PACKAGE LEAFLET: INFORMATION FOR THE USER Omnic Ocas®
0,4 prolonged release tablets (film-coated) 0.4 mg tamsulosin hydrochloride

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Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1 What Omnic Ocas 0,4 is and what it is used for
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1. WHAT OMNIC OCAS 0,4 IS AND WHAT IT IS USED FOR

The active ingredient in Omnic Ocas 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.

Omnic Ocas 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. BEFORE YOU TAKE OMNIC OCAS 0,4

Do not use Omnic Ocas

- if you are allergic (hypersensitive) to tamsulosin or to any of the other ingredients in Omnic Ocas. 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).

Take special care with Omnic Ocas

- Periodic medical examinations are necessary to monitor the development of the condition you are being treated for.
- Rarely, fainting can occur during the use of Omnic Ocas, 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, tell your doctor.
- 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 Omnic Ocas. 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.

Taking other medicines

Taking Omnic Ocas together with other medicines from the same class (alpha$_1$-adrenoceptor blockers) may cause an unwanted decrease in blood pressure.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

Taking Omnic Ocas with food and drink

You can take Omnic Ocas with or without food.

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 evidence that Omnic Ocas 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 OMNI OCAS 0,4

Always take Omnic Ocas exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure. The dosage is 1 tablet per day. You can take Omnic Ocas with or without food, preferably at the same time of each day. The tablet must be swallowed whole and not be crunched or chewed.
Omnic Ocas 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, Omnic Ocas is prescribed for long periods of time. The effects on the bladder and on urination are maintained during long-term treatment with Omnic Ocas.

If you take more Omnic Ocas than you should

Taking too many Omnic Ocas 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 Omnic Ocas.

If you forget to take Omnic Ocas

You may take your daily Omnic Ocas 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 Omnic Ocas

When treatment with Omnic Ocas is stopped prematurely, your original complaints may return. Therefore use Omnic Ocas 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, Omnic Ocas can cause side effects, although not everybody gets them.

Common (less than 1 in 10, more than 1 in 100 (1-10%)): 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 (more than 1 in 1000, less than 1 in 100 (0,1-1%)):
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 (more than 1 in 10,000, less than 1 in 1000 (0,01-0,1%)):
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 (less than 1 in 10,000 (<0,01%):
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 Omnic Ocas, 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as indicated below.

ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

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

5. HOW TO STORE OMNIC OCAS 0,4

Keep Omnic Ocas out of the reach and sight of children.

Do not use Omnic Ocas after the expiry date, which is stated on the blister pack and on the carton after 'EXP' (month and year). The expiry date refers to the last day of that month.

Store this medicine in the original pack.

This medicinal product does not require any special storage conditions.

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 to protect the environment.

6. FURTHER INFORMATION

What Omnic Ocas contains

The active ingredient is 0.4 mg tamsulosin hydrochloride (equivalent to 0.367 mg tamsulosin).

The other ingredients are: in the tablet core: macrogol 7.000.000, macrogol 8.000, magnesium stearate (E470b), butylhydroxytoluene (E321), colloidal silica (E551); in the tablet coating: hypromellose (E464) and the colorant yellow iron oxide (E172).

What Omnic Ocas looks like

Omnic Ocas tablets are round, yellow, film-coated and coded ‘04’.

Omnic Ocas tablets are packed in aluminium blisters that are supplied in a cardboard box printed Omnic Ocas 0,4. The packs contain 10, 14, 20, 28, 30, 50, 56, 60, 90, 100, or 200 tablets. Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturing site

Marketing Authorisation Holder
Astellas Pharmaceuticals A.E.B.E.
7 Kifisias Av. & 2 Neapoleos Str.
15123 Maroussi
Athens - Greece
Tel.: +30 210 8189900

Manufacturing site
Delpharm Meppel B.V.
Hogemaat 2
7942 JG Meppel
The Netherlands

Omnic Ocas is available on prescription only.

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