



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	388744	NUTRA-LIFE PROSTATE COMPLETE
ARTG entry for	Medicine Listed	
Sponsor	Vitaco Health Australia Pty Ltd	
Postal Address	PO Box 399, NORTH RYDE BC, NSW, 1670 Australia	
ARTG Start Date	20/05/2022	
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 . NUTRA-LIFE PROSTATE COMPLETE

Product Type	Single Medicine Product	Effective Date	20/05/2022
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support healthy eye function
Maintain/support eye health
Maintain/support healthy eyesight/vision
Traditionally used in Western herbal medicine to nutritive tonic
Maintain/support general health and wellbeing
Maintain/support hair health
Maintain/support bone health
Maintain/support healthy thyroid gland function in healthy adults
Maintain/support healthy thyroid hormones in healthy adults
Aid/assist thyroid hormone production in healthy adults
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support muscle function
Aid/assist/helps protein synthesis in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Maintain/support cognitive function/mental function in healthy adults
Maintain/support nerve conduction
Maintain/support nervous system function
Maintain/support reproductive system health in males
Maintain/support healthy reproductive hormones
Traditionally used in Western herbal medicine to help maintain/support healthy prostate function
Traditionally used in Western herbal medicine to maintain/support prostate health
Maintain/support sperm health in healthy males
Maintain/support sperm motility in healthy males

Public Summary



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Maintain/support sperm production in healthy males
Maintain/support testosterone level
Maintain/support skin health
Maintain/support skin integrity/structure
Maintain/support skin regeneration
Maintain/support wound healing
Traditionally used in Western herbal medicine to maintain/support urogenital health
Traditionally used in Western herbal medicine to enhance/promote/increase urine output in males
Traditionally used in Western herbal medicine to maintain/support healthy urine output in males

Indication Requirements

Product presentation must not imply or refer to any thyroid related diseases.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Product presentation must not imply or refer to serious genitourinary conditions like Benign Prostatic Hypertrophy, erectile dysfunction or hormone therapy.
Product presentation must not imply or refer to infertility.
Product presentation must not imply or refer to serious immunological diseases.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to hormone imbalances.
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 kidney 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).

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).
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
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Components

1 . Formulation 1

Dosage Form	Capsule, soft
Route of Administration	Oral

Visual Identification

Active Ingredients

colecalfiferol	5 microgram
selenomethionine	10 mg
Equivalent: selenium	50 microgram
Serenoa repens fruit Extract liquid concentrate standardised	500 mg
Equivalent: Serenoa repens (Fresh)	5 g
zinc sulfate monohydrate	41.2 mg
Equivalent: zinc	15 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate

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Coconut Oil
dl-alpha-tocopherol
Gelatin
glycerol
iron oxide red
lecithin
purified water
Soya Oil
vegetable oil
yellow beeswax

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