

Package leaflet: Information for the user
Kirnom XL 400 micrograms
Prolonged-Release Hard Capsules
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, please ask your doctor or nurse.
- 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.

The name of your medicine is Kirnom XL 400 micrograms Prolonged-Release Hard Capsules. In the rest of this leaflet it is called Kirnom XL Capsules.

What is in this leaflet

1. What Kirnom XL Capsules are and what they are used for
2. What you need to know before you take Kirnom XL Capsules
3. How to take Kirnom XL Capsules
4. Possible side effects
5. How to store Kirnom XL Capsules
6. Contents of the pack and other information

1. What Kirnom XL Capsules are and what they are used for

The active substance in Kirnom XL Capsules is tamsulosin (as hydrochloride). This is a selective $\alpha_{1A/1D}$ -adrenoceptor antagonist. It reduces tension of the smooth muscles in the prostate and urethra, enabling urine to pass more readily through the urethra and facilitating urination. In addition, it diminishes sensations of urge.

Kirnom XL Capsules 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 Kirnom XL Capsules

Do not take Kirnom XL Capsules:

- if you are allergic (hypersensitive) to tamsulosin hydrochloride or to any of the other ingredients in 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 severe liver problems
- if you have ever fainted or felt dizzy when suddenly sitting or standing up. Dizziness can sometimes occur when taking Kirnom XL Capsules, particularly if you are also taking other α_1 - blockers. If you do feel weak or dizzy make sure you sit or lie down straight away until the symptoms have disappeared.

Warnings and precautions

Talk to your doctor before taking Kirnom XL Capsules

- if you have kidney problems
- 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 tamsulosin hydrochloride. 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 Kirnom XL Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Kirnom XL Capsules can affect the way that some other medicines work and some other medicines can affect the way that Kirnom XL Capsules works.

Please check with your doctor if you are taking any of the following (or any other medication):

- medicines used to lower your blood pressure such as verapamil and diltiazem
- medicines used to treat HIV such as ritonavir or indinavir
- medicines used to treat fungal infections such as ketoconazole or itraconazole
- other alpha-blockers such as doxazosin, indoramin, prazosin or alfuzosin
- erythromycin, an antibiotic used to treat infections.

Tell your doctor or dentist that you are on Kirnom XL Capsules before any operation or dental procedure as there is a potential that your medicine may interfere with the effects of the anaesthetic.

Pregnancy, breast-feeding and fertility

Kirnom XL Capsules 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

Kirnom XL Capsules may cause drowsiness, blurred vision and dizziness. If you are affected you should not drive or operate machinery.

Kirnom XL Capsules contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Kirnom XL Capsules

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

The recommended dose is one capsule per day to be taken after breakfast or the first meal of each day. Swallow the capsule whole. Do not crunch or chew. Your doctor may want to examine you from time to time whilst taking this medicine

If you take more Kirnom XL Capsules than you should

Taking too many Capsules 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.

If you forget to take Kirnom XL Capsules

You may take your capsule later the same day if you have forgotten to take it earlier. If you have missed a day, just continue to take your daily capsule from the next day. Do not take a double dose to make up for a forgotten dose.

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.

Stop taking this medicine and consult your doctor immediately if any of the following occur – you may need medical treatment.

Rare (may affect up to 1 in 1,000 people)

- Swelling of the face, throat or tongue with breathing problems linked to allergy

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

- Persistent painful erection usually unrelated to sexual activity.
- Rash, inflammation and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (Stevens-Johnson syndrome).

The following side effects have also been reported:

Common (may affect up to 1 in 10 people)

- dizziness
- abnormal ejaculation (ejaculation disorder). This means that 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.

Uncommon (may affect up to 1 in 100 people)

- weakness
- headache
- runny or blocked nose
- dizziness as you sit or stand up
- palpitations (rapid or irregular heart beat)
- gastro-intestinal symptoms such as nausea and vomiting (feeling or being sick), diarrhoea or constipation
- hypersensitivity reactions such as rash, itching, redness, local swelling and breathing problems

Rare (may affect up to 1 in 1,000 people)

- fainting

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

- blurred vision
- impaired vision
- nose bleeds (epistaxis)
- serious skin rashes (erythema multiform, dermatitis exfoliative)
- abnormal irregular heart rhythm (atrial fibrillation, arrhythmia, tachycardia), difficult breathing (dyspnoea).
- dry mouth As with other medicines of this type, drowsiness, blurred vision or swelling of the hands and feet can occur.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 676 2517. Website: www.hpra.ie; email: medsafety@hpra.ie.

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

5. How to store Kirnom XL Capsules

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 and blister. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.

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 Kirnom XL Capsules contains

The active substance is tamsulosin hydrochloride. Each capsule contains 400 micrograms of tamsulosin hydrochloride (equivalent to 367 micrograms tamsulosin).

The other ingredients are microcrystalline cellulose, methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 per cent, talc, purified water, magnesium stearate and triethyl citrate. The outer shell of the capsule contains hard gelatin, sodium laurilsulfate, quinoline yellow (E104), titanium dioxide (E171), brilliant blue (E133), shellac and black iron oxide (E172).

What Kirnom XL Capsules look like and contents of the pack

Kirnom XL Capsules consist of a light green opaque cap printed with W 516 and light yellow opaque body containing white to off white pellets. The capsules are contained in a blister pack in a cardboard box. They are available in packs of 30 capsules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

This medicinal product is authorised in the Member States of the EEA under the following names:

UK: Pinexel PR 400 micrograms Prolonged-Release Hard Capsules

Ireland: Kirnom XL 400 micrograms Prolonged-Release Hard Capsules

Cyprus: Pinexel PR 400 micrograms Prolonged-Release Hard Capsules

Malta: Pinexel PR 400 micrograms Prolonged-Release Hard Capsules

Germany: Pinexel PR 400 mikrogram Hartkapseln, retardiert

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call:

+44 1978 669272 (Republic of Ireland only)

Please be ready to give the following information:

Product name	Reference number
Kirnom XL 400 micrograms Prolonged-Release Hard Capsules	1339/20/1

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in 08/2022