

PACKAGE LEAFLET: INFORMATION FOR THE USER

# UROSTEMOL™

## Prosta capsules

### Pumpkin seed soft extract

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist, or qualified healthcare practitioner has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or qualified healthcare practitioner. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor or qualified healthcare practitioner if you do not feel better or if you feel worse.

### What is in this leaflet

1. What UROSTEMOL™ Prosta is and what it is used for
2. What you need to know before you take UROSTEMOL™ Prosta
3. How to take UROSTEMOL™ Prosta
4. Possible side effects
5. How to store UROSTEMOL™ Prosta
6. Contents of the pack and other information

### 1. WHAT UROSTEMOL™ PROSTA IS AND WHAT IT IS USED FOR

UROSTEMOL™ Prosta is 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 enlarged prostate (benign prostatic hyperplasia; BPH). This is based on traditional use only.

Used to relieve symptoms such as:

- urgency to urinate
- frequent urination day and night
- incomplete emptying of the bladder
- weak or interrupted urinary flow.

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

### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE UROSTEMOL™ PROSTA

#### Do not take UROSTEMOL™ Prosta:

- if you are allergic to pumpkin seeds or other pumpkin-like plants (such as watermelon, courgettes, etc.), or any of the other ingredients of this medicine (listed in section 6).

#### Warnings and precautions

You must see your doctor, pharmacist or qualified healthcare practitioner if you have any of the following symptoms or if they occur during the use of this product:

- a fever
- bladder spasms
- blood in your urine
- pain when urinating
- difficulty urinating
- loin, back or stomach pain

You must talk to a doctor if you feel worse.

#### Children and adolescents

The use of UROSTEMOL™ Prosta in children and adolescents

under 18 years of age is not recommended, because lower urinary tract symptoms in these patients require medical supervision.

#### Other medicines and UROSTEMOL™ Prosta

Tell your doctor, pharmacist or qualified healthcare practitioner if you are taking or have recently taken any other medicines.

#### Pregnancy and breast-feeding

UROSTEMOL™ Prosta is intended for men only, and is not indicated for use by women.

#### Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. UROSTEMOL™ Prosta does not contain any ingredients that are known to cause drowsiness.

### 3. HOW TO TAKE UROSTEMOL™ PROSTA

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or qualified healthcare practitioner has told you. Check with them if you are not sure.

For oral use only.

Adults and the elderly: The recommended dose is one capsule 2 times a day.

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

Do not exceed the stated dose.

Long-term use should be discussed with your doctor or qualified healthcare practitioner.

**Use in children and adolescents under 18 years of age**

UROSTEMOL™ Prosta is not recommended for patients under 18 years of age.

**If you take more UROSTEMOL™ Prosta than you should**

Contact your doctor, qualified healthcare practitioner or pharmacist if you have accidentally taken more than the recommended dosage of UROSTEMOL™ Prosta.

**If you forget to take UROSTEMOL™ Prosta**

Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time as you would normally.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or qualified healthcare practitioner.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Common**

- Mild stomach complaints such as stomach pain or discomfort, indigestion, feeling or being sick, swallowing problems and diarrhoea have been reported.

**There have been post marketing reports of**

- Allergic reactions such as skin rashes, hives, itching, fluid retention and anaphylactic shock. The frequency is not known.

If allergic reactions should occur, discontinue the use of this medicinal product and consult a doctor immediately.

**Reporting of side effects**

If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly

via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE UROSTEMOL™ PROSTA**

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions and should be stored in the original package.

Do not use this medicine after the expiry date which is stated on the blister and the carton after "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. CONTENTS OF THE PACK AND OTHER INFORMATION**

**What UROSTEMOL™ Prosta contains**

- Each hard capsule contains 500 mg Pumpkin seed soft extract (*Cucurbita pepo* L. convar. *citrullina* l. Greb. var. *styriaca* l. Greb) (15–25 : 1), extraction solvent ethanol 92 % (m/m).
- The other ingredients are: hydrophobic colloidal silica, gelatin, iron oxide black (E 172), iron oxide red (E 172) and iron oxide yellow (E 172).

**What UROSTEMOL™ Prosta looks like and contents of the pack**

UROSTEMOL™ Prosta are brown, gelatin capsules in a PVC/PVdC-aluminium blister.

Pack sizes: 20, 40, 80 or 140 hard capsules.

Not all pack sizes may be marketed.

**Traditional Herbal Registration Holder**

Omega Pharma Ltd.,  
32 Vauxhall Bridge Road,  
London, SW1V 2SA, UK.

**Manufacturer**

Omega Pharma Manufacturing  
GmbH & Co. KG  
Benzstr. 25  
71083 Herrenberg  
Germany



THR 02855/0241

**This leaflet was last revised in 04/2015.**

LF-2552A/1000005415