

Package leaflet: Information for the user

OMSULA[®] 0.4 mg prolonged-release capsules, hard
tamsulosin hydrochloride

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

1. What Omsula is and what it is used for

The active ingredient in Omsula is tamsulosin. This is a selective alpha1A/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.

Omsula is used to treat the symptoms of an enlarged prostate - a condition technically known as benign prostatic hyperplasia or BPH. If the gland becomes enlarged, it can squeeze the urethra, interfering with the flow of urine. This can cause difficulty in starting urination, a weak flow of urine, and the need to urinate urgently or more frequently. Omsula doesn't shrink the prostate. Instead, it relaxes the muscle around it, freeing the flow of urine and decreasing urinary symptoms.

2. What you need to know before you take Omsula

Do not take Omsula

- if you are allergic to tamsulosin hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you feel dizzy when you stand up.
- if you have severe liver insufficiency.

Warnings and precautions

Talk to your doctor or pharmacist before taking Omsula.

- Before starting treatment you should tell your doctor if you are suffering from any other disease, particularly from kidney and liver disorders, heart and circulatory system diseases.
- Rarely, fainting can occur during the use of Omsula, 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.
- Periodic medical examinations are necessary to monitor the development of the condition you are being treated for.
- If you are undergoing eye surgery because of cloudiness of the lens (cataract) or increased pressure in the eye (glaucoma), please inform your eye specialist that you are using or have previously used Omsula. This is because Omsula may cause complications (Intraoperative Floppy Iris Syndrome (IFIS)) during the surgery. 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 adolescent under 18 years because it does not work in this population.

Other medicines and Omsula

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

In particular tell your doctor or pharmacist if you are taking:

- Diclofenac (an anti-inflammatory painkiller) and warfarin (used to prevent blood clotting). These medicines may have an influence on how fast tamsulosin is removed from the body.
- Medicines to lower your blood pressure such as verapamil or diltiazem.
- Medicines to treat a fungal infection such as ketoconazole or itraconazole.
- Other alpha blockers such as doxazosin, indoramin, prazosin or alfuzosin.
- Other alpha1A-blockers such as doxazosin, indoramin, prazosin or alfuzosin. Tamsulosin may lower your blood pressure when taken together with these medicines.
- Erythromycin, an antibiotic used to treat infections.

Please inform your doctor or dentist that you are on Omsula before any operation or dental procedure as there is a potential that your medicine may interfere with the effects of the anaesthetic.

You should only take medicines concomitantly with Omsula if your doctor allows it.

Pregnancy, breast-feeding and fertility

Omsula 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

No data is available whether Omsula adversely affects the ability to drive or operate machines. However it should be taken into account that in some patients drowsiness, blurred vision, dizziness and transient loss of consciousness (syncope) may occur.

Omsula contains sodium

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

3. How to take Omsula

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

If it is not prescribed otherwise by your doctor the recommended dose is one capsule daily, to be taken after breakfast or the first meal of the day.

Do not crunch or chew the capsule, swallow it whole.

If you take more Omsula than you should

Contact your doctor immediately or visit the emergency department of the nearest hospital as the consequences of accidental or deliberate overdose may require medical intervention.

If you forget to take Omsula

Take the forgotten capsule on the same day. However, on the next day do not take a double dose to make up for a forgotten dose; just resume treatment at one capsule a day.

If you stop taking Omsula

You should not stop taking it without consulting your doctor before. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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4. Possible side effects

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

Serious side effects are rare or very rare. Stop taking this medicine and see a doctor straight away if you experience any of the following symptoms - you may need medical treatment:

- a severe inflammatory eruption of the skin and mucous membranes, which is an allergic reaction to drugs or other substances called Stevens-Johnson syndrome, (may affect up to 1 in 10,000 people)
- swelling of the lower layers of the skin, often around the mouth or of the mucosa of the mouth or throat which can appear very quickly (may affect up to 1 in 1,000 people)
- priapism (painful, persistent, involuntary erection of the penis), in which case immediate medical aid is needed (may affect up to 1 in 10,000 people)
- serious skin rashes (erythema multiforme, dermatitis exfoliative) (frequency cannot be estimated from the available data).

The following side effects have also been reported:

Do not be alarmed by this list of possible side effects, you may not have any of them. Most patients do not notice any side effects. However if you do and they bother you, talk to your doctor.

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

- 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.
- dizziness, especially when you are getting up from a chair or bed.

Uncommon (may affect up to 1 in 100 people):

- dropping of blood pressure especially when standing up
- feeling of rapid heartbeat
- headache
- constipation
- diarrhoea
- nausea
- vomiting
- hives
- rash
- itching
- weakness
- obstructed or runny nose.

Rare (may affect up to 1 in 1000 people):

- fainting.

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

- nose bleeding
- dry mouth
- blurred vision, visual impairment.

If you begin to feel light-headed or dizzy, sit or lie down until you feel better.

As with other medicines of this type, drowsiness, blurred vision or swelling of the hands and feet can occur.

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 tamsulosin hydrochloride, the pupil may dilate poorly and the iris (the coloured circular part of the eye) may become floppy during the procedure (see also section 2 "Warnings and precautions").

In addition to the adverse events listed above, very rapid uncoordinated contractions of the heart, abnormal heart rhythm, abnormally rapid heartbeat and shortness of breath have been reported in association with Omsula use. Because these spontaneously reported events are from the worldwide post-marketing experience, the frequency of events and the role of Omsula in their causation cannot be reliably determined.

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 Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Omsula

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

Do not store above 30°C.

Store in the original package in order to protect from light.

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

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 Omsula contains

- The active substance is tamsulosin hydrochloride. Each capsule contains 0.4 mg of tamsulosin hydrochloride.
- The other ingredients are:

capsule filling:

microcrystalline cellulose, methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 per cent (including polysorbate 80, sodium laurylsulfate), talc, triethyl citrate, calcium stearate.

capsule shell:

yellow iron oxide (E172), black iron oxide (E172), red iron oxide (E172), titanium dioxide (E171), gelatin.

What Omsula looks like and contents of the pack

White or off-white pellets are filled in the capsules which sizes are about 18 mm lengthwise and 6.3 mm in external diameter, the upper part is brown opaque, lower part is buff opaque. 30, 90 or 100 capsules are packed into clear or white opaque PVC/PVDC//Aluminium blisters.

The blisters are packed into folding box with a package leaflet.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Hungary

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