



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

## Public Summary

<b>Summary for ARTG Entry:</b>	323152	Mind 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>	13/09/2019	
<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 . Mind Ease

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	8/02/2021
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### Permitted Indications

- Traditionally used in Ayurvedic medicine to medhya/brain tonic/improve memory and cognition
- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Aids/assists with recovery from illness/convalescence
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility
- Maintain/support energy production
- Traditionally used in Ayurvedic medicine to helps enhance/promote/increase vitality
- Traditionally used in Ayurvedic medicine to maintain/support vitality
- Traditionally used in Ayurvedic medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress
- Traditionally used in Ayurvedic medicine to support healthy stress response in the body
- Support healthy stress response in the body
- Decrease/reduce/relieve symptoms of mild anxiety
- Maintain/support memory/mental recall
- Maintain/support nervous system health
- Traditionally used in Ayurvedic medicine to nervine/support nervous system
- Maintain/support nervous system function
- Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
- Maintain/support healthy sleeping patterns
- Traditionally used in Ayurvedic medicine to enhance/improve/promote/increase sleep quality/deep sleep

### Indication Requirements

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Product presentation must not imply or refer to chronic fatigue syndrome.

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

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

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

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right for you.

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**

No Warnings included on Record

**Additional Product information**

**Pack Size/Poison information**

Pack Size	Poison Schedule
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**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>Lavandula angustifolia flower Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Lavandula angustifolia (Dry)	400 mg
<b>Withania somnifera root Extract dry concentrate standardised</b>	<b>300 mg</b>
Equivalent: Withania somnifera (Dry)	3.75 g

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
Carnauba Wax  
colloidal anhydrous silica  
croscarmellose sodium  
crospovidone  
hypromellose  
macrogol 400  
magnesium stearate  
maltodextrin  
microcrystalline cellulose  
povidone

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