



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	379152	Testosterone & Immunity Formula
ARTG entry for	Medicine Listed	
Sponsor	Old Bull Health Pty Ltd	
Postal Address	PO Box 234, Manly, NSW, 2095 Australia	
ARTG Start Date	26/11/2021	
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 . Testosterone & Immunity Formula

Product Type	Single Medicine Product	Effective Date	27/03/2023
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support collagen formation
- Traditionally used in Chinese medicine to dispel/expel/disperse/clear external/exogenous coldness
- Traditionally used in Chinese medicine to warm and nourish/strengthen stomach
- Maintain/support energy levels
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence
- Maintain/support energy production
- Maintain/support body electrolyte balance
- Maintain/support general health and wellbeing
- Traditionally used in Ayurvedic medicine to 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 connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support bone health
- Maintain/support bone strength
- Help maintain/support bone mineralisation
- Maintain/support blood health
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support heart health
- Maintain/support blood capillary health
- Maintain/support blood vessel health
- Maintain/support healthy thyroid gland function
- Maintain/support healthy thyroid hormones
- Aid/assist thyroid hormone production
- Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite

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Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)
Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
Traditionally used in Western herbal medicine to sialagogue/promote saliva production
Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal spasm
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
Traditionally used in Western herbal medicine to relieve digestive discomfort
Traditionally used in Western herbal medicine to digestive tonic/Improve digestive weakness
Helps maintain/support bile secretion/flow
Maintain/support liver health
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support muscle function
Maintain/support healthy neuromuscular system/function
Aid/assist/helps protein synthesis in the body
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate in elderly individuals
Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when sun exposure is inadequate
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when sun exposure is inadequate
Traditionally used in Ayurvedic medicine to maintain/support memory/mental recall
Maintain/support nerve conduction
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support testosterone level
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold
Maintain/support skin health
Maintain/support wound healing

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

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 circulatory disorders/diseases/conditions e.g. thrombosis.

Product presentation must not imply or refer to disease in any body organ.

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.

Product presentation must not imply or refer to any thyroid related diseases.

Product presentation must not imply or refer to serious musculoskeletal or neurological 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).

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 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).

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 chronic fatigue syndrome.

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Product presentation must not imply or refer to eating disorders.

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).



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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

Allium sativum bulb Extract dry concentrate	4 mg/g
Equivalent: Allium sativum (Dry)	200 mg/g
ascorbic acid	40 mg/g
colecalfiferol	.005 mg/g
Curcuma longa rhizome Extract dry concentrate	20 mg/g
Equivalent: Curcuma longa (Dry)	400 mg/g
magnesium citrate	258.9 mg/g
Equivalent: magnesium	40 mg/g
menaquinone 7	.018 mg/g
selenomethionine	.0397 mg/g
Equivalent: selenium	.016 mg/g
Withania somnifera root Extract dry concentrate	64 mg/g
Equivalent: Withania somnifera (Dry)	800 mg/g
zinc citrate dihydrate	15.58 mg/g
Equivalent: zinc	5 mg/g
Zingiber officinale rhizome Extract dry concentrate	36.36 mg/g
Equivalent: Zingiber officinale (Dry)	400 mg/g

Other Ingredients (Excipients)

Acacia

Candelilla Wax

colloidal anhydrous silica

dl-alpha-tocopherol

Flavour

glycine

maize starch

maltodextrin

medium chain triglycerides

silicon dioxide

Stevia rebaudiana

sucrose

thaumatin

yellow beeswax

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