

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Urostemol Men capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 400 mg of pumpkin seed, crushed (*Cucurbita pepo* L. convar. *citrullina* I. Greb. var. *styriaca* I. Greb); 340 mg of pumpkin seed oil (*Cucurbita pepo* L. convar. *citrullina* I. Greb. var. *styriaca* I. Greb); 75 mg of extract (as dry extract) from saw palmetto fruit (*Serenoa repens* (Bartram) small) (7–13 : 1), extraction solvent ethanol 90% (m/m).

Excipient(s) with known effect: lactose 56.25 mg.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard capsules.

Brown gelatin hard capsules.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A traditional herbal medicinal product for the relief of lower urinary tract symptoms in men related to an overactive bladder or bladder weakness, such as urgency to urinate, urinary incontinence or frequent urination day and night. 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 elderly patients

One capsule to be taken three times a day.

Paediatric population

The use in children and adolescents under 18 years of age is not recommended (see section 4.4).

Method of administration

For oral use only.

The capsules should be taken with sufficient fluids, ideally before meals.

Hepatic and 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 worsen during use or persist after 4 weeks of use a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

4.3 Contraindications

Hypersensitivity to the active substances, to other members of the Cucurbitaceae family (such as watermelon, courgettes etc.), or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

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.

If symptoms worsen during use or persist after 4 weeks of use a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

If symptoms such as pyrexia, spasms, haematuria, urinary retention, painful urination, loin pain, abdominal or back pain are present or develop during use, medical advice must be sought.

A few cases of suspected interactions between saw palmetto extract and warfarin have been reported. Increased INR-values have been described.

Due to the possible risk of saw palmetto extract enhancing the anticoagulant or antiplatelet effect, the combination of Urostemol Men with anticoagulant or antiplatelet medication should be used with caution.

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 with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine

Paediatric population

The use in children and adolescents under 18 years of age is not recommended, because lower urinary tract symptoms in these populations require medical supervision.

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Fertility, pregnancy and lactation

UROSTEMOL Men is not indicated for use by women.
No fertility data available.

4.7 Effects on ability to drive and use machines

UROSTEMOL Men has no influence on the ability to drive and use machines.

4.8 Undesirable effects

There has been one case report of intraoperative haemorrhage associated with the use of saw palmetto. The assessment of the frequency of undesirable effects is based on the following definitions: Very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/10,000$), not known (cannot be estimated from the available data).

Common: Mild gastrointestinal complaints (abdominal pain, dyspepsia, nausea, vomiting, stomach discomfort, dysphagia, oesophageal pain, diarrhoea and eructation).

Frequency not known: Hypersensitivity reactions (rash, urticaria, erythema, pruritus, oedema and anaphylactic shock). If these occur, discontinue use.

Nervous system disorders: Headache may occur.

If other adverse reactions not mentioned above occur, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

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 16764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

No cases of an overdose were reported.

Supportive and symptomatic treatment should be provided as appropriate

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The active constituents of pumpkin seed have not been finally substantiated. Seeds from specifically cultivated medicinal pumpkin species *C. pepo L. convar. citrullina I. Greb. var. styriaca I. Greb* contain fatty oil with specific non-ubiquitous phytosterols (delta-7-sterols) which are suggested to contribute to its activity.

The active substances pumpkin seed powder, pumpkin seed oil and saw palmetto fruit extract are traditionally used in ailments of the bladder-prostate system. The use of this combination is documented for over 30 years.

Urodynamic and antiphlogistic effects were shown for medicinal pumpkin seeds and pumpkin seed oil.

5.2 Pharmacokinetic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data

No genotoxic potential was observed in the AMES test for this specific product formulation.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal anhydrous silica
Lactose monohydrate
Gelatin
Black iron oxide (E 172)
Yellow iron oxide (E 172)
Red iron oxide (E 172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

PVC/PVdC-aluminium-blister.

Packs with 30, 60, 120, 150 or 200 hard capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

Chefaro Ireland DAC
Treasury Building
Lower Grand Canal Street
Dublin 2
Ireland

8 REGISTRATION NUMBER(S)

TR1186/007/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 24th of March 2016.

10 DATE OF REVISION OF THE TEXT

July 2017