

PACKAGE LEAFLET: INFORMATION FOR THE USER

OMNIC OCAS

400 micrograms prolonged-release tablets

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?

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1. WHAT OMNIC OCAS IS AND WHAT IS IT USED FOR

What is OMNIC OCAS

OMNIC OCAS contains the active substance tamsulosin hydrochloride. It acts by relaxing the muscles in the prostate and urethra (the tube that carries urine to the outside), and lets urine pass more readily through the urethra and aids urination.

In the prostate gland, bladder and urethra there are specialised cells containing α_{1A} -receptors that cause the muscles in the urethra to tighten.

OMNIC OCAS is an α_{1A} -adrenoceptor blocker, which reduces the action of these specialised cells and relaxes the muscles making it easier to pass water.

What OMNIC OCAS is used for

OMNIC OCAS is used to treat the symptoms associated with benign prostatic hyperplasia (BPH) which is enlargement of the prostate gland. These symptoms include difficulty in starting to pass water, frequent trips to the toilet to pass water, a feeling of not completely emptying the bladder and having to get up several times in the night to pass water.

2. BEFORE YOU TAKE OMNIC OCAS

Do not use OMNIC OCAS if you

- are **allergic to tamsulosin or any of the other ingredients of OMNIC OCAS**
- have a **severe liver condition**
- have **ever fainted or felt dizzy when suddenly sitting or standing up**. Dizziness can sometimes occur when taking OMNIC OCAS, particularly if you are also taking other alpha1- 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 using OMNIC OCAS

- 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 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 OCAS

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

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

- Medicines to lower your blood pressure such as verapamil and diltiazem
- Medicines to treat HIV such as ritonavir or indinavir
- Medicines to treat a fungal infection such as ketoconazole or itraconazole
- Other alpha blockers such as doxazosin, indoramin, prazosin or alfuzosin
- Erythromycin, an antibiotic used to treat infections

Please inform your doctor that you are on OMNIC OCAS 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

OMNIC OCAS 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 information available on whether OMNIC OCAS affects the ability to drive or to operate machinery or equipment. However, it is known that OMNIC OCAS may cause drowsiness, blurred vision, dizziness and fainting. If you suffer from these do not drive or operate machinery.

3. HOW TO TAKE OMNIC OCAS

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

The recommended dose for adults and the elderly is one tablet each day.

It can be taken with or without food. Swallow the tablet whole. Do not crunch or chew. Your doctor may want to examine you from time to time whilst you are taking this medicine.

If you take more OMNIC OCAS than you should

If you have taken too many tablets, contact your doctor immediately or go to the nearest hospital casualty department taking any remaining medication and this patient information leaflet with you.

If you forget to take OMNIC OCAS

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

If you have any further questions on the use of this product, ask your doctor, pharmacist or nurse.

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 (affects less than 1 in 1000 people)

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

Very rare (affects less than 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).
- Abnormal irregular heart rhythm (atrial fibrillation, arrhythmia, tachycardia), difficult breathing (dyspnoea).

The following side effects have also been reported:

Common (affects less than 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 (affects less than 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 (affects less than 1 in 1000 people)

- fainting

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

- blurred vision
- impaired vision
- nose bleeds (epistaxis)
- serious skin rashes (erythema multiforme, dermatitis exfoliative)
- 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE OMNIC OCAS

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 (EXP). The expiry date refers to the last day of that month.

Store below 30°C in the original package.

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.