



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

## Public Summary

<b>Summary for ARTG Entry:</b>	200382	Sleep Ease
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Herbs of Gold Pty Ltd	
<b>Postal Address</b>	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
<b>ARTG Start Date</b>	27/08/2012	
<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 . Sleep Ease

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	6/04/2021
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### Permitted Indications

- Traditionally used in Western herbal medicine to analgesic/Anodyne/relieve pain
- Traditionally used in Western herbal medicine to antispasmodic/spasmodic
- Traditionally used in Chinese medicine to calms the mind
- Traditionally used in Western herbal medicine to calms the mind
- Traditionally used in Chinese medicine to calm/soothe/nourish/balance spirit
- Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy
- Traditionally used in Chinese medicine to 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 soporific/induces sleep
- Traditionally used in Chinese medicine to enhance/promote/increase refreshing sleep
- Traditionally used in Western herbal medicine to enhance/promote/increase refreshing sleep
- Traditionally used in Western herbal medicine to maintains/supports refreshing sleep
- Traditionally used in Chinese medicine to maintains/supports refreshing sleep
- Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Chinese medicine to decrease/reduce/relieve disturbed/restless sleep
- Traditionally used in Chinese medicine to enhance/improve/promote/increase sleep quality/deep sleep
- Traditionally used in Western herbal medicine to enhance/improve/promote/increase sleep quality/deep sleep

### Indication Requirements

Product presentation must only refer to mild anxiety.

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

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

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.



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**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

No Warnings included on Record

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Eschscholzia californica herb Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Eschscholzia californica (Dry)	400 mg
<b>Magnolia officinalis stem bark inner Extract dry concentrate</b>	<b>125 mg</b>
Equivalent: Magnolia officinalis (Dry)	1 g
<b>Passiflora incarnata herb flowering and fruiting Extract dry concentrate</b>	<b>150 mg</b>
Equivalent: Passiflora incarnata (Dry)	750 mg
<b>Ziziphus jujuba var. spinosa seed Extract dry concentrate</b>	<b>300 mg</b>
Equivalent: Ziziphus jujuba var. spinosa (Dry)	3 g

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
colloidal anhydrous silica  
hypromellose  
magnesium stearate  
purified water

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