

SUMMARY OF PRODUCT CHARACTERISTICS

PROSTASAN SAW PALMETTO CAPSULES

1 NAME OF THE MEDICINAL PRODUCT

Prostasan Saw Palmetto Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 capsule contains 320mg of extract (as soft extract) from Saw palmetto fruit (*Serenoa repens* (Bartram) Small fructus (*Sabal serrulata* (Michaux) Nichols fructus)) (9-12 :1).

Extraction solvent: Ethanol 96% V/V.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Soft capsule.

It is an oval-shaped, dark brown coloured soft capsule containing a clear, yellow-brown coloured oil.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Traditional herbal medicinal product used for the relief of lower urinary tract symptoms in men who have a confirmed diagnosis of benign prostatic hypertrophy (BPH), based on traditional use only.

Prior to treatment other serious conditions should have been ruled out by a doctor.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Adults and the elderly: One capsule daily to be taken with food.

Children and adolescents less than 18 years old: This product is not indicated in patients less than 18 years.

Hepatic and renal impairment: The safety of Saw palmetto has not been studied in patients with hepatic and/or renal impairment.

4.3 CONTRAINDICATIONS

This product should not be used:

- In patients who have a known hypersensitivity to Saw palmetto or any of the other ingredients used in this product.
- By patients who are under 18 years of age.

- By women who are pregnant or breastfeeding.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Do not exceed stated dose.

This product is intended for use in men who have had benign prostatic hypertrophy already diagnosed by a medical practitioner. If symptoms worsen consult a healthcare practitioner.

If symptoms include haematuria or pyrexia medical advice must be sought immediately.

Saw palmetto is unlikely to have an effect on levels of serum prostate specific antigen (PSA).

There has been a case report of intra-operative haemorrhage associated with the use of Saw palmetto. The prolonged bleeding time may have been a result of platelet dysfunction caused by cyclooxygenase inhibition by Saw palmetto. As a precaution Saw palmetto should be discontinued and the platelet function assessed prior to patients undergoing surgery.

Patients taking medication for Benign Prostatic Hypertrophy should consult their doctor before using Prostan Capsules.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Limited interaction studies have identified no clinically important drug interactions. Saw palmetto does not appear to significantly affect the cytochrome P450 linked enzyme system.

4.6 PREGNANCY AND LACTATION

The safety of this product during pregnancy and lactation has not been established, therefore the use of this product during pregnancy and lactation should be avoided.

Fertility: Non-clinical data on constituents of Saw palmetto indicate a potential effect of reduced sperm motility, viability and sperm concentration. The relevance of these findings to humans is not known. (See Section 5.3).

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No studies on the effects on the ability to drive and use machines have been performed.

4.8 UNDESIRABLE EFFECTS

There has been one case report of intraoperative haemorrhage associated with the use of Saw palmetto.

Based on post-marketing data other adverse events that have been reported are:

Rare (>1/10,000 to <1/1,000):

- Eructation and gastrointestinal discomfort
- Allergic reactions

4.9 OVERDOSE

There are no data on human overdose with Saw palmetto. Appropriate symptomatic and supportive treatment should be administered as clinically indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

The active constituents of Saw palmetto have not been established definitively, however the fatty acid and phytosterol (such as β -sitosterol) components are considered to play a role in its activity.

5.2 PHARMACOKINETIC PROPERTIES

No definitive pharmacokinetic data are available.

5.3 PRECLINICAL SAFETY DATA

Data on reproductive toxicity are limited. Carcinogenicity studies have not been performed.

An Ames test conducted with the extract to investigate genotoxic potential was negative.

β -sitosterol (5mg/kg) given subcutaneously for 32 or 48 days had an antifertility effect on male rats by reducing sperm motility, viability and sperm concentration. The relevance of these findings to humans is not known, but it is considered that the low levels of β -sitosterol in this product are unlikely to have an effect on human fertility.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Gelatin

Glycerol

Sorbitol

Ferric oxide red

Ferric oxide black

Ferric oxide yellow

Purified water

6.2 INCOMPATIBILITIES

Not applicable.

6.3 SHELF LIFE

Unopened 60 months.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

This medicinal product does not require any special storage conditions.

Keep out of the sight and reach of children.

6.5 NATURE AND CONTENTS OF CONTAINER

Amber glass bottles (Type III glass) with aluminium pilfer proof closure with a polyethylene liner.

Pack sizes: 30 capsules

60 capsules

90 capsules

Not all pack sizes may be marketed.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Bioforce (UK) Ltd

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8 MARKETING AUTHORISATION NUMBER(S)

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10/09/2007

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