Package leaflet: Information for the user

Uprox XR, 0.4 mg, prolonged release tablets

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 XR is and what it is used for

The active ingredient in Uprox XR 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 XR 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 XR

Do not take Uprox XR:
- 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 on changing position from lying down to sitting or standing.

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 XR 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 XR. 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 XR
Taking Uprox XR 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 XR from the body for example, ketoconazole (used to treat fungal infections), erythromycin (antibiotic).

Uprox XR with food and drink
Uprox XR can be taken with or without food.

Pregnancy, breast-feeding and fertility
Uprox XR is not indicated for use in women.

In men, abnormal ejaculation has been reported (ejaculation disorder).
This means that the semen does not leave the body via the urethra, but instead goes into the bladder (retrograde ejaculation) or the ejaculation volume is reduced or absent (ejaculation failure). This phenomenon is harmless.

Driving and using machines
There is no evidence that Uprox XR 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 XR

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

The dosage is 1 tablet per day to be taken with or without food, preferably at the same time each day.

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

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

If you take more Uprox XR than you should
Taking too many Uprox XR 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 XR.

If you forget to take Uprox XR
You may take your daily Uprox XR 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 tablet as prescribed.

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

If you stop taking Uprox XR

When treatment with Uprox XR is stopped prematurely, your original complaints may return. Therefore use Uprox XR 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 XR 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 on changing position from lying down to sitting or standing,
- 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 multifore),
- 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 XR, 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 XR

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 in order to protect from light.

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 XR contains:
- The active substance is tamsulosin as tamsulosin hydrochloride;
- The other ingredients are:
  Inner core tablet: Hypromellose, Cellulose, microcrystalline, Carbomer, Silica colloidal anhydrous, Iron oxide red, Magnesium stearate
  Outer core tablet: Cellulose, microcrystalline, Hypromellose, Carbomer, Silica colloidal anhydrous, Magnesium stearate.

What Uprox XR looks like and contents of the pack

Prolonged release tablet. White, un-scored, round tablets with a diameter of 9 mm debossed on one side with "T9SL" and "0.4" on the other side.

Tablets are packed in blisters in boxes. One box contains 30, 60 or 90 prolonged release tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Recordati Polska sp. z o.o.
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Manufacturer
Synthon BV
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