

PACKAGE LEAFLET: INFORMATION FOR THE USER

# UROSTEMOL<sup>®</sup>

## Men capsules

**Pumpkin seed, Pumpkin seed oil and dry extract from Saw Palmetto fruit**

**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<sup>®</sup> Men is and what it is used for
2. What you need to know before you take UROSTEMOL<sup>®</sup> Men
3. How to take UROSTEMOL<sup>®</sup> Men
4. Possible side effects
5. How to store UROSTEMOL<sup>®</sup> Men
6. Contents of the pack and other information

### 1. WHAT UROSTEMOL<sup>®</sup> MEN IS AND WHAT IT IS USED FOR

UROSTEMOL<sup>®</sup> Men is a traditional herbal medicinal product used for the relief of lower urinary tract symptoms in men related to an overactive bladder or bladder weakness. This is exclusively

based on long-standing use.

Used to relieve symptoms such as:

- frequent urination day and night
- urgency to urinate
- urinary incontinence/accidental leakage of urine

### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE UROSTEMOL<sup>®</sup> MEN

#### Do not take UROSTEMOL<sup>®</sup> Men:

- if you are allergic to the active substances, 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 before use to rule out any underlying conditions.

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

If you are taking warfarin or any other medicine that may increase your risk of bleeding, talk to your doctor before taking this product.

If you are due to undergo surgery you should stop taking this medicine and contact your doctor.

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<sup>®</sup> Men 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<sup>®</sup> Men

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<sup>®</sup> Men.

#### Pregnancy and breast-feeding

UROSTEMOL<sup>®</sup> Men is not indicated for use by women.

#### Driving and using machines

UROSTEMOL<sup>®</sup> Men has no effect on your ability to drive and use machines.

#### UROSTEMOL<sup>®</sup> Men contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### 3. HOW TO TAKE UROSTEMOL<sup>®</sup> MEN

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 3 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® Men is not recommended for patients under 18 years of age.

**If you take more UROSTEMOL® Men than you should**

Contact your doctor or pharmacist if you have accidentally taken more than the recommended dosage of UROSTEMOL® Men.

**If you forget to take UROSTEMOL® Men**

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, diarrhoea and belching have been reported.

**There have been post marketing reports of**

- Allergic reactions such as skin rashes, hives, itching, fluid retention and anaphylactic shock.
- Headaches.  
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](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE UROSTEMOL® MEN**

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® Men contains**

- The active substances are pumpkin seed, crushed and pumpkin seed oil from specifically cultivated medicinal pumpkin species and dry extract from saw palmetto fruit. Each capsule contains 400 mg pumpkin seed, crushed (*Cucurbita pepo* L. convar. *citrullina* l. Greb. var. *styriaca* l. Greb); 340 mg pumpkin seed oil (*Cucurbita pepo* L. convar. *citrullina* l. Greb. var. *styriaca* l. 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).

- The other ingredients are: anhydrous colloidal silica; lactose monohydrate; gelatin; black, yellow and red iron oxide (E 172).

**What UROSTEMOL® Men looks like and contents of the pack**

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

Pack sizes: 30, 60, 120, 150 or 200 hard capsules.

Not all pack sizes may be marketed.

**TR Holder**



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

**Manufacturer**

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

**This leaflet was last revised in 08/2016.**

LF-2665B/1000007988

Brand:	Application:	Item code(s):	Market:	Master text version:	Barcode 1 type:	N/A	Component size (flat):	Cutter guide nr.	Manufacturer:							
Urostemol	Capsules	LF-2665B	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:							
Men	60-120	pc	english	leaflet	Barcode 2 nr:	-	-	852	-							
	1: Black		5:		<b>Marketing Approval:</b> Name: ..... Date: ... / ... / ... Signature:	<b>Regulatory Approval:</b> Name: ..... Date: ... / ... / ... Signature:	 www.athena-graphics.be									
	2: Cutter guide		6:													
	3:		7:													
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