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

The medicine is dispensed with a doctor's prescription only

Omnic Ocas 0.4 Prolonged-release film-coated tablets

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

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 for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

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

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the treatment of functional disorders of the lower urinary tract associated with benign prostatic hyperplasia (BPH).

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

The mode of action of the active ingredient of the preparation is to reduce tension of the smooth muscles in the prostate and urethra, enabling urine to pass more readily through the urethra and thereby facilitating urination. In addition, it diminishes sensations of urge.

2. BEFORE USING THE MEDICINE:

X Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient 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 in breathing and/or itching and rash (angioedema).
- you suffer from severe liver problems.
- you suffer from fainting due to decreased blood pressure when changing posture, for example when transitioning to a standing or sitting position.

! Special warnings regarding use of the medicine

- Consult with the doctor before taking the medicine.
- In rare cases, as with other preparations from the same family, Omnic Ocas can cause fainting. When you suffer from dizziness or fainting, sit or lie down until the signs pass.
- **Before treatment with Omnic Ocas, inform the doctor:**
  - if you suffer from severe kidney problems.
  - If you are undergoing or are scheduled for eye surgery for cataracts or surgery to treat increased intraocular pressure (glaucoma). Inform the ophthalmologist about present use, intention to use or past use of the medicine. When necessary, the ophthalmologist will take prophylactic measures (medicinal or surgical). Consult the

treating doctor about stopping treatment with the medicine before cataract surgery or surgery to treat increased intraocular pressure.

Children and adolescents
The medicine is not intended for children and adolescents below 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:

- Antihypertensive medicines from the same class (alpha adrenoreceptor blockers). The combination may cause an undesirable decrease in blood pressure.
- Medicines that may decrease clearance of the medicine Omnic Ocas from the body (e.g., ketoconazole and erythromycin).

Use of the medicine and food:
Omnic Ocas can be taken with or without food.

Pregnancy, breastfeeding and fertility:
Omnic Ocas is not intended for use in 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 Ocas affects the ability to drive or to operate machines that require alertness.
However, Omnic Ocas 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 tablet per day, recommended to be taken at the same hour every day.

Do not exceed the recommended dose.
Crushing/splitting/chewing:
Do not chew or crush! Swallow the medicine whole with a little water.

Remnants of the tablet may appear in the stools. Since the active ingredient has been released, the effectiveness does not decrease.

If you accidentally take too high a dosage, this may cause an undesirable drop in blood pressure, an increase in heart rate and a feeling of faintness.
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, you may take the medicine later the same day. If you forgot to take the medicine and missed a day of treatment, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment regimen as recommended by the doctor, even if your medical problems have disappeared.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.
If you stop taking the medicine earlier than recommended to you by the doctor, your medical problems may recur.
Always consult with the doctor if you are considering discontinuing the treatment.

Do not take medicines in the dark! Check the label and dose <u>each time</u> 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. <u>SIDE EFFECTS:</u>

As with any medicine, the use of Omnic Ocas 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 transitioning to a sitting or standing position.
- abnormal ejaculation - 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
- heart palpitations (awareness of a heartbeat which is more rapid than normal)
- decreased blood pressure accompanied by dizziness (e.g., when getting up quickly from a seating or lying position)
- runny nose or nasal congestion (rhinitis)
- constipation, diarrhoea, nausea, vomiting
- weakness (asthenia)
- rash, itching, 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 (unwanted prolonged painful 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 with unknown frequency (effects whose frequency has not yet been determined):
- blurred vision
- impaired vision
- nose bleeds (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 cataracts or surgery to treat increased intraocular pressure (glaucoma), and you are taking or have previously taken Omnic Ocas, a constricted non-dilating pupil may occur during surgery as well as a floppy iris (the coloured part of the eye)
- 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 closed place out of the reach and sight of children and/or infants in order 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:
Store at a temperature below 25°C.
Store in the original package.

6. FURTHER INFORMATION:

In addition to the active ingredient, the medicine also contains:
Macrogol 7000000, Macrogol 8000, Magnesium stearate, Hypromellose, Iron oxide yellow (E172).

What does the medicine look like and what are the contents of the package:
The Omnic Ocas tablet is round and has a yellow colour. The tablet is imprinted with "04".
Omnic Ocas is packaged in packs of 10, 14, 28, 30, 50, 56, 60, 90 tablets.
Not all package sizes may be marketed.

License holder 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

The format of this leaflet was determined by the Ministry of Health, and its content was checked and approved by the Ministry of Health in 10/2014. It was updated, in accordance with Ministry of Health guidelines, in 12/2020.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 136-04-31299