

# Omnice<sup>®</sup> MR

tamsulosin hydrochloride modified release capsules

## What is Omnice MR?

Omnice MR contains 400 microgram tamsulosin hydrochloride in each modified release capsule, equivalent to 367 microgram tamsulosin. The capsules also contain: microcrystalline cellulose, methacrylic acid-ethyl acrylate copolymer 1:1, polysorbate, sodium laurilsulfate, triacetin, calcium stearate and talc. These all help to make the granules which are in the capsule. The capsule shell contains gelatin, and is coloured with indigotin (E132), titanium dioxide (E171), and yellow and red iron oxide (E172).

Omnice MR capsules have an orange body and an olive-green cap. The capsules are supplied in blister packs of 30.

Tamsulosin hydrochloride, the active ingredient of Omnice MR is an  $\alpha_{1A}$ -adrenoceptor blocker. It relaxes the muscles in the prostate and urethra, and lets urine pass more readily through the urethra and aids urination.

The product licence for Omnice MR is held by Astellas Pharma Ltd, Lovett House, Lovett Road, Staines, Middlesex. TW18 3AZ. The capsules are manufactured by Astellas Pharma Europe B.V., Elisabethhof 19, 2353 EW Leiderdorp, The Netherlands, at their site at Hogemaat 2, 7942 JG Meppel, The Netherlands.

## What is Omnice MR used for?

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

In the prostate gland, bladder and urethra there are specialised cells containing  $\alpha_{1A}$ -receptors that cause the muscles in the urethra to tighten. Omnice MR is an  $\alpha_{1A}$ -adrenoceptor blocker, which reduces the action of these specialised cells and relaxes the muscles making it easier to pass water.

## Before using Omnice MR

You should not use Omnice MR if you are allergic to tamsulosin or any of the inactive ingredients, or if you have a severe liver condition.

If you have ever fainted or felt dizzy when suddenly sitting or standing up, you should not take Omnice MR.

Dizziness can sometimes occur when taking Omnice MR, particularly if you are also taking other  $\alpha_1$ -blockers. If you do feel weak or dizzy make sure you sit or lie down straight away until the symptoms have disappeared. You should not drive or operate machinery if you feel faint, dizzy, drowsy or have blurred vision until the symptoms have passed. Make sure you tell your doctor about all other medicines you are taking particularly those that lower blood pressure as there maybe a theoretical risk of an enhanced effect whilst taking Omnice. If you are undergoing eye surgery because of cloudiness of the lens (cataract), please inform your eye specialist that you are using or have previously used 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.

## Taking Omnice MR.

For adults and the elderly, the dose is one capsule after the same meal each day. Swallow the capsule whole with a drink of water. Do not chew or crunch the capsule. Your doctor may want to examine you from time to time whilst you are taking this medicine.

## If you have missed your dose of Omnice MR

You may take your capsule later the same day after food if you have forgotten to take it earlier. If you have missed a day, just continue to take your daily capsule from the next day. If you have taken too many capsules, tell your doctor straight away.

## After taking Omnice MR.

A small number of people may show side-effects after taking Omnice MR. The following have been reported: Runny or blocked nose, fainting, dizziness, abnormal ejaculation (i.e. less, or no noticeable, semen ejaculated), dizziness as you sit or stand up, weakness,

headache or palpitations (rapid or irregular heart beat). The following side-effects have been reported less often: Gastro-intestinal symptoms such as nausea and vomiting (feeling or being sick), diarrhoea or constipation and hypersensitivity reactions such as rash, itching, redness or local swelling. As with other medicines of this type, drowsiness, blurred vision, dry mouth or swelling of the hands and feet can occur.

Tell your doctor if any of these symptoms become troublesome.

There have been very rare reports of angioedema (swelling of the face, throat or tongue linked to allergy) and priapism (persistent and painful erection usually unrelated to sexual activity). Consult your doctor immediately if these occur.

You should also tell your doctor or pharmacist if you have any other side-effects after taking Omnic MR.

If you are undergoing eye surgery because of cloudiness of the lens (cataract) and are already taking or have previously taken tamsulosin hydrochloride, the pupil may dilate poorly and the iris (the coloured circular part of the eye) may become floppy during the procedure. This only occurs during the operation and it is important for the eye specialist to be aware of this possibility as the operation may need to be performed differently.

#### **General information**

Keep all medicines out of the reach of children. Do not use the capsules after the expiry date printed on the pack. They may be kept at temperatures of up to 30 °C in the pack in which they are supplied.

Remember your medicines have been prescribed for you. Never give your medicines to others, even if it does seem that they have the same conditions as you.

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