

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 or pharmacist have 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor 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 exclusively based on long-standing use.

Used to relieve symptoms such as:

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

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

Visit your doctor to rule out any underlying conditions.

This medicinal product may only alleviate the discomfort caused by an enlarged prostate without reversing the enlargement itself. Therefore, you should visit your doctor regularly.

If you are taking other medication for benign prostatic hyperplasia (BPH) you should consult your doctor before taking UROSTEMOL[®] Prosta.

You must see your doctor or pharmacist 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
- groin, back or stomach pain

You must talk to your doctor or pharmacist if you feel worse during use of this product, or if your symptoms do not improve after 4 weeks of use.

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

If you are speaking to your doctor, pharmacist or nurse always remember to tell them about any medicines you are taking, including herbal remedies such as Urostemol[®] Prosta.

There are no known interactions.

Pregnancy and breast-feeding

UROSTEMOL[®] Prosta is not indicated for use by women.

Driving and using machines

UROSTEMOL[®] Prosta has no effect on your ability to drive and use machines.

3. HOW TO TAKE UROSTEMOL[®] PROSTA

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

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.

Enough data has not been gathered to establish the safety of this product for long term use. For long term use, consult your healthcare professional.

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 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 or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Common (may affect up to 1 in 10 people)

- 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 get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: <http://www.hpra.ie>; E-mail: medsafety@hpra.ie. 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.

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

- The active substance is pumpkin seed soft extract from specifically cultivated medicinal pumpkin species. Each capsule contains 500 mg of extract (as soft extract) from Cucurbita pepo L. convar. citrullina l. Greb. var. styriaca l. Greb, semen (pumpkin seed) (15-25 : 1). Extraction solvent: ethanol 92% m/m.
- The other ingredients are: partially methylated colloidal anhydrous silica; gelatin; black, red and yellow iron oxide (E 172).

What UROSTEMOL® Prosta looks like and contents of the pack

UROSTEMOL® Prosta are brown, gelatin capsules in a PVC-Aluminium blister.

Pack sizes: 20, 40, 80 or 140 hard capsules. Not all pack sizes may be marketed.

TR Holder



Chefaro Ireland Limited, First Floor, Block A, The Crescent Building, Northwood Office Park Dublin 9, Ireland.

Manufacturer

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

This leaflet was last revised in 05/2016.

LF-XXXXX/100000XXXX

Brand:	Application:	Item code(s):	Market:	Master text version:	Barcode 1 type:	N/A	Component size (flat):	Cutter guide nr.	Manufacturer:							
Urostemol	Capsules	LF-XXXXX	IE	--	Barcode 1 nr:	N/A	-	-	OPManuf.GMBH							
Variant:	Size:	Unit of measurement:	Languages on the component:	Packaging type:	Barcode 2 type:	-	Folded size:	PO nr:	Printer:							
Prosta	40-80	pc	english	leaflet	Barcode 2 nr:	-	-	2165	-							
		1: Black		5:		Marketing Approval: Name: Date: ... / ... / ... Signature:	Regulatory Approval: Name: Date: ... / ... / ... Signature:		 www.athena-graphics.be							
		2: Cutter guide		6:												
		3:		7:												
		4:		8:												
Pass nr:	Pass date:	Pass nr:	Pass date:	Pass nr:	Pass date:	Pass nr:	Pass date:	Pass nr:	Pass date:	Pass nr:	Pass date:	Pass nr:	Pass date:	Pass nr:	Pass date:	Athena reference nr.:
0	08-06-2016	1	-	2	-	3	-	4	-	5	-	6	--	7	-	779948-004
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