



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

## Public Summary

<b>Summary for ARTG Entry:</b>	231502	Prostate Pro
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Herbs of Gold Pty Ltd	
<b>Postal Address</b>	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
<b>ARTG Start Date</b>	5/12/2014	
<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.

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 . Prostate Pro

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	15/04/2020
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#### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Maintain/support general health and wellbeing  
Help maintain/support healthy prostate function  
Maintain/support prostate health  
Maintain/support urinary tract health in males  
Maintain/support urinary tract function in males  
Relieve urinary frequency in males  
Maintain/support healthy urine output in males

#### Indication Requirements

Label statement: If symptoms persist, talk to your health professional.  
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

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral 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.  
If symptoms persist consult your healthcare practitioner (or words to that effect).

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**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**

<b>conifer phytosterol complex</b>	<b>130 mg</b>
Equivalent: sitosterol	91 mg
<b>lycopene</b>	<b>2 mg</b>
<b>selenomethionine</b>	<b>124 microgram</b>
Equivalent: selenium	50 microgram
<b>Vaccinium macrocarpon fruit Powder</b>	<b>250 mg</b>
<b>zinc amino acid chelate</b>	<b>50 mg</b>
Equivalent: zinc	10 mg

**Other Ingredients (Excipients)**

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

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