Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Prostasan soft capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 320 mg of extract (as soft extract) from *Serenoa repens* (Bartram) Small fructus (*Sabal serrulata* (Michaux) Nichols fructus) (saw palmetto fruit) (9-12:1).
Extraction solvent: ethanol 96% v/v.

Excipients with known effect:
Each capsule contains 7.7 mg sorbitol (as dry matter).

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

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

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used for the relief of lower urinary tract symptoms in men who have a confirmed diagnosis of benign prostatic hyperplasia (BPH). This is exclusively based on long-standing use.

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

4.2 Posology and method of administration

Posology

Adults and older people: One capsule daily to be taken with food.

There is no relevant use of Prostasan in women, or in children or adolescents under the age of 18 (see Section 4.1).

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

Due to a lack of data the safety of this product for long term use has not been established.

If symptoms persist, worsen or do not improve after 8 weeks use of Prostasan a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

Method of Administration

For oral use only.

4.3 Contraindications

Hypersensitivity to saw palmetto or any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Do not exceed stated dose.

This product is for use in men. There is no relevant use of Prostasan in women, or in children or adolescents under the age of 18 (see Section 4.1).

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

It is strongly advised that you see a doctor before taking this product as urinary symptoms may be due to a serious underlying condition which only your doctor can diagnose.

The need to urinate frequently (especially at night) may be a symptom of Diabetes mellitus, a doctor or qualified healthcare professional should be consulted.

If symptoms include fever, spasms, blood in the urine, painful urination, urinary retention, back pain or groin pain medical advice must be sought immediately.

If symptoms persist, worsen or do not improve after 8 weeks use of Prostasan a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

This medicine contains sorbitol. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

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 Hyperplasia should consult their doctor before using Prostasan 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.

A few cases of suspected interactions with warfarin have been reported. Increased INR-values have been described.

4.6 Fertility, pregnancy and lactation

This product is for use in men only.
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.

The following effects have been reported as uncommon – Nausea, vomiting, diarrhoea, abdominal pain (especially when taken on an empty stomach).

The frequency of the following effects is not known – allergic or hypersensitivity reactions, headache.

Reporting of Suspected Adverse Reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

No case of overdose has been reported. 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
Liquid sorbitol (non-crystallising)
Iron oxide red (E172)
Iron oxide black (E172)
Iron oxide yellow (E172)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

Use within 5 months of opening.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

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

Amber glass bottles (Type III glass) with coated aluminium foil sealing and 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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 REGISTRATION HOLDER

A.Vogel Ireland Limited
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8 REGISTRATION NUMBER(S)

TR2309/002/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 25th May 2012

Date of last renewal: 24th May 2017

10 DATE OF REVISION OF THE TEXT

September 2020