



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

## Public Summary

<b>Summary for ARTG Entry:</b>	372559	Mag3 Mood
<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 . Mag3 Mood

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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 Ayurvedic 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 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  
Traditionally used in Ayurvedic medicine to maintain/support nervous system health  
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 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

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

#### 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

**Route of Administration** Oral

##### Visual Identification

##### Active Ingredients

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