



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|------------------------------|
| Summary for ARTG Entry: | 308311 | 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 | 17/08/2018 | |
| 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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 | 27/03/2020 |
|---------------------|-------------------------|-----------------------|------------|

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

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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
 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 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: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to infertility.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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

Product presentation must not imply or refer to serious genitourinary conditions like Benign Prostatic Hypertrophy, erectile dysfunction or hormone therapy.
 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 immunological diseases.

Product presentation must not imply or refer to hormone imbalances.

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 |
|------------------|------------------------|

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 |



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Equivalent: zinc

15 mg

Other Ingredients (Excipients)

calcium carbonate

Coconut Oil

dl-alpha-tocopherol

Gelatin

glycerol

iron oxide red

lecithin

purified water

Soya Oil

vegetable oil

yellow beeswax

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