

Package leaflet: Information for the user

Uprox 0.4 mg, modified-release capsules, hard

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.

What is in this leaflet

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

1. What Uprox is and what it is used for

The active ingredient in Uprox is tamsulosin. This is a selective $\alpha_{1A/1D}$ -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.

Uprox is used in men for the treatment of the complaints of the lower urinary tract associated with an enlarged prostatic gland (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 Uprox

Do not take Uprox:

- if you are allergic (hypersensitive) to tamsulosin or 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), difficult breathing and/or itching and rash (angioedema).
- if you have a serious liver problems.
- if you feel dizzy or faint when you suddenly sit or stand up.

Warnings and precautions

- 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 Uprox 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 pressure in the eye (glaucoma), please inform your eye specialist that you have previously used, are using, or are planning to use Uprox. 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 pressure in the eye (glaucoma).

Children

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

Other medicines and Uprox

Taking Uprox together with other medicines from the same class (α_1 -adrenoceptor antagonists) may cause an unwanted decrease in blood pressure.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is especially important to inform your doctor if you are being treated at the same time with medicines that may decrease the removal of Uprox from the body for example, ketoconazole (used to treat fungal infections), erythromycin (antibiotic).

Uprox with food and drink

Uprox must be taken after breakfast or the first meal of the day.

Pregnancy, breast-feeding and fertility

Uprox is not indicated for use in women.

Driving and using machines

There is no evidence that Uprox affects the ability to drive or to operate machinery or equipment. However, you should bear in mind that dizziness can occur, in which case you should not undertake activities that require attentiveness.

3. How to take Uprox

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

The dosage is 1 capsule per day to be taken after breakfast or the first meal of each day.

The capsule must be swallowed whole and not be crunched or chewed.

Usually, Uprox is prescribed for long periods of time. The effects on the bladder and on urination are maintained during long- term treatment with Uprox.

If you take more Uprox than you should

Taking too many Uprox may lead to an unwanted decrease in blood pressure and an increase in heart rate, with feelings of faintness. Contact your doctor immediately if you have taken too much Uprox.

If you forget to take Uprox

You may take your daily Uprox later the same day if you have forgotten to take it as recommended. If you have missed a day, just continue to take your daily capsule as prescribed.

Never take a double dose to make up for the forgotten capsule.

If you stop taking Uprox

When treatment with Uprox is stopped prematurely, your original complaints may return. Therefore use Uprox as long as your doctor prescribes, even if your complaints have disappeared already. Always consult your doctor, if you consider stopping this therapy.

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

4. Possible side effects

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

You should contact your doctor immediately if you notice any of the following side effects (it may be an allergic reaction):

- lumpy skin rash (urticaria)
- swollen feet, hands, lips, tongue or throat and difficulty breathing.

If you feel weak or dizzy, when taking tamsulosin, you should sit or lie down straight away until the symptoms have disappeared.

Common (less than 1 in 10, more than 1 in 100 (1-10%)):

- dizziness, particularly when going to sit or stand up,
- ejaculation disorders, ejaculation failure, retrograde ejaculation (it means that semen does not leave the body via the urethra, but instead goes into the bladder. This phenomenon is harmless.)

Uncommon (more than 1 in 1000, less than 1 in 100 (0,1-1%)):

- headache,
- palpitations (the heart beats more rapidly than normal and it is also noticeable),
- reduced blood pressure e.g. when getting up quickly from a seating or lying position sometimes associated with dizziness,
- runny or blocked nose,
- diarrhoea or constipation,
- feeling sick or being sick,
- allergic reactions (skin rash, itchy or inflamed skin),
- weakness (asthenia).

Rare (more than 1 in 10,000, less than 1 in 1000 (0,01-0,1%)):

- syncope,
- faintness and sudden local swelling of the soft tissues of the body (e.g. the throat or tongue) difficult breathing and / or itching and rash, often as an allergic reaction (angioedema).

Very rare (less than 1 in 10,000 (<0,01%)):

- inflammation and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (Stevens-Johnson syndrome),
- painful prolonged unwanted erection for which immediate medical treatment is required (priapism).

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

- vision blurred,
- visual impairment,
- nose bleeds,
- itchy pink-red blotches on the extremities (erythema multiforme),
- red and scaly skin (dermatitis exfoliative),
- abnormal irregular heart rhythm (atrial fibrillation, arrhythmia, tachycardia),
- difficult breathing (dyspnoea),
- dry mouth.

If you are undergoing eye surgery because of cloudiness of the lens (cataract) or increased pressure in the eye (glaucoma) and are already taking or have previously taken Uprox, the pupil may dilate poorly and the iris (the coloured circular part of the eye) may become floppy during the procedure.

Reporting of 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 Departament Monitorowania Niepożądanych Działań Produktów Leczniczych Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, Al. Jerozolimskie 181C, 02-222 Warszawa, Poland, tel.: + 48 22 49 21 301, faks: + 48 22 49 21 309, e-mail: ndl@urpl.gov.pl.

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

5. How to store Uprox

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

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

Store in the original package.

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 Uprox contains:

- The active substance is tamsulosin as tamsulosin hydrochloride;
- The other ingredients are:

Content of capsule: microcrystalline cellulose, methacrylic acid-ethyl acrylate copolymer (1:1), dispersion 30%, polysorbate 80, sodium laurylsulfate, triethylcitrate, talc.

Capsule body: gelatin, indigo carmine (E 132), titanium dioxide (E 171), yellow iron oxide (E 172), red iron oxide (E 172), black iron oxide (E 172).

What Uprox looks like and contents of the pack

Uprox are orange/olive-green modified-release capsules, hard. Capsules contain white to off-white pellets.

Capsules are packed in blisters PVC/PE/PVDC/Aluminium in boxes. One box contains 30, 60 or 90 modified-release capsules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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