



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	387756	Immune Tonic+ Advanced
ARTG entry for	Medicine Listed	
Sponsor	Ora Health Pty Ltd	
Postal Address	24/10-18 Orchard Road, Brookvale, NSW, 2100 Australia	
ARTG Start Date	2/05/2022	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

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/nourish/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
Traditionally used in Chinese medicine to maintain/support general health and wellbeing
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
Traditionally used in Western herbal medicine to maintain/support immune system health
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
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

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

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.

Product presentation must not imply or refer to serious immunological diseases.

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.

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 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).

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.

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

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).

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

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	Capsule, hard
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Route of Administration	Oral
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Visual Identification

Active Ingredients

Astragalus membranaceus root Extract dry concentrate	225 mg
Equivalent: Astragalus membranaceus (Dry)	2.25 g
colecalfiferol	.0125 mg
Eleutherococcus senticosus root Extract dry concentrate	33.33 mg



Australian Government
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Equivalent: Eleutherococcus senticosus (Dry)	1.5 g
Ganoderma lucidum fruiting body Extract dry concentrate	37.5 mg
Equivalent: Ganoderma lucidum (Dry)	750 mg
quercetin dihydrate	250 mg
Schisandra chinensis fruit Extract dry concentrate	60 mg
Equivalent: Schisandra chinensis (Dry)	1.5 g
zinc citrate dihydrate	62.31 mg
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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Public Summary