

# Prolosin 400 microgram Prolonged Release 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, please ask your doctor or your 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.

In this leaflet:

- 1. What Prolosin 400 microgram Prolonged Release Capsules (thereafter Prolosin Prolonged Release Capsules) are and what they are used for**
- 2. What you need to know before you take Prolosin Prolonged Release Capsules**
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## 1. What Prolosin Prolonged Release Capsules are and what they are used for

Prolosin Prolonged Release Capsules contain a medicine called Tamsulosin. Tamsulosin belongs to a group of medicines known as alpha1-receptor blockers, which relax the muscles in the prostate and urethra to enable urine to pass more readily.

Prolosin Prolonged Release Capsules have been prescribed for the treatment of symptoms such as difficulty with urinating and increased frequency of urination associated with a condition known as benign prostatic hyperplasia (enlarged prostate).

## 2. What you need to know before you take Prolosin Prolonged Release Capsules

### Do not take Prolosin Prolonged Release Capsules:

- if you are allergic (hypersensitive) to tamsulosin hydrochloride or to any of the other ingredients of this medicine (listed in section 6). Hypersensitivity may present as sudden local swelling of the soft tissues of the body (e.g. the throat or tongue), difficulty breathing and/or itching and rash (angiodema).
- if you suffer from severe liver problems.
- if you suffer from dizziness, light-headedness or fainting caused by a fall in blood pressure on standing up.
- if you are taking certain medicines prescribed by your doctor (see "Other medicines and Prolosin Prolonged Release Capsules" below).

### Warnings and Precautions

Talk to your doctor or pharmacist before taking Prolosin Prolonged Release Capsules:

- if you suffer from severe kidney problems, or are taking any other medication.
- if you are planning to have eye surgery because of cloudiness of the lens (cataract). Please inform your eye specialist that you have previously used, are using or are planning to use Prolosin Prolonged Release Capsules.
- If you feel weak or dizzy, you should sit or lie down until the symptoms have passed.

Additional monitoring tests while taking Prolosin Prolonged Release Capsules:

- Before starting treatment with Prolosin, your doctor may want to carry out tests to check that you do not have any other conditions which are causing your symptoms.
- Regular medical examinations should be performed during long-term use of this product.

### Children

Do not give this medicine to children or adolescent under 18 years because it does not work in this population.

## Other medicines and Prolosin Prolonged Release Capsules

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

In particular, tell your doctor if you are taking:

- Medicines to treat a fungal infection such as ketoconazole or itraconazole or the antibiotic Clarithromycin. Prolosin Prolonged Release Capsules cannot be taken at the same time.
- Erythromycin, an antibiotic used to treat infections.
- Medicines used to lower your blood pressure such as verapamil and diltiazem.
- Medicines used to treat HIV such as ritonavir or indinavir.
- Medicines used to treat ulcers such as cimetidine.
- Other alpha receptor blockers such as doxazosin, prazosin and indoramin. These may cause your blood pressure to fall, resulting in dizziness and weakness.
- Diclofenac (an anti-inflammatory painkiller) and warfarin (used to thin the blood). These may affect the speed at which Prolosin Capsules are removed from your body.

## Pregnancy, breast-feeding and fertility

Prolosin Prolonged Release Capsules is intended for male patients only.

Difficulty with ejaculation has been observed.

## Driving and using machines

Prolosin Prolonged Release Capsules should not affect your ability to drive or use machinery. However, in some people Prolosin Prolonged Release Capsules may cause dizziness, if you are affected do not drive or use machinery.

## 3. How to take Prolosin Prolonged Release Capsules

Always take Prolosin Prolonged Release Capsules exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

**Dosage:** The usual dose is one capsule daily.

**When to take:** The capsule should be taken after breakfast or the first meal of the day.

**How to take:** Take Prolosin Prolonged Release Capsules whole by mouth with a small amount of liquid. Do not crush or chew the capsules.

### DO NOT EXCEED THE PRESCRIBED DOSE.

### If you take more Prolosin Prolonged Release Capsules than you should

If you accidentally take more than the prescribed dose, or in the event of an overdose, seek medical advice immediately. The symptoms of an overdose are low blood pressure, vomiting and diarrhoea. Contact your doctor or nearest hospital Casualty Department and, if possible, take your capsules with you.

### If you forget to take Prolosin Prolonged Release Capsules

If you have forgotten to take your capsule after the first meal of the day, it can be taken later the same day after food. If you have missed a day, just continue to take your daily capsule as prescribed, at the usual time.

Do not take a double dose to make up for forgotten individual doses.

## 4. Possible side effects

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

**Stop taking this medicine and consult your doctor immediately if any of the following occur – you may need medical treatment:**

- Allergic reaction – (affects less than 1 in 1,000 people). The signs may include finding it difficult to breathe, having an itchy rash, having a swollen face, throat or tongue (angioedema)
- Inflammatory skin reaction (frequency not known) – itchy red blotchy rash (erythema multiforme)
- Long-lasting and painful erection (priapism), usually unrelated to sexual activity – affects less than 1 in 10,000 people
- A severe skin reaction, known as Stevens-Johnson syndrome; symptoms could include skin blistering. It is very rare, affecting less than 1 in 10,000 people.

**The following side effects have also been reported:**

**Common side effects** (affecting up to 1 in 10 people) are:

- dizziness
- ejaculation disorders

**Uncommon side effects** (affecting up to 1 in 100 people) are:

- headache
- palpitations (fast or irregular heart beat)
- low blood pressure
- rhinitis (blocked or runny nose)
- constipation
- diarrhoea
- nausea
- vomiting
- rash
- itching
- hives (itchy, red bumps on the skin)
- little or no semen during ejaculation
- weakness

**Rare side effects** (affecting up to 1 in 1,000 people) are:

- feeling faint

**Very rare side effects** (affecting up to 1 in 10,000 people) are:

- intraoperative floppy iris syndrome (IFIS), associated with cataract surgery

**Frequency not known** (frequency cannot be estimated from the available data):

- there have been reports of irregular heart beat/pulse rate, racing heart and difficulty breathing associated with Tamsulosin use.
- nose bleeds
- scaling and itching of the skin with loss of hair (exfoliative dermatitis)
- ejaculation disorders
- blurred vision

As with other medicines of this type, the following symptoms may also occur:

- drowsiness
- blurred vision
- dry mouth
- swelling of the hands or feet

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

## 5. How to store Prolosin Prolonged Release Capsules

Keep out of the sight and reach of children.

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

Do not use these capsules after the expiry date, which is marked on both the blister strip and the outer carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Contents of the pack and other information

### What Prolosin Prolonged Release Capsules contain

Each capsule contains 400 microgram Tamsulosin Hydrochloride as active ingredient. Each prolonged release capsule also contains the following inactive ingredients: calcium stearate, microcrystalline cellulose, methacrylic acid-ethyl acrylate copolymer (1:1), polysorbate 80, sodium laurilsulfate, triethyl citrate, talc, titanium dioxide (E171), black iron oxide (E172), yellow iron oxide (E172), red iron oxide (E172) and gelatin.

### What Prolosin Prolonged Release Capsules look like and contents of the pack

Prolosin Prolonged Release Capsules are size 2 capsules with buff opaque body and brown opaque cap.

Prolosin Prolonged Release Capsules are packed in blisters and available in pack sizes of 30 capsules.

### Marketing Authorisation Holder and Manufacturer

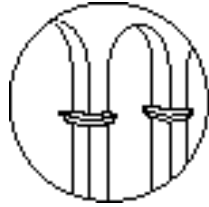
#### Marketing Authorisation Holder:

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#### Manufactured by:

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**This leaflet was last revised in:** February 2013



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<b>Title:</b>	Prolosin 400mcg Tablets PIL
<b>Date of Origination:</b>	18/7/05
<b>Dimensions:</b>	300mm x 210mm
<b>Pharma Code:</b>	2273
<b>Component Code:</b>	27209041
<b>EAN Code:</b>	N/A
<b>Software:</b>	QuarkXpress 4.1
<b>Version Number:</b>	17
<b>Revision Date:</b>	<b>15/02/2013</b>
<b>Reason for Revision:</b>	REmoval of Niche UK as manufacturing site
<b>Colours:</b>	■ Black
<b>Regulatory Approval Date:</b>	
<b>Customer Approval Date:</b>	
<b>Quality Approval Date:</b>	
<b>Submission Date:</b>	