

 **PACKAGE LEAFLET:**
Information for the patient

PROSTACURE

Prolonged-release hard capsules, 0.4 mg
(*Tamsulosin hydrochloride*)

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please 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 your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Prostacure is and what it is used for
2. What you need to know before you use Prostacure
3. How to use Prostacure
4. Possible side effects
5. How to store Prostacure
6. Contents of the pack and other information

1. What Prostacure is and what it is used for

Prostacure is used in the treatment of functional symptoms of benign prostatic hyperplasia, such as difficult urination. The active ingredient of Prostacure is tamsulosin. Tamsulosin is an alpha1-receptor blocker which reduces the tension in muscles of prostate and urethra. Thus an easier flow of urine through the urethra and urination are facilitated.

2. What do you need to know before you use Prostacure

Do not use Prostacure,

- if you are allergic to tamsulosin or any of the other ingredients of this medicine (listed in section 6)
- if you suffer orthostatic hypotension
- if you suffer from severe hepatic insufficiency.

Warnings and precautions

Talk to your doctor or pharmacist before taking Prostacure

- if you suffer from orthostatic hypotension (dizziness caused by low blood pressure after sitting or standing up)
- if you take other alpha1-receptor blockers
- if you suffer from severe renal insufficiency.

If you are undergoing eye surgery because of cataract (cloudiness of the lens) please inform your eye specialist before the operation that you are using or have previously used Prostacure. This is because Prostacure may cause complications during the surgery which can be managed if your specialist is prepared in advance.

Prostacure with food and drink

Prostacure should be taken after breakfast or after the first meal of the day with a glass of water.

Pregnancy, breast-feeding and fertility

Prostacure is intended for male patients only.

Driving and using machines

No data is available on whether tamsulosin adversely affects the ability to drive or operate machines. However, in this respect patients should be aware of the fact that Prostacure may cause dizziness

Other medicines and Prostacure

Tell your doctor or pharmacist if you are taking/using or have recently taken/used or might take/use any other medicines. Concomitant use of tamsulosin with other alpha1-receptor blockers (prazosin, alfuzosin) may cause hypotension.

3. How to use Prostacure

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

The recommended dose is one capsule per day.

Prostacure should be taken after breakfast or after the first meal of the day with a glass of water.

The capsule should be swallowed whole while sitting or standing (not in lying position). The capsule should not be broken or chewed as this will interfere with the modified release of the active ingredient.

If you have the impression that the effect of Prostacure is too strong or too weak, talk to your doctor or pharmacist.

If you take more Prostacure than you should

If you have taken more Prostacure than the doctor prescribed, contact your doctor or a hospital.

If you forget to take Prostacure

If you forget to take the medicine after breakfast, you can take it later the same day. You should skip the dose if you do not notice forgetting it until the following day.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following adverse effects have been reported during the use of Prostacure :

Common: may affect up to 1 in 10 people
Dizziness, ejaculation disorders.

Uncommon: may affect up to 1 in 100 people

Headache, palpitations, dizziness especially when sitting down or standing up from the lying position, rhinitis, gastrointestinal reactions (constipation, diarrhoea, nausea, vomiting), allergic reactions (skin rash, pruritus, urticaria), weakness.

Rare: may affect up to 1 in 1,000 people

Fainting, angioedema.

Very rare: may affect up to 1 in 10,000 people

Stevens-Johnson syndrome, priapism (persistent and painful erection).

Not known: frequency cannot be estimated from the available data

Irregular heart beat (atrial fibrillation, arrhythmia), increased heart rate (tachycardia), shortness of breath (dyspnoea).

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

5. How to store Prostacure

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

Store in the original package.

Do not store above 30 °C.

Do not use this medicine after the expiry date which is stated on the blister and on the carton after "Skad". The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Prostacure contains

- The active substance is tamsulosin hydrochloride.

Each prolonged-release capsule contains 0.4 mg of tamsulosin hydrochloride.

- The other ingredients are

Capsule contents: sodium alginate, methacrylic acid – ethyl acrylate copolymer (1:1), glycerol dibehenate, maltodextrin, sodium laurilsulphate, macrogol 6000, polysorbate 80, sodium hydroxide, simeticone emulsion (simeticone, methylcellulose, sorbic acid), colloidal anhydrous silica.

Capsule shell: gelatine, red iron oxide (E172), titanium dioxide (E171), yellow iron oxide (E172).

Contents of the pack

Prostacure is available in blister packs with 20 and 30 capsules.

Marketing Authorisation Holder and Manufacturer:



PROFARMA Sh.a.
Rruga "Myslym Keta"
Tel. Fax: 00 355 4 23 62 800
Tirana - ALBANIA

This leaflet was last revised in August 2014.

PAY ATTENTION, all the layers are visible.
If you have to print this document please
check or uncheck the specific layers.

 SPECIFICATION

 CROPPING AREA 12 x 19 cm