



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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

Product Type	Single Medicine Product	Effective Date	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
- Traditionally used in Chinese medicine to maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- 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 Western herbal medicine to help maintain/support emotional wellbeing
- Traditionally used in Chinese 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 nervine/support nervous system
 Traditionally used in Chinese medicine to maintain/support nervous system function
 Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness
 Traditionally used in Western herbal 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 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.

Product presentation must not imply or refer to kidney disease.

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 cardiovascular conditions.

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

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
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Components

1 . Formulation 1

Dosage Form	Powder, oral
Route of Administration	Oral

Visual Identification

Active Ingredients

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

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