



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	372559	Mag3 Mood
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 . Mag3 Mood

Product Type	Single Medicine Product	Effective Date	10/08/2021
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Permitted Indications

- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence
- Traditionally used in Ayurvedic medicine to relieve weariness/tiredness/fatigue/feeling of weakness in healthy elderly individuals
- Traditionally used in Ayurvedic medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Maintain/support general health and wellbeing
- Traditionally used in Ayurvedic 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 Ayurvedic medicine to adaptogen/Help body adapt to stress
- Traditionally used in Western herbal medicine to help maintain/support emotional wellbeing
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of stress
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
- Traditionally used in Ayurvedic medicine to maintain/support cognitive function/mental function
- Traditionally used in Ayurvedic medicine to maintain/support memory/mental recall
- Traditionally used in Ayurvedic medicine to maintain/support general mental wellbeing
- Traditionally used in Western herbal medicine to maintain/support general mental wellbeing

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Maintain/support neuromuscular function
 Maintain/support nervous system health
 Traditionally used in Ayurvedic medicine to 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 Ayurvedic medicine to maintain/support nervous system function
 Traditionally used in Ayurvedic medicine to support healthy emotional/mood balance
 Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
 Traditionally used in Western herbal medicine to maintain/support healthy sleeping patterns

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
 Product presentation must not imply or refer to chronic fatigue syndrome.
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to serious cardiovascular conditions.
 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: [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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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.
 If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Powder
Route of Administration	Oral

Visual Identification

Active Ingredients

Cordyceps sinensis fruiting body Extract dry concentrate	100 mg/g
Equivalent: Cordyceps sinensis (Dry)	400 mg/g
magnesium amino acid chelate	100 mg/g
Equivalent: magnesium	10 mg/g
magnesium citrate	290.32 mg/g
Equivalent: magnesium	45 mg/g
magnesium glycerophosphate	66.67 mg/g
Equivalent: magnesium	7 mg/g
Melissa officinalis leaf Extract dry concentrate	75 mg/g
Equivalent: Melissa officinalis (Dry)	300 mg/g
Withania somnifera root Extract dry concentrate	48 mg/g
Equivalent: Withania somnifera (Dry)	600 mg/g



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Other Ingredients (Excipients)

citric acid

colloidal anhydrous silica

Flavour

Gardenia jasminoides

glycine

maltodextrin

riboflavin

thaumatin

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