

PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE; COMBINATION PRODUCT

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

BIOGEN PROSTATE PRO (VEGETARIAN CAPSULE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegetarian capsule contains:		*%NRV
<i>Curcuma longa</i> L. (Turmeric) [Rhizome, as 68,00 mg of a 25:1 extract standardised to 95 % curcuminoids]	1 700,00 mg	
<i>Serenoa repens</i> (W.Bartram) Small (Saw Palmetto) [Fruit, as 33,33 mg of a 10:1 extract]	333,30 mg	
<i>Cucurbita pepo</i> L. (Pumpkin) [Seed, as 10,50 mg of a 10:1 extract]	105,00 mg	
<i>Urtica dioica</i> L. (Stinging Nettle) [Root, as 10,00 mg of a 10:1 extract]	100,00 mg	
<i>Piper nigrum</i> L. (Black pepper) [Fruit, as 1,67 mg of a 50:1 extract standardised to min 95 % piperine]	83,50 mg	
Lycopene	2,17 mg	
Pyridoxine (Vitamin B6) as Pyridoxine hydrochloride	8,33 mg	490 %
Zinc (as Zinc gluconate)	3,33 mg	30 %
dl- α -tocopheryl acetate (Vitamin E)	3,33 IU (2,23 mg α -TE)	15 %
Selenium (as Selenium yeast 0,2 %)	16,67 μ g	30 %
Cholecalciferol (Vitamin D3)	66,69 IU (1,67 μ g)	15 %

*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010).

Contains sugar 0,43 mg (sucrose) per capsule.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Vegetarian Capsule.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BIOGEN PROSTATE PRO, supports prostate health and promotes healthy urinary function in men. May assist with the relief of symptoms associated with mild to moderate benign prostatic hyperplasia (BPH).

4.2 Posology and method of administration

Posology

Adults 18 years and older:

Take 1 (one) vegetarian capsule three times daily, or as recommended by a healthcare provider.

Do not exceed the recommended dose.

Not suitable for children.

Method of administration

For oral use. To be taken with food.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Special care should be taken with BIOGEN PROSTATE PRO. If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

- Consult a healthcare provider prior to use to exclude a diagnosis of prostate cancer.
- Consult a healthcare provider if symptoms persist or worsen whilst using BIOGEN PROSTATE PRO.
- Discontinue use at least two weeks prior to elective surgical procedures. Saw palmetto, stinging nettle and lycopene may potentially cause excessive bleeding during surgery due to possible antiplatelet effects.

4.5 Interactions with other medicines and other forms of interactions

- Saw palmetto, stinging nettle and lycopene may increase the risk of bleeding when used with other anticoagulant or antiplatelet medications.
- Saw palmetto may reduce the effectiveness of contraceptive medications.
- Saw palmetto may reduce the effectiveness of estrogens due to potential antiestrogenic effects.
- Stinging nettle may have additive effects with diabetes medications, as stinging nettle may decrease blood glucose levels in patients with diabetes.
- Stinging nettle may reduce excretion of lithium, thereby increasing levels of lithium. The dose of lithium may need to be adjusted.
- Stinging nettle may have a diuretic effect. Concomitant use with other diuretic medication may have additive effects.
- Stinging Nettle, Zinc, and Vitamin B6 may increase risk of kidney disorders. Use cautiously or avoid if you have kidney disease or dysfunction.
- Individuals with liver dysfunction should use caution due to the metabolism of multiple ingredients by the liver.
- Use cautiously in individuals with autoimmune diseases, as some selenium may stimulate the immune system.

4.6 Fertility, pregnancy, and lactation

Safety in fertility, pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

BIOGEN PROSTATE PRO is not likely to cause drowsiness. Patients should take caution before performing activities requiring their attention, until they are reasonably certain that BIOGEN PROSTATE PRO does not adversely affect their performance.

4.8 Undesirable effects

BIOGEN PROSTATE PRO is generally well tolerated but may cause gastrointestinal discomfort in some patients.

Gastrointestinal disorders: *Frequency:* nausea, vomiting, constipation, diarrhoea, gastralgia, halitosis. *Frequency unknown:* duodenal ulcer, dyspepsia, heartburn, meteorism, flatulence, abdominal distension, anorexia.

Respiratory disorders: *Frequency:* rhinitis.

Nervous system disorders: *Frequency unknown:* headaches, dizziness, insomnia, fatigue.

Urogenital disorders: *Frequency unknown:* erectile dysfunction, ejaculatory disturbance, altered and/or decreased libido.

Cardiovascular disorders: *Frequency unknown:* hypertension, postural hypotension, tachycardia, angina pectoris, arrhythmia, extrasystole, angiodopathy, myocardial infarction, congestive heart failure.

Hematological disorders: *Frequency unknown:* increased risk of bleeding.

Musculoskeletal disorders: *Frequency unknown:* muscle fatigue, weakness, muscle pain, back pain.

Skin disorders: *Frequency unknown:* rash, allergic skin reaction.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit / risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Class and category: D 33.7 Combination product.

BIOGEN PROSTATE PRO supports prostate health and promotes healthy urinary function in men. May assist with the relief of symptoms associated with mild to moderate benign prostatic hyperplasia (BPH).

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on BIOGEN PROSTATE PRO.

5.3 Preclinical safety data

No pre-clinical safety data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Green vegetarian capsule (hypromellose, titanium dioxide and copper complex of chlorophyllins), Microcrystalline cellulose, and Magnesium stearate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

24 Months / 2 Years.

6.4 Special precautions for storage

Store at or below 25 °C.

Store in a dry place away from direct sunlight and moisture.

Store in the original packaging until required for use.

6.5 Nature and contents of the container

250 ml White PET container with a Biogen cap.

Pack size: 90 Dark green vegetarian capsules with a bright orange powder fill.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen.

23 Stag Road,

Glen Austin,

South Africa.

Tel: 0860 347 243.

Email: info@biogen.co.za

Website: www.biogen.co.za

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.