



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

## Public Summary

**Summary for ARTG Entry:** 166191 ETHICAL NUTRIENTS PROSTATE HEALTH

**ARTG entry for** Medicine Listed  
**Sponsor** Metagenics (Aust) Pty Ltd  
**Postal Address** PO Box 675, VIRGINIA BC, QLD, 4014  
Australia  
**ARTG Start Date** 20/10/2009  
**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. ETHICAL NUTRIENTS PROSTATE HEALTH

**Product Type** Single Medicine Product **Effective Date** 25/05/2020

#### Permitted Indications

Help maintain/support healthy prostate function  
Helps enhance/promote prostate health  
Maintain/support prostate health  
Maintain/support urinary tract health  
Maintain/support urinary tract function  
Relieve urinary frequency  
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.  
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

#### Specific Indications

No Specific Indications included on Record

#### Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

#### Additional Product information

#### Pack Size/Poison information



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Pack Size

Poison Schedule

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, soft

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

**Serenoa repens fruit Extract dry concentrate standardised** **320 mg**

Equivalent: Serenoa repens (Dry) 3.2 g

**Urtica dioica root and rhizome Extract dry concentrate** **240 mg**

Equivalent: Urtica dioica (Dry) 2.4 g

**Other Ingredients (Excipients)**

colloidal anhydrous silica

Gelatin

glycerol

iron oxide black

iron oxide red

lecithin

Soya Oil

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Public Summary