PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Omnic 0.4
Modified-Release Capsules

The active ingredient and its quantity per dosage unit:
Tamsulosin Hydrochloride 0.4 mg/cap

For a list of the inactive and allergenic ingredients in the preparation - see Section 6.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

The medicine is not intended for children or adolescents under the age of 18.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the treatment of functional symptoms caused by benign prostatic hyperplasia (BPH).

Therapeutic group: Selective alpha$_{1A,1D}$-adrenoreceptor antagonist.

2. BEFORE USING THE MEDICINE:

X Do not use the medicine if:

- you are sensitive (allergic) to tamsulosin or to any of the other ingredients contained in the medicine. Hypersensitivity may present as sudden local swelling of the soft tissues of the body (e.g., the throat or tongue), difficulty breathing and/or itching and rash (angioedema).
- you suffer from severe liver failure.
- you suffer from dizziness or faint due to decreased blood pressure when changing posture (transitioning to a sitting or standing position).

! Special warnings regarding use of the medicine

- Periodic medical examinations are necessary to monitor the progression of the condition you are being treated for.
- In rare instances, this medicine can cause fainting. At the first signs of dizziness or weakness, the patient should sit or lie down until the signs pass.
- **Before treatment with Omnic 0.4, inform the doctor if:**
  - you suffer or have suffered in the past from severe kidney problems.
  - you are about to undergo eye surgery for cataract or you suffer from elevated intraocular pressure (glaucoma). Inform the ophthalmologist of present or past use of the medicine. When necessary, the ophthalmologist will take precautions (medicinal or surgical). Consult your doctor about stopping treatment with the medicine before eye surgery for cataract or surgery to treat elevated intraocular pressure (glaucoma).

! Children and adolescents

The medicine is not intended for children and adolescents under the age of 18, as the preparation is not effective in this population.

Tests and follow-up
You should undergo periodic medical examinations necessary for monitoring your medical condition.

Drug interactions
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is especially important to inform the doctor or pharmacist if you are taking:

- Medicines from the alpha blocker class for lowering blood pressure - the combination may cause an unwanted drop in blood pressure.
- Medicines that may decrease the clearance of Omnic 0.4 from the body – for example: ketoconazole, erythromycin.

Use of the medicine and food
Omnic 0.4 should be taken after breakfast or after the first meal of the day.

Pregnancy, breastfeeding and fertility
Omnic 0.4 is not intended for women.
In men, cases of abnormal ejaculation have been reported (ejaculation disorder). This means that the semen does not leave the body via the urethra, but instead goes into the urinary 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 0.4 affects the ability to drive or to operate machines that require alertness.
However, Omnic 0.4 may cause dizziness, and therefore caution must be exercised when driving and/or operating machines that require alertness.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally one capsule per day.
Do not exceed the recommended dose. It is recommended to take the capsule at the same time every day.
How to take - Swallow the medicine whole with water.
Do not chew or crush the capsule.

If you accidentally take too high a dosage, this may cause an unwanted drop in blood pressure, an increase in heart rate and fainting.
If you took an overdose, or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of medicine with you.

If you forgot to take this medicine at the required time, do not take a double dose. Take the next dose at the usual time and consult the doctor.

Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.
If you prematurely stop taking the medicine, your symptoms may return.
Always consult with the doctor if you are considering stopping the treatment.

Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS:

As with any medicine, the use of Omnic 0.4 may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Common side effects – effects that occur in 1-10 users in 100:
- dizziness, especially when suddenly transitioning to a sitting or standing position.
- abnormal ejaculation (ejaculation disorder). This means that semen does not leave the body via the urethra, but instead goes into the urinary bladder (retrograde ejaculation), or the ejaculation volume is reduced or absent (ejaculation failure). This phenomenon is harmless.

Uncommon side effects - effects that occur in 1-10 users in 1,000:
- headache, palpitations (the heart beats faster than usual in a noticeable manner), low blood pressure (sometimes experienced as dizziness when getting up quickly from a sitting or lying position), runny or blocked nose (rhinitis), constipation, diarrhea, nausea, vomiting, weakness (asthenia), rash, itching and hives (urticaria).

Rare side effects – effects that occur in 1-10 users in 10,000:
- faintness and sudden swelling of the soft tissues of the body (e.g., throat, tongue), breathing difficulties and/or itching and rash, sometimes as an allergic reaction (angioedema).

Very rare side effects – effects that occur in less than one user in 10,000:
- 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, nose or genitals (Stevens-Johnson syndrome).

Side effects of unknown frequency (effects whose frequency has not yet been determined):
- blurred vision.
- impaired vision.
- nosebleeds (epistaxis).
- severe skin rash (erythema multiforme, exfoliative dermatitis).
- irregular heart rhythm (atrial fibrillation, arrhythmias, tachycardia), breathing difficulty (dyspnea).
- if you are undergoing eye surgery for cataract or for elevated intraocular pressure (glaucoma), and are taking or have previously taken this medicine, there may be a phenomenon during the surgery of a constricted pupil that does not dilate, and the colored part of the eye may become floppy (IFIS).
- dry mouth.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (EXP) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions:
Do not store at a temperature that exceeds 30°C.
Store in the original package.

6. FURTHER INFORMATION:

In addition to the active ingredient, the medicine also contains:
Microcrystalline Cellulose, Methylacrylic Acid - Ethyl Acrylate Copolymer (1:1), Triacetin, Polysorbate 80, Talc, Calcium Stearate, Sodium Lauryl Sulphate.

Capsule composition:
Hard Gelatin, Titanium Dioxide E171, Yellow Iron Oxide E172, Red Iron Oxide E172, Indigotin E132.

What does the medicine look like and what are the contents of the package:
The Omnic 0.4 mg capsule is orange/olive-green. “0.4”, logo and “701” are imprinted on the capsule. Omnic 0.4 mg is packaged in packs of 10 and 30 capsules. Not all package sizes may be marketed.

License holder/ importer and address: CTS Ltd., 4 Haharash St., Hod Hasharon, 4524075.

Manufacturer name and address: Astellas Pharma Europe B.V.
Sylviusweg 62, 2333 BE Leiden, P.O.B. 344, 2300 Ah Leiden, The Netherlands.

This leaflet was revised in 08/2022 according to the Ministry of Health guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 111-91-29428-00