



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	316653	MediHerb ProstaCo
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	16/04/2019	
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 . MediHerb ProstaCo

Product Type	Single Medicine Product	Effective Date	5/03/2021
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Permitted Indications

- Traditionally used in Western herbal medicine to help maintain/support healthy prostate function In older males
- Traditionally used in Western herbal medicine to help maintain/support healthy prostate function
- Traditionally used in Western herbal medicine to help maintain/support healthy prostate function in males
- Traditionally used in Western herbal medicine to maintain/support prostate health In older males
- Traditionally used in Western herbal medicine to maintain/support prostate health
- Traditionally used in Western herbal medicine to maintain/support prostate health in males
- Traditionally used in Western herbal medicine to maintain/support healthy bladder function
- Traditionally used in Western herbal medicine to maintain/support healthy bladder function In older males
- Traditionally used in Western herbal medicine to maintain/support healthy bladder function in males
- Traditionally used in Western herbal medicine to maintain/support bladder health
- Traditionally used in Western herbal medicine to maintain/support bladder health in males
- Traditionally used in Western herbal medicine to maintain/support bladder health In older males
- Traditionally used in Western herbal medicine to maintain/support urinary tract health
- Traditionally used in Western herbal medicine to maintain/support urinary tract health In older males
- Traditionally used in Western herbal medicine to maintain/support urinary tract health in males
- Traditionally used in Western herbal medicine to maintain/support urinary tract function in males
- Traditionally used in Western herbal medicine to maintain/support urinary tract function
- Traditionally used in Western herbal medicine to maintain/support urinary tract function In older males

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 kidney disease.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record



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Warnings

For practitioner dispensing only.
If symptoms persist, seek the advice of a healthcare professional.

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

Crateva magna stem bark Extract dry concentrate	90 mg
Equivalent: Crateva magna (Dry)	900 mg
Serenoa repens fruit Extract soft concentrate	107 mg
Equivalent: Serenoa repens (Dry)	1.07 g
Urtica dioica root Extract dry concentrate	104 mg
Equivalent: Urtica dioica (Dry)	666 mg

Other Ingredients (Excipients)

caramel
Gelatin
glycerol
lecithin
maltodextrin
Olive Oil
Pumpkin seed oil
silicon dioxide
yellow beeswax

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