



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	227291	BLACKMORES PROSTATE HEALTH FORMULA
ARTG entry for	Medicine Listed	
Sponsor	Blackmores Ltd	
Postal Address	PO Box 1725, WARRIEWOOD, NSW, 2102 Australia	
ARTG Start Date	27/08/2014	
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. BLACKMORES PROSTATE HEALTH FORMULA

Product Type	Single Medicine Product	Effective Date	16/07/2020
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Helps maintain/support testosterone formation/synthesis
Help maintain/support healthy prostate function in males
Maintain/support prostate health in males
Maintain/support testosterone level
Traditionally used in Western herbal medicine to enhance/promote/increase urine output In older males

Indication Requirements

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

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



Australian Government
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Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

d-alpha-tocopherol	50.3 mg
Equivalent: d-alpha-tocopherol	75 IU
Lycopersicon esculentum	41.7 mg
selenomethionine	125 microgram
Equivalent: selenium	50 microgram
Serenoa repens fruit Extract liquid concentrate standardised	160 mg
Equivalent: Serenoa repens (Dry)	1.6 g
Urtica dioica root Extract dry concentrate standardised	150 mg
Equivalent: Urtica dioica (Dry)	1.13 g
zinc sulfate monohydrate	20.8 mg
Equivalent: zinc	7.5 mg

Other Ingredients (Excipients)

colloidal anhydrous silica
Gelatin
glycerol
hydrogenated vegetable oil
iron oxide black
iron oxide red
lecithin
maltodextrin
purified water
Soya Oil
yellow beeswax

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