

## Pamsvax XL 400 micrograms Capsules

tamsulosin hydrochloride

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.
- The full name of this medicine is Pamsvax XL 400 micrograms Capsules but within the leaflet it will be referred to as Pamsvax XL.

**What is in this leaflet:**

- 1 What Pamsvax XL is and what it is used for**
- 2 What you need to know before you take Pamsvax XL**
- 3 How to take Pamsvax XL**
- 4 Possible side effects**
- 5 How to store Pamsvax XL**
- 6 Contents of the pack and other information**

### **1 What Pamsvax XL is and what it is used for**

The active ingredient in Pamsvax XL is tamsulosin hydrochloride. This is a selective alpha<sub>1A/1D</sub>-adrenoceptor antagonist. It reduces tension of the smooth muscles in the prostate and the urethra, enabling urine to pass more readily through the urethra and facilitating urination. In addition, it diminishes sensations of urge.

Pamsvax XL is used in men for the treatment of the complaints of the lower urinary tract associated with an enlarged prostate (benign prostatic hyperplasia). These complaints may include difficulty urinating (poor stream), dribbling, urgency and having to urinate frequently at night as well as during the day.

### **2 What you need to know before you take Pamsvax XL**

**Do not take Pamsvax XL if you:**

- are **allergic** to tamsulosin hydrochloride or any of the other ingredients of this medicine (listed in section 6). Hypersensitivity may present as sudden local swelling of soft tissues of the body (e.g. the throat or tongue), difficult breathing and/or itching and rash (angioedema).
- have **severe liver insufficiency**.
- suffer from fainting due to **reduced blood pressure** when changing posture (going to sit or stand up).

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Pamsvax XL.

- Periodic **medical examinations** are necessary to monitor the development of the condition you are being treated for.

- Rarely, **fainting** can occur during the use of tamsulosin, as with other medicinal products of this type. At the first signs of dizziness or weakness you should sit or lie down until they have disappeared.
- If you suffer from severe **kidney** problems, tell your doctor.
- If you are undergoing or have been scheduled for eye surgery because of cloudiness of the lens (**cataract**) or increased internal pressure of the eye (**glaucoma**), please inform your eye specialist that you are using or have previously used Pamsvax XL. This is because Pamsvax XL may cause complications during the surgery. The specialist can then take appropriate precautions with respect to medication and surgical techniques to be used. Ask your doctor whether or not you should postpone or temporarily stop taking this medicine when undergoing eye surgery because of a cloudy lens (cataract) or increased internal pressure of the eye (glaucoma).

### **Children and adolescents**

Do not give this medicine to children or adolescents under 18 years because there is no relevant indication for use of Pamsvax XL in this age group and its efficacy has not been established in this population.

### **Other medicines and Pamsvax XL**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Certain medicines (e.g. medicines preventing blood clotting called anticoagulants such as warfarin, anti-inflammatory drugs such as diclofenac) can influence the effects of tamsulosin. Therefore, you can only take medicines concomitantly with Pamsvax XL if your doctor allows it.

### **Pregnancy, breast-feeding and fertility**

Pamsvax XL is not indicated for use in women.

In men, abnormal ejaculation has been reported (ejaculation disorder). This means that the semen does not leave the body via the urethra, but instead goes into the bladder (retrograde ejaculation) or the ejaculation volume is reduced or absent (ejaculation failure). This phenomenon is harmless.

### **Driving and using machines**

Pamsvax XL can adversely affect the ability to drive or operate machines. It should be taken into account that in some patients dizziness may occur.

### **Information on sodium content**

This medicine contains less than 1 mmol sodium (23mg) per prolonged-release capsule, hard, that is to say essentially 'sodium-free'.

### **3 How to take Pamsvax XL**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If it is not prescribed otherwise by your doctor the recommended dose is one capsule daily, to be taken after breakfast or the first meal of the day.

Do not crunch or chew the capsule, swallow it whole.

### **If you take more Pamsvax XL than you should**

Taking more Pamsvax XL may lead to unexpected drop of blood pressure and rapid heartbeat, followed by dizziness. Contact your doctor immediately or visit the emergency department of the nearest hospital as the consequences of accidental or deliberate overdose may require medical intervention.

### **If you forget to take Pamsvax XL**

Take the forgotten capsule on the same day. However, on the next day do not take a double dose to make up for a forgotten dose; just resume treatment at one capsule a day.

### **If you stop taking Pamsvax XL**

You should not stop taking it without consulting your doctor before.

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. Do not be alarmed by this list of possible side effects, you may not have any of them. Most patients do not notice any side effects. However if you do and they bother you, talk to your doctor.

If you begin to feel light-headed or dizzy, sit or lie down until you feel better.

#### **Common** (may affect up to 1 in 10 people):

- dizziness, especially when you are getting up from a chair or bed
- ejaculation disorders
- retrograde ejaculation (ejaculation into the bladder)
- failure of ejaculation.

#### **Uncommon** (may affect up to 1 in 100 people):

- headache
- rapid heartbeat
- dropping of blood pressure especially when standing up
- obstructed or runny nose
- constipation
- diarrhoea
- nausea
- vomiting
- rash
- nettle rash
- itching
- weakness.

#### **Rare** (may affect up to 1 in 1,000 people):

- fainting
- swelling of the lower layers of the skin, often around the mouth or of the mucosa of the mouth or throat which can appear very quickly.

#### **Very rare** (may affect up to 1 in 10,000 people):

- priapism (painful, persistent, involuntary erection of the penis), in which case immediate medical aid is needed
- a severe inflammatory eruption of the skin and mucous membranes, which is an allergic reaction to drugs or other substances called Stevens-Johnson syndrome.

#### **Not known** (frequency cannot be estimated from the available data):

- nose bleeding
- vision blurred, visual impairment
- dry mouth
- serious skin rashes (erythema multiforme, dermatitis exfoliative).

If you are undergoing eye surgery because of cloudiness of the lens (cataract) or increased internal pressure of the eye (glaucoma), and are already taking or have previously taken tamsulosin hydrochloride, the pupil may dilate poorly and the iris (the coloured circular part of the eye) may become floppy during the procedure (see also section 2 "Warnings and precautions").

In addition to the adverse events listed above:

- very rapid uncoordinated contractions of the heart
  - irregular rhythm of the heartbeat
  - abnormally rapid heart rate and
  - difficulty in breathing
- have been reported in association with Pamsvax XL use. Because these spontaneously reported events are from the worldwide post-marketing experience, the frequency of events and the role of Pamsvax XL in their causation cannot be reliably determined.

### **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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

## **5 How to store Pamsvax XL**

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

Store in the original package in order to protect from light.

Do not take this medicine after the expiry date which is stated on 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 Pamsvax XL contains**

The active substance is tamsulosin hydrochloride. Each capsule, hard contains 400 micrograms of tamsulosin hydrochloride.

The other ingredients are:

capsule filling: microcrystalline cellulose (E460), methacrylic acid-ethyl acrylate copolymer 1:1 (including polysorbate, sodium laurilsulfate), talc, triethyl citrate, calcium stearate  
capsule shell: yellow iron oxide (E172), black iron oxide (E172), red iron oxide (E172), titanium dioxide (E171), gelatin.

### **What Pamsvax XL looks like and contents of the pack**

Each prolonged-release capsule, hard is filled with white to off-white pellets, in size No. 2 capsules which upper part is brown opaque and lower part is buff opaque.  
10, 20, 30, 50, 90 or 100 capsules are packed into PVC/PVDC/Aluminium blisters and carton.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Accord, Barnstaple, EX32 8NS, UK

### **Manufacturer**

Gedeon Richter Plc., 1103 Budapest, Gyömrői út 19-21, Hungary

**This leaflet was last revised in March 2021.**