Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Urostemol Prosta capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 500 mg of extract (as soft extract) from *Cucurbita pepo* L. convar. *citrullina* I. Greb. var. *styriaca* I. Greb, semen (pumpkin seed) (15-25 : 1). Extraction solvent: ethanol 92% m/m.

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 used for the relief of lower urinary tract symptoms in men related to an overactive bladder or who have a confirmed diagnosis of benign prostatic hyperplasia (BPH), such as urgency to urinate, frequent urination day and night, incomplete emptying of the bladder and weak or interrupted urinary flow. 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 twice 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.

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 substance, to other members of the Cucurbitaceae family (such as water melon, 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.

Patients with confirmed benign prostatic hyperplasia (BPH) This product is intended for men who have had benign prostatic hyperplasia (BPH) already diagnosed by a medical practitioner. Patients taking medication for benign prostatic hyperplasia (BPH) should consult their doctor before taking this product.

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.

This medicinal product may alleviate the discomfort caused by an enlarged prostate but will not reverse the enlargement itself. Therefore, the patient should visit his doctor regularly.

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.

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

No interaction studies have been performed.
There are no known interactions.

4.6 Fertility, pregnancy and lactation

UROSTEMOL Prosta is not indicated for use by women.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

The assessment of the frequency of undesirable effects is based on the following definitions: Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥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 and diarrhoea).

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

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 1 6764971;

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. 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 tests for preparations from *Cucurbita pepo* L. convar. *citrullina* I. Greb. var. *styriaca* I. Greb.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Partially methylated colloidal anhydrous silica
Gelatin
Black iron oxide (E 172)
Red iron oxide (E 172)
Yellow 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-alumininium-blister.
Packs with 20, 40, 80, 140 hard capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

Chefaro Ireland Limited
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8 REGISTRATION NUMBER(S)

TR1186/004/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 7th of October 2016.

10 DATE OF REVISION OF THE TEXT