

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT  
PROSTALEN 10 mg prolonged-release tablets  
*Alfuzosin hydrochloride*

**Read all of this carefully before you start taking this medicine**

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4

**In this leaflet:**

1. What is Prostalen is and what it is used for
2. Before you take Prostalen
3. How to take Prostalen
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**1. WHAT IS PROTALEN AND WHAT IT IS USED FOR**

Prostalen belongs to a group of medicines called alpha-blockers.

It is indicated in:

- Symptomatic treatment of benign prostatic hyperplasia (unusual growth).
- Supportive therapy during the insertion of a catheter in case of acute urinary retention (inability to urinate) associated with benign prostatic hyperplasia.

**2. BEFORE YOU START TAKING PROSTALEN**

**Do not take Prostalen if:**

- You are allergic (hypersensitive) to alfuzosin or any of the other ingredients of Prostalen (see section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, throat, or tongue.
- You have something called orthostatic hypotension. This is a drop in blood pressure which usually happens when you stand up. It can make you feel dizzy, light-headed or faint when you stand up or sit up quickly.
- You are taking another alpha-blocker. See section below on 'Taking other medicines'.
- You have liver problems.
- In paediatric population (2-16 years of age).

**Take special care with Prostalen**

Check with your doctor before taking your medicine:

- If you have signs of orthostatic hypotension (sudden fall in arterial blood pressure when changing position).  
Orthostatic hypotension can appear in the few hours that follow the intake of the medicine. It usually appears at the initiation of the treatment and if you are concomitantly treated for hypertension. Orthostatic hypotension can come along with: light-headedness, tiredness, sweating. In that case, you have to lie down until the symptoms completely disappear. Generally, the treatment can then be followed. Caution should be paid if you have a low

arterial blood pressure following the use of a medicine of the same category ( $\alpha_1$ -receptors blockers).

- If you have an advanced age, you are more at risk for developing a severe hypotension. If you have history a hypersensitivity (allergy) to a medicine of the same category ( $\alpha_1$ -receptors blockers).
- If you are elderly
- If you use medicine that lower your arterial blood pressure, nitro derivatives or medicines for other heart or vascular diseases. Your doctor should regularly check your blood pressure, especially at the initiation of the treatment. Your doctor should also decide if the simultaneous use of Prostalen is possible.
- If you have heart failure or heart rhythm disorder. Refer to your doctor who should decide if the simultaneous use of Prostalen is possible.
- In very rare cases, alfuzosin may cause priapism, a painful erection of the penis which will not go away. This is a serious condition and you should contact your doctor.
- If you have to undergo cataract surgery, you should advise your surgeon that you use Prostalen.
- If you have a condition where your kidneys are hardly working at all.
- If you take other medicines, refer to the section "Taking other medicines".

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription.

### **Do not take Prostalen concomitantly with the following medicines:**

- Other  $\alpha_1$ -receptors blockers.

### **Attention should be paid when using Prostalen in combination with the following medicines:**

- Medicines that lower your arterial blood pressure.
- Nitro derivatives (medicines for angina (oppression (or sometimes stabbing) feeling behind the sternum), heart disease).
- General anaesthetics.
- Medicines for chest pain (angina)
- Medicines for fungal infections (such as itraconazole).
- Medicines for HIV (such as ritonavir).
- Medicines for bacterial infections (such as clarithromycin, telithromycin).
- Medicines for treatment of depression (such as nefazodone).
- Ketoconazole tablets (used to treat Cushing's syndrome - when the body produces an excess of cortisol).
- Medicines for erection troubles: some patients that follow an alpha-blockers treatment for high blood pressure or benign prostatic hyperplasia may get dizzy due to a hypotension when sitting or getting up quickly. Some patients had experimented those symptoms while taking drugs against erectile dysfunction (impotence) with alpha-blockers. To reduce these symptoms, take a regular daily dose of alpha-blockers before starting to take the medicines against erectile dysfunction.
- Medicines with electrocardiogram influence (QTc prolongation)

In order to prevent interactions with other medicines, you should advise your doctor of any other treatment systematically.

### **Pregnancy and lactation**

If you are pregnant or breast-feeding, if you think to be pregnant or planned a pregnancy, you should advise your doctor or your pharmacist before taking this medicine.

### **Driving and using machines**

You may experience fatigue, fall in arterial blood pressure, light-headedness, dizziness or weakness at the beginning of the treatment. If this happens, do not drive or operate any tools or machines.

### **3. How to take Prostalen**

Always take Prostalen exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

#### **The recommended dose is**

The usual dose is one Prostalen tablet once a day.

In case of acute urinary retention one Prostalen tablet a day from the day you have the catheter inserted.

#### **Administration**

Swallow your tablets whole with plenty of water. Do not break, crush, or chew your tablets. This can affect the release of your medicine into the body. Take this medicine after a meal.

#### **Use in children and adolescents:**

The effectiveness of Prostalen has not been established in children aged from 2 to 6 years old. Prostalen is contraindicated in paediatric population.

#### **If you take more Prostalen than you should**

Contact your doctor, pharmacist or the Poison Center immediately. Massive intake requires a treatment in a hospital environment. The main symptoms of overdose are related to a sudden decrease in blood pressure.

#### **If you forgot to take Prostalen**

Do not take a double dose to make up for a forgotten tablet. Miss it out and then go on as before.

#### **If you stop taking Prostalen**

Keep taking your tablets, even if your symptoms improve. Only stop if your doctor tells you so. The symptoms are better controlled if you continue taking the same dose of this medicine.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Prostalen can cause side effects, although not everybody gets them

<i>Very common</i>	(happening in more than 1 patient out of a 10).
<i>Common</i>	(happening in 1 to 10 patients out of a 100).
<i>Uncommon</i>	(happening in 1 to 10 patients out of a 1,000).
<i>Rare</i>	(happening in 1 to 10 patients out of 10,000).
<i>Very rare</i>	(happening in less than 1 patient out of 10,000).
Not known	(cannot be estimated from the available data).

The following side effects can arise

#### ***Nervous system disorders***

*Common:* faintness, dizziness, headache.

*Uncommon:* syncope, vertigo, malaise, drowsiness.

#### ***Cardiac and vascular disorders***

*Uncommon:* orthostatic hypotension (brutal decrease in the arterial tension following sudden standing up when sitting or lying down), acceleration of heart rate, hot flashes.

*Very rare:* new onset, aggravation or recurrence of angina pectoris in patients with pre-existing coronary artery disease

*Unknown:* atrial fibrillation (heart rate disorders).

#### **Haematological and lymphatic system disorders**

*Unknown:* neutropenia (deficiency in white blood cells), thrombocytopenia (deficiency in platelets)

#### **Gastrointestinal disorders**

*Common:* nausea, abdominal pain, stomach pain.

*Uncommon:* diarrhoea, vomiting.

#### **Skin and subcutaneous disorders**

*Uncommon:* rash, pruritus.

*Very rare:* urticaria, angioedema (swelling of the face, tongue and throat).

#### **Hepatobiliary disorders**

*Unknown:* hepatocellular injury, cholestatic liver disease (interruption in bile flow).

#### **Eye disorders**

*Unknown:* Intraoperative Floppy Iris Syndrome

#### **Respiratory disorders**

*Uncommon:* rhinitis (inflammation of the nose mucosal layer).

#### **General disorders and administration site conditions**

*Common:* asthenia.

*Uncommon:* flushes, oedema, chest pain

#### **Reproductive system and breast disorders**

*Frequency unknown:* painful erection of the penis (priapism)

The following side effects have been described with alfuzosin 5 mg prolonged release tablets and cannot be excluded:

#### **Eye disorders**

*Uncommon:* vision abnormal

#### **Cardiac and vascular disorders**

*Uncommon:* palpitations.

#### **General disorders and administration site conditions**

*Common:* malaise (weakness or tiredness).

#### **Gastrointestinal disorders**

*Common:* dry mouth.

#### **Nervous system disorders**

*Uncommon:* drowsiness.

### **Reporting of suspected side effects**

If you get 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 national reporting system.

### **5. HOW TO STORE PROSTALEN**

Keep out of the sight and reach of children.

Store in the original package. Store below 30°C.

Do not use Prostalen after the expiry date which is stated on the carton and blister strip. The expiry date refers to the last day of that month.

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

### **6. FURTHER INFORMATION**

#### **What Prostalen contains**

- The active ingredient in Prostalen is alfuzosin hydrochloride.  
Each tablet contains 10 mg alfuzosin hydrochloride in a prolonged-release formulation.
- The other ingredients are: hypromellose, microcrystalline cellulose, anhydrous colloidal silica, magnesium stearate, Opadry II white.

#### **What Prostalen looks like and contents of the pack**

Prostalen tablets are film-coated, white and round. The tablets are packaged in blister strip of 10 tablets. Each box contains 3 blisters of 10 tablets (30 tablets).

#### **Product license holder and manufacturer**

##### ***Product license holder***

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##### ***Manufacturer***

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