persist, seek the advice of a healthcare professional.  
Keep out of reach of children (or words to that effect).  
Do not use while breastfeeding.



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**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
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**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Capsule, hard
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>Humulus lupulus flower Extract dry concentrate</b>	<b>125 mg</b>
Equivalent: Humulus lupulus (Dry)	500 mg
<b>Medicago sativa leaf Extract dry concentrate</b>	<b>85 mg</b>
Equivalent: Medicago sativa (Dry)	7.65 g
<b>Oryza sativa flower Extract dry concentrate</b>	<b>5 mg</b>
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

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