



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	316653	MediHerb ProstaCo
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd	
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
<b>ARTG Start Date</b>	16/04/2019	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	5/03/2021
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### Permitted Indications

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 older males  
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 males  
Traditionally used in Western herbal medicine to maintain/support prostate health  
Traditionally used in Western herbal medicine to maintain/support prostate health In older males  
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  
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 In older males  
Traditionally used in Western herbal medicine to maintain/support bladder health in males  
Traditionally used in Western herbal medicine to maintain/support bladder health  
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 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 function In older 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 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

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