

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 to 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 take Prostacure?
3. How to take Prostacure?
4. Possible side effects
5. How to store Prostacure?
6. Content 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 alpha-1-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 YOU NEED TO KNOW BEFORE YOU TAKE PROSTACURE?

Do not take Prostacure,

- if you are allergic to tamsulosin or any of the excipients of this medicine (listed in section 6);
- if you suffer orthostatic hypotension;
- if you suffer from severe liver impairment.

Warnings and precautions

Talk to your doctor or pharmacist before taking Prostacure.

In some cases during treatment, there may be a fall in blood pressure that can lead to fainting. If you notice the first signs of a drop in blood pressure (such as dizziness, weakness), you should sit or lie down until the symptoms have disappeared.

Before the start of treatment, the doctor should rule out with appropriate examinations other diseases that cause the same symptoms as the benign enlargement of the prostate gland (benign prostatic hyperplasia).

A palpation examination of the rectum (digital rectal examination) and, if necessary, the determination of prostate-specific antigen should be made before the start of treatment and then at regular intervals by the doctor.

Special caution is needed if you have severe renal impairment with a creatinine clearance < 10 ml / min as there is no experience.

Rarely, tissue swelling (angioedema) after administration of tamsulosin has been reported. If you experience tissue swelling during treatment, discontinue taking tamsulosin immediately and consult a doctor.

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 necessary because some patients who have been treated with tamsulosin at the same time or earlier have experienced difficulty in surgery (e.g. insufficiently dilated pupil, relaxed iris during the procedure). The ophthalmologist may then take appropriate precautions regarding the medication and surgical technique used. Please ask your doctor if you should delay or temporarily stop taking your medication for the cataract surgery.

Prostacure with food and drink

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

Children

Do not give this medicine to children and adolescents under the age of 18 because it does not work in this age group.

Pregnancy, breastfeeding and fertility

Prostacure is intended for male patients only.

There are reports of ejaculation disorders, retrograde ejaculation and ejaculation failure.

Driving and using machines

No data is available on whether tamsulosin adversely affects the ability to drive or operate machines.

However, in this respect be aware of the fact that Prostacure may cause dizziness.

Other medicines and Prostacure

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

Concomitant use of tamsulosin with other alpha-1-receptor blockers (e.g. prazosin, alfuzosin) may cause hypotension.

Diclofenac (an anti-inflammatory analgesic) and warfarin (used for blood thinning) can affect the processing of tamsulosin in your body.

Ketoconazole (antifungal) can increase the exposure to tamsulosin.

3. HOW TO TAKE PROSTACURE?

Always take 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 take 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.

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. The following adverse effects have been reported during the use of tamsulosin:

Common: may affect up to 1 in 10 people

Dizziness, ejaculation disorders, retrograde ejaculation, ejaculation failure, a special form of the syndrome of the narrow pupil (floppy iris syndrome [IFIS], which can occur during cataract surgery).

Uncommon: may affect up to 1 in 100 people

Headache, palpitations, dizziness due to lowering of blood pressure especially when sitting down or standing up from the lying position (orthostatic hypotension), rhinitis, constipation, diarrhoea, nausea, vomiting, 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

Blurred vision, visual disturbances, irregular heart beat (atrial fibrillation, arrhythmia), increased heart rate (tachycardia), shortness of breath (dyspnoea), nose bleeding (epistaxis), skin inflammation (erythema multiforme, exfoliative dermatitis), dry mouth.

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.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What Prostacure contains

The **active substance** is tamsulosin hydrochloride.

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

The **excipients** are:

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

Capsule shell: gelatin, red iron oxide, titanium dioxide, yellow iron oxide.

Content of the pack

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

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

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