



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	387756	Immune Tonic+ Advanced
<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>	2/05/2022	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

**Conditions**

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 . Immune Tonic+ Advanced**

Product Type	Single Medicine Product	Effective Date	2/05/2022
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Traditionally used in Chinese medicine to engender Fluid
- Traditionally used in Chinese medicine to tonify/hourish/strengthen/replenish Qi
- Traditionally used in Chinese medicine to warm and nourish/strengthen/tonify/enrich kidneys/kidney-yang
- Traditionally used in Western herbal medicine to aids/assists with recovery from illness/convalescence
- Traditionally used in Chinese medicine to relieve feelings of general malaise/general debility
- Traditionally used in Western herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Chinese medicine to decrease/reduce/relieve spontaneous sweating
- Traditionally used in Western herbal medicine to restorative tonic
- Maintain/support general health and wellbeing
- 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 healthy teeth
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
- Maintain/support healthy blood circulation
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support immune system health
- Traditionally used in Western herbal medicine to maintain/support immune system health
- Traditionally used in Western herbal medicine to maintain/support healthy immune system function
- Maintain/support healthy immune system function
- Traditionally used in Western herbal medicine to maintain/support immune system to fight illness
- Maintain/support muscle health
- Maintain/support muscle function
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Maintain/support (state vitamin/mineral/nutrient) levels in the body

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- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress
- Traditionally used in Chinese medicine to help maintain/support emotional wellbeing
- Traditionally used in Western herbal medicine to maintain/support mental concentration/focus/clarity
- Traditionally used in Western herbal medicine to maintain/support cognitive function/mental function
- Traditionally used in Chinese medicine to maintain/support nervous system health
- Traditionally used in Western herbal medicine to maintain/support nervous system health
- Traditionally used in Chinese medicine to maintain/support nervous system function
- Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Chinese medicine to maintain/support healthy sleeping patterns
- Traditionally used in Chinese medicine to decrease/reduce/relieve cough
- 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 chronic fatigue syndrome.
- 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 mental illnesses, disorders or conditions.
- 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 kidney disease.
- Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
- Product presentation must not imply or refer to serious immunological diseases.
- If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- If product is indicated for supplementation, 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).
- 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).
- Label statement: If symptoms persist, talk to your health professional.
- Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.

**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).
- Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).
- WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (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

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**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Astragalus membranaceus root Extract dry concentrate</b>	<b>225 mg</b>
Equivalent: Astragalus membranaceus (Dry)	2.25 g
<b>colecalfiferol</b>	<b>.0125 mg</b>
<b>Eleutherococcus senticosus root Extract dry concentrate</b>	<b>33.33 mg</b>
Equivalent: Eleutherococcus senticosus (Dry)	1.5 g
<b>Ganoderma lucidum fruiting body Extract dry concentrate</b>	<b>37.5 mg</b>
Equivalent: Ganoderma lucidum (Dry)	750 mg
<b>quercetin dihydrate</b>	<b>250 mg</b>
<b>Schisandra chinensis fruit Extract dry concentrate</b>	<b>60 mg</b>
Equivalent: Schisandra chinensis (Dry)	1.5 g
<b>zinc citrate dihydrate</b>	<b>62.31 mg</b>
Equivalent: zinc	20 mg

**Other Ingredients (Excipients)**

Acacia  
colloidal anhydrous silica  
d-alpha-tocopherol  
hypromellose  
leucine  
maize starch  
maltodextrin  
medium chain triglycerides  
microcrystalline cellulose  
povidone  
silicified microcrystalline cellulose  
silicon dioxide  
sodium ascorbate

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