



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	329307	ProstaCare
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	31/01/2020	
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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . ProstaCare

Product Type	Single Medicine Product	Effective Date	31/01/2020
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Anti-inflammatory/relieve inflammation
Traditionally used in Western herbal medicine to maintain/support reproductive system health in males
Traditionally used in Western herbal medicine to male tonic
Helps maintain/support testosterone formation/synthesis in males
Help maintain/support healthy prostate function
Maintain/support prostate health
Maintain/support sperm health
Maintain/support urinary tract health
Aid/assist flushing of the urinary tract
Maintain/support healthy urine output

Indication Requirements

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.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to kidney disease.

Standard Indications

No Standard Indications included on Record



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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 Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

conifer phytosterol complex	46.43 mg
Equivalent: sitosterol	32.5 mg
Crateva magna stem bark Extract dry concentrate	137.5 mg
Equivalent: Crateva magna (Dry)	1.375 g
Cucurbita pepo seed Extract dry concentrate	125 mg
Equivalent: Cucurbita pepo (Dry)	2.5 g
lycopene	2.5 mg
Prunus africana stem bark Extract dry concentrate	44.44 mg
Equivalent: Prunus africana (Dry)	3 g
selenomethionine	46.57 microgram
Equivalent: selenium	18.75 microgram
Serenoa repens fruit Extract dry concentrate	320 mg
Equivalent: Serenoa repens (Dry)	1.28 g
zinc amino acid chelate	31.25 mg
Equivalent: zinc	6.25 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
calcium phosphate
Carnauba Wax
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
dl-alpha-tocopheryl acetate
hypromellose
liquid glucose
macrogol 8000
magnesium stearate
maize starch
maltodextrin
microcrystalline cellulose
sodium ascorbate
soluble maize starch

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