

PATIENT INFORMATION LEAFLET

OMNIC[®] 0.4mg MODIFIED- RELEASE HARD CAPSULES Tamsulosin Hydrochloride

**WE ADVISE YOU TO READ THIS PACKAGE
INSERT EVEN IF YOU HAVE USED OMNIC
0.4MG BEFORE.
THE INFORMATION MAY HAVE CHANGED.**

What Omnic 0.4mg Capsules Contain

Omnic 0.4mg capsules contain 0.4mg tamsulosin hydrochloride

Omnic 0.4mg capsules are orange and olive green with '0.4' on the olive green part and the 'Yamanouchi logo' and '701' on the orange part.

They also contain the following inactive ingredients: microcrystalline cellulose, methylacrylic acid-ethyl acrylate copolymer (1:1), polysorbate 80, sodium laurilsulfate, triacetin, calcium stearate and talc. The capsule wall contains: gelatin, indigotine (E132), titanium dioxide (E171), yellow and red iron oxide (E172).

Pack sizes: Omnic 0.4mg capsules are available in blister packs of 30 capsules.

HOW DOES OMNIC WORK?

The active ingredient of Omnic is tamsulosin. This is an alpha-1-receptor blocker which reduces tension of the muscles in the prostate and urethra. This enables urine to pass more readily through the urethra and facilitates urination.

PRODUCT PROCURED FROM WITHIN THE EU BY THE PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing,
Unit 10, Ashbourne Business Park, Rath,
Ashbourne, Co. Meath.

Manufacturer: Omnic 0.4mg Capsules is manufactured by Astellas Pharma Europe B.V., Sylviusweg 62, 2333 BE Leiden, The Netherlands

What can Omnic be used for?

Omnic is used in men for the treatment of the complaints associated with benign prostatic hyperplasia such as: difficulty with urinating, dribbling, urgency and having to urinate frequently at night as well as during the day.

What you should know before using Omnic

WHEN YOU SHOULD NOT USE OMNIC

You should not take Omnic if you are hypersensitive to tamsulosin or to one of the inactive ingredients or suffer from serious liver insufficiency. You should also not take Omnic if you have suffered from dizziness when going to sit or stand up.

PRECAUTIONS FOR THE USE OF OMNIC

Periodic medical examinations are necessary during long term use of this product. Rarely, fainting can occur during the use of Omnic. At the first signs of dizziness or weakness you should sit or lie down until they have disappeared. If you are due to have cataract surgery, inform your doctor that you are taking Omnic.

Children

Do not give this medicine to children or adolescent under 18 years because it does not work in this population.

INTERACTIONS

So far, no interactions have been reported but combining different drugs can have damaging consequences, so make sure your doctor knows about any other medicines you are taking.

EFFECTS ON THE ABILITY TO DRIVE OR TO OPERATE MACHINERY

There is no evidence that Omnic affects the ability to drive or operate machinery. However, you should bear in mind that dizziness can occur, in which case you should not partake in these activities.

WARNING CONCERNING CERTAIN ADDITIVES

The capsule wall contains the colouring substance E171, which may rarely cause hypersensitivity reactions of the skin (itching, red spots).

Guidelines for the use of Omnic

PPA 465/86/1

HOW SHOULD OMNIC BE USED?

The normal dose is one capsule daily. This should be taken after breakfast or the first meal of the day. The capsule is swallowed whole. Do not chew or crunch the capsule.

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HAVE YOU MISSED A DOSE OF OMNIC?

You may take your daily Omnic capsule 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.

Repackaged and distributed by:

PCO Manufacturing,
Unit 10, Ashbourne Business Park,
Rath, Ashbourne, Co. Meath.

HAVE YOU TAKEN TOO MUCH OMNIC?

It is advisable to contact your doctor if you have taken too much Omnic

Leaflet prepared by PCO Manufacturing on July 2013

SIDE EFFECTS

Dizziness, particularly when going to sit or stand up, abnormal ejaculation, weakness, headache, palpitations, runny or blocked nose and hypersensitivity reactions such as rash, itching and local swelling. Occasionally, sickness and vomiting, diarrhoea and constipation. Rarely, faintness. Very rarely, priapism (a painful, prolonged, unwanted erection for which immediate medical treatment is required). If you experience any other side effects, check with your doctor or pharmacist.

HOW TO STORE OMNIC

- The capsule should not be used after the date stated on the carton label and blister pack.
- Store in the original package.
- Keep out of the reach and sight of children.

GENERAL GUIDELINES

- This medicine has been prescribed to you by your doctor. You should, therefore, strictly follow his/her directions. If you have any questions please consult your doctor or the pharmacist who supplied the medicine.
- Never give your medicine to other people and never use other people's medicine yourself
- Always make sure you are using the right medicine.
- Do not keep any medicine you no longer need. Do not throw medicines away but return them to your pharmacist.
- In case of complaints always mention the batch number. (see package)

Parallel Product Authorisation number: