



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

## Public Summary

<b>Summary for ARTG Entry:</b>	372560	Profound Sleep
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Ora Health Pty Ltd	
<b>Postal Address</b>	24/10-18 Orchard Road, Brookvale, NSW, 2100 Australia	
<b>ARTG Start Date</b>	10/08/2021	
<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 . Profound Sleep

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	10/08/2021
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### Permitted Indications

Traditionally used in Chinese medicine to decrease/reduce/relieve excessive perspiration/sweating  
Traditionally used in Chinese medicine to decrease/reduce/relieve spontaneous sweating  
Maintain/support general health and wellbeing  
Traditionally used in Western herbal medicine to maintain/support general health and wellbeing  
Traditionally used in Chinese medicine to maintain/support general health and wellbeing  
Maintain/support healthy teeth  
Maintain/support bone health  
Help maintain/support bone mineralisation  
Maintain/support heart health  
Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative  
Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention  
Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal cramping  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia  
Traditionally used in Western herbal medicine to relieve digestive discomfort  
Maintain/support muscle health  
Maintain/support muscle function  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Traditionally used in Chinese medicine to relieve irritability  
Traditionally used in Chinese medicine to help maintain/support emotional wellbeing  
Traditionally used in Western herbal medicine to help maintain/support emotional wellbeing  
Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress  
Traditionally used in Chinese medicine to decrease/reduce/relieve nervous tension/unrest  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety  
Traditionally used in Western herbal medicine to maintain/support general mental wellbeing  
Maintain/support neuromuscular function  
Traditionally used in Chinese medicine to maintain/support nervous system health



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Maintain/support nervous system health

Traditionally used in Western herbal medicine to calmative/nervous system relaxant

Traditionally used in Western herbal medicine to nerve/support nervous system

Traditionally used in Chinese medicine to maintain/support nervous system function

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 Western herbal medicine to maintain/support healthy sleeping patterns

Traditionally used in Chinese medicine to maintain/support healthy sleeping patterns

Traditionally used in Chinese medicine to maintain/support lung health

Traditionally used in Chinese medicine to maintain/support urinary tract health

Traditionally used in Chinese medicine to maintain/support urinary tract function

Traditionally used in Chinese medicine to maintain/support urogenital health

Traditionally used in Chinese medicine to maintain/support kidney function

Traditionally used in Chinese medicine to maintain/support kidney health

#### Indication Requirements

Product presentation must not imply or refer to kidney disease.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.  
Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

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

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

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must only refer to mild anxiety.

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Product presentation must not imply or refer to serious cardiovascular 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).

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

#### Additional Product information

#### Pack Size/Poison information

Pack Size

Poison Schedule

#### Components

##### 1. Formulation 1

**Dosage Form** Powder, oral

**Route of Administration** Oral

#### Visual Identification

#### Active Ingredients

<b>magnesium glycinate dihydrate</b>	<b>398.72 mg/g</b>
Equivalent: magnesium	45.45 mg/g
<b>Matricaria chamomilla flower Extract dry concentrate</b>	<b>34.09 mg/g</b>
Equivalent: Matricaria chamomilla (Dry)	272.72 mg/g
<b>Melissa officinalis leaf Extract dry concentrate</b>	<b>68.18 mg/g</b>
Equivalent: Melissa officinalis (Dry)	272.72 mg/g



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<b>Passiflora incarnata herb top flowering Extract dry concentrate</b>	<b>18.18 mg/g</b>
Equivalent: Passiflora incarnata (Dry)	363.6 mg/g
<b>Schisandra chinensis fruit Extract dry concentrate</b>	<b>14.55 mg/g</b>
Equivalent: Schisandra chinensis (Dry)	363.75 mg/g
<b>Ziziphus jujuba seed Extract dry concentrate</b>	<b>60.61 mg/g</b>
Equivalent: Ziziphus jujuba (Dry)	1.8183 g/g

**Other Ingredients (Excipients)**

citric acid  
colloidal anhydrous silica  
Flavour  
Gardenia jasminoides  
glycine  
maltodextrin  
thaumatin

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