

PACKAGE LEAFLET: INFORMATION FOR THE USER

Omnexel® 400 micrograms prolonged release tablets (film-coated)

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 further questions, ask your doctor or your 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 Omnexel is and what it is used for
2. What you need to know before you take Omnexel
3. How to take Omnexel
4. Possible side effects
5. How to store Omnexel
6. Contents of the pack and other information

1. WHAT OMNEXEL IS AND WHAT IT IS USED FOR

The active ingredient in Omnexel 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.

Omnexel 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 OMNEXEL

Do not use Omnexel

- If you are allergic (hypersensitive) to tamsulosin or to any of the other ingredients in Omnexel. 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 suffer from severe liver problems
- If you suffer from fainting due to reduced blood pressure when changing posture (going to sit or stand up).

Warnings and precautions

Talk to your doctor or pharmacist before taking Omnexel

- because periodic medical examinations are necessary to monitor the development of the condition you are being treated for.
- because, rarely, fainting can occur during the use of Omnexel, 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.

- 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 Omnexel. 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 and adolescents

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

Other medicines and Omnexel

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

Taking Omnexel together with other medicines from the same class (alpha₁-adrenoceptor blockers) may cause an unwanted decrease in blood pressure.

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 Omnexel from the body (for example, ketoconazole, erythromycin).

Omnexel with food and drink

You can take Omnexel with or without food

Pregnancy, breast-feeding and fertility

Omnexel 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 Omnexel 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 in these activities that require attentiveness.

3. HOW TO TAKE OMNEXEL

Always take Omnexel exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

The recommended dose is 1 tablet per day. You can take Omnexel with or without food, preferably at the same time of each day.

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

Omnexel is a specially designed tablet from which the active ingredient is gradually released, once the tablet has been ingested. It is possible that you observe a remnant of the tablet in your stool. Since the active ingredient has been released already, there is no risk of the tablet being less effective.

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

If you take more Omnexel than you should

Taking too many Omnexel tablets 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 Omnexel.

If you forget to take Omnexel

You may take your daily Omnexel tablet 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 Omnexel

When treatment with Omnexel is stopped prematurely, your original complaints may return. Therefore use Omnexel 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Common (may affect up to 1 in 10 people):

- dizziness, particularly when going to sit or stand up.
- 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):

- 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 (rhinitis), diarrhoea, feeling sick and vomiting, constipation, weakness (asthenia), rashes, itching and hives (urticaria)

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

- 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 (may affect up to 1 in 10,000 people):

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

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).
- 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 Omnexel, the pupil may dilate poorly and the iris (the coloured circular part of the eye) may become floppy during the procedure.
- Dry mouth

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, Website: www.hpra.ie.

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

5. HOW TO STORE OMNEXEL

- Do not store above 25 °C.
- Keep this medicine out of the sight and reach of children.
- Do not use Omnexel after the expiry date which is stated on the blister pack and on the carton and label after 'EXP' (month/year)
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What Omnexel contains:

Each prolonged release tablet contains 400 micrograms tamsulosin hydrochloride.

Product imported from France, Spain, Greece, Poland and the Netherlands: macrogol 7,000,000, macrogol 8,000, magnesium stearate (E470b), butylhydroxytoluene (E321), colloidal anhydrous silica (E551), hypromellose (E464), iron oxide yellow (E172)

Product imported from Hungary: magnesium stearate, macrogol 7,000,000, macrogol 8,000

Film-coating: opadry yellow O3F22733 (Hypromellose, macrogol 8000, Iron oxide yellow (E172))

What Omnexel looks like and the contents of the pack:

Omnexel 400 microgram Tablets are round, biconvex, yellow, film-coated and debossed with the code '04'.

Omnexel tablets are packed in blisters that are supplied in an overlabelled cardboard carton containing 30 tablets.

Parallel Product Authorisation Number:

Omnexel Tablets - PPA0465/171/001

Product procured from within the EU and repackaged by the Parallel Product Authorisation Holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Manufacturer:

Astellas Pharmaceuticals Europe BV, Elisabethhof 19, 2353 EW, Leiderdorp, the Netherlands or Astellas Pharma Europe B.V., Sylviusweg 62, 2333 BE Leiden, The Netherlands or Delpharm Meppel B.V., Hogemaat 2, 7942 JG Meppel, The Netherlands.

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