

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### OMNIC 0,4 mg modified release capsules, hard 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 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 symptoms 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.

#### **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
5. How to store OMNIC
6. Further information

#### **1. What OMNIC is and what it is used for**

The active ingredient in OMNIC 0,4mg 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 0,4mg 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**

##### **Do not take OMNIC**

- if you are allergic (hypersensitive) to tamsulosin or to any of the other ingredients in OMNIC 0,4mg. 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**

- 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 0,4mg 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 0,4mg. 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 0,4mg together with other medicines from the same class ( $\alpha_1$ -adrenoceptor antagonists) 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 OMNIC 0,4mg from the body (for example, ketoconazole, erythromycin).

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

### **Taking OMNIC with food and drink**

OMNIC 0,4mg must be taken after breakfast or the first meal of the day.

### **Pregnancy ,breast-feeding and fertility**

OMNIC 0,4mg 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 0,4mg 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 activities that require attentiveness.

## **3. How to take OMNIC**

Always take OMNIC 0,4mg 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 capsule per day to be taken after breakfast or the first meal of each day. The capsule must be swallowed whole and not be crunched or chewed. Usually, OMNIC 0,4mg is prescribed for long periods of time. The effects on the bladder and on urination are maintained during long-term treatment with OMNIC 0,4mg.

### **If you take more OMNIC than you should**

Taking too many OMNIC 0,4mg 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 0,4mg.

### **If you forget to take OMNIC**

You may take your daily OMNIC 0,4mg 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 capsule as prescribed. Never take a double dose to make up for the forgotten capsule.

### **If you stop taking OMNIC**

When treatment with OMNIC 0,4mg is stopped prematurely, your original complaints may return. Therefore use OMNIC 0,4mg 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 0,4mg 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 0,4, the pupil may dilate poorly and the iris (the coloured circular part of the eye) may become floppy during the procedure.
- Dry mouth

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.

#### **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 (for details see below). By reporting side effects you can help provide more information on the safety of this medicine.

#### **Greece**

National Organization for Medicines

284 Mesogeion

GR-15562 Cholargos, Athens

Tel: +30 21 32040380/337

Fax: +30 21 06549585

Website: <http://www.eof.gr>

## **Cyprus**

Pharmaceutical Services

Ministry of Health

CY-1475 Nicosia

Fax: + 357 22608649

Website: [www.moh.gov.cy/phs](http://www.moh.gov.cy/phs)

### **5. How to store OMNIC**

Store in the original package.

Keep out of the reach and sight of children.

Do not use OMNIC 0,4mg after the expiry date which is stated on the blister pack and on the carton after EXP. The expiry date refers to the last day of that month.

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 contains**

- The active substance is tamsulosin hydrochloride
- The other ingredients are microcrystalline Cellulose (E460), methacrylic acid - ethyl acrylate copolymer (1:1), polysorbate 80 (E433), sodium laurilsulfate, triacetin (E1518), calcium stearate (E470a) and talc (E553b) in the capsule content. Hard gelatin, indigotine (E132), titanium dioxide (E171), yellow iron oxide (E172) and red iron oxide (E172) in the capsule shell. Shellac (E904), Propylene glycol E1520 and black iron oxide (E172) in the printing ink.

#### **What OMNIC looks like and contents of the pack**

Greece

Carton with foil blisters containing 20 capsules. The capsules are orange/olive-green coloured.

Cyprus

OMNIC 0,4mg are orange/olive-green coloured capsules coded '0.4' and logo and '701'. OMNIC 0,4mg are packed in aluminium blisters that are supplied in a cardboard box. The packs contain 10, 20, 30, 50, 60, 90, 100 or 200 capsules. Not all pack sizes may be available.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Astellas Pharmaceuticals AEBE

6-8 Agisilaou Str.

151 23 Marousi

Athens – Greece

Tel no: +30 210 8189900

Fax no: +30 216 8008998

#### **Manufacturer**

Astellas Pharma Europe BV

Sylviusweg 62

2333 BE Leiden  
The Netherlands

**This leaflet was last approved on 14 June 2017 in Greece and Cyprus.**