

PACKAGE LEAFLET: INFORMATION FOR THE USER

OMNIC

400micrograms MR capsules

TAMSULOSIN HYDROCHLORIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What OMNIC is and what it is used for
2. Before you take OMNIC
3. How to take OMNIC
4. Possible side effects
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1. WHAT OMNIC IS AND WHAT IS IT USED FOR

OMNIC modified-release capsules are used to treat symptoms caused by an enlarged prostate gland (benign prostatic hyperplasia BPH).

The prostate gland surrounds the urethra (the tube with which urine passes from the bladder). When the prostate gland is enlarged it presses on the urethra causing it to narrow, so that it is difficult to pass urine. OMNIC modified-release capsules relax the muscles in the prostate gland, making the urethra wider and easing the passing of urine.

Before starting treatment with OMNIC, your doctor may want to carry out tests to check that you do not have any other conditions which are causing your symptoms.

2. BEFORE YOU TAKE OMNIC

Do not take OMNIC:

- If you are **allergic** to tamsulosin hydrochloride or any of the other ingredients of this medicine. Symptoms include sudden swelling of hands or feet, difficulty in breathing and/or itch and rash (angioedema).
- If you have a history of being dizzy or fainting when standing suddenly caused by low blood pressure (**orthostatic hypotension**).
- If you have **severe liver** problems.

Warnings and precautions

Talk to your doctor or pharmacist before taking OMNIC if you:

- suffer from **severe kidney** problems
- experience dizziness or fainting whilst taking your medicine. Please sit or lie down straight away until the symptoms disappear.
- have experienced rapid swelling of the hands or feet, breathing difficulties (angioedema) and/or skin rash and itching due to an allergic reaction.
- are planning to have cataract surgery (cataract removal eye surgery): Tell your ophthalmologist if you have used or are currently using this drug (or any other tamsulosin containing drug). This will influence your doctor's decisions concerning your medication as well as the surgery technique to be used. Ask your doctor if you should stop taking the medication for the duration of the surgery.

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 OMNIC

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

- When used with other alpha 1A-blockers e.g. doxazosin, prazosin and indoramin. If you take these with OMNIC your blood pressure may fall.
- Diclofenac (an anti-inflammatory painkiller) and warfarin (used to thin blood) may affect the way that OMNIC is handled by your body.
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OMNIC with food and drink

Tamsulosin should be taken after the first meal of the day.

Taking tamsulosin on an empty stomach may aggravate its adverse effects.

Pregnancy and breast-feeding

OMNIC is intended for **males only**.

Driving and using machines

OMNIC should not affect your ability to drive or use machinery. However, in some people OMNIC may cause dizziness, if you are affected do not drive or use machinery.

3. HOW TO TAKE OMNIC

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

Take after the first meal of the day whilst standing or sitting upright (not lying down). Swallow whole with a glass of water. Do not open the capsule this will affect how the medicine works.

The recommended dose is one capsule a day.

Your doctor has prescribed a suitable dose for you and your illness, and has specified the duration of the treatment.

You should not change the dose without speaking to your doctor first.

If you take more than you should

The symptoms of overdose are low blood pressure, vomiting and diarrhoea.

If you (or someone else) swallow a lot of capsules at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately.

If you forget to take the capsules

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose after the first meal of the day, it can be taken later the same day after food. If you have missed a day skip the forgotten dose and then take the next dose at the right time.

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 OMNIC and contact your doctor at once if you experience sudden swelling of hands or feet, difficulties in breathing and/or itch and rash, caused by an allergic reaction (angio-oedema).

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- **Common** (occurs in less than 1 in 10 users): dizziness, ejaculation disorders.
- **Uncommon** (occurs in less than 1 in 100 users): headache, rapid or irregular heart beat, dizziness especially when sitting or standing up, nasal inflammation causing a runny nose, constipation, diarrhoea, feeling sick, being sick, rash, itching, feeling of weakness.
- **Rare** (occurs in less than 1 in 1,000 users): swelling of hands or feet, difficulties in breathing and/or itch and rash (angioedema). Symptoms of low blood pressure (dizziness, fainting or weakness) occur rarely, sit or lie down straight away until the symptoms disappear. If you do not feel better please contact your doctor.
- **Very rare** (occurs in less than 1 in 10,000 users): painful, prolonged, unwanted erection (priapism), severe skin flushing (Stevens-Johnson syndrome).
- **Frequency not known:** There have been reports of irregular heart beat/pulse rate, racing heart and difficulty breathing associated with Tamsulosin use.

Changes in the eye have been noticed during cataract surgery.

If you get any side effects, talk to your doctor or pharmacist.

This includes any side effects not listed in this leaflet.

5. HOW TO STORE OMNIC

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

Store in the original package.

Keep the container tightly closed.

Do not use OMNIC after the expiry date which is stated on the label, blister and 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 to protect the environment.