



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	287538	Thompson's Prostate Support
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	4/04/2017 11:00:00 PM	
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. Thompson's Prostate Support

Product Type	Single Medicine Product	Effective Date	21/07/2021
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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 general health and wellbeing
Maintain/support healthy immune system function
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Maintain/support (state vitamin/mineral) within normal range
Maintain/support reproductive system health
Help maintain/support healthy prostate function
Maintain/support prostate health
Maintain/support sperm health
Maintain/support sperm motility
Maintain/support sperm production
Maintain/support urogenital health in males
Maintain/support urogenital health In older males
Enhance/promote/increase urine output in males
Enhance/promote/increase urine output In older males

Indication Requirements

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

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 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



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Specific Indications

No Specific Indications included on Record

Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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	.025 mg
conifer phytosterol complex	185.71 mg
Equivalent: sitosterol	130 mg
lycopene	15 mg
selenomethionine	372.6 microgram
Equivalent: selenium	150 microgram
Urtica dioica root Extract dry concentrate	18.75 mg
Equivalent: Urtica dioica (Dry)	300 mg
zinc gluconate	114.85 mg
Equivalent: zinc	15 mg

Other Ingredients (Excipients)

chlorophyllin-copper complex
dl-alpha-tocopherol
Gelatin
glycerol
hydrogenated vegetable oil
lecithin
Maize Oil
powdered cellulose
purified water
Soya Oil
titanium dioxide
vegetable oil
yellow beeswax

Public Summary

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