



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	194239	METAGENICS PALMETTO PLUS
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	1/02/2012	
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 . METAGENICS PALMETTO PLUS

Product Type	Single Medicine Product	Effective Date	25/05/2022
---------------------	-------------------------	-----------------------	------------

Permitted Indications

Maintain/support reproductive system health
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.
Product presentation must not imply or refer to kidney disease.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to infertility.

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

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
------------------	------------------------



Australian Government
Department of Health
Therapeutic Goods Administration

Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

Serenoa repens fruit Extract soft concentrate standardised	320 mg
Equivalent: Serenoa repens (Dry)	3.2 g
Trifolium pratense herb top flowering Extract dry concentrate standardised	300 mg
Equivalent: Trifolium pratense (Fresh)	24 g
Urtica dioica root Extract dry concentrate	240 mg
Equivalent: Urtica dioica (Dry)	2.4 g
zinc amino acid chelate	120 mg
Equivalent: zinc	24 mg

Other Ingredients (Excipients)

citric acid
colloidal anhydrous silica
Colour
Gelatin
glycerol
glycine
lecithin
purified water
Soya Oil
yellow beeswax

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary