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

The medicine is dispensed with a doctor's prescription only

Tamsulin®

Modified release capsules

Active ingredient:
Each capsule of Tamsulin contains:
0.4 mg tamsulosin hydrochloride

For the list of the inactive ingredients and allergens in the medicine - see section 6.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, please refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

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

1. What is the medicine intended for?

The medicine is intended for treatment of functional symptoms caused as a result of benign prostate enlargement.

Therapeutic group: Alpha$_{1A,1D}$-adrenoreceptor selective antagonist.

2. Before using the medicine:

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (for the list of the additional ingredients, see section 6). Hypersensitivity may be manifested by sudden local swelling of soft body tissues (e.g. throat or tongue), difficulty breathing and/or itching and rash (angioedema).
- You suffer from severe liver failure.
- You suffer from dizziness or fainting as a result of a drop in blood pressure when changing position (transition to sitting or standing).

Special warnings regarding the use of the medicine:

- Periodic medical examinations are required to monitor the development of the medical condition for which you are being treated.
- In rare cases, this medicine can cause fainting. Upon the appearance of the first symptoms of dizziness or weakness, the patient should sit down or lie down until the effect disappears.

  Before treatment with Tamsulin tell the doctor if:
- You suffer or have suffered in the past from severe kidney problems.
- If you are going to have eye cataract surgery or if you suffer from increased pressure in the eye (glaucoma), inform the eye doctor of current or past use of the medicine. If necessary, the eye doctor will take medicinal or surgical preventive measures. Consult the attending doctor about discontinuing treatment with the medicine before eye cataract surgery, or surgery for treatment of increased

pressure in the eye (glaucoma).

Children and adolescents:
The medicine is not intended for children and adolescents under the age of 18 years, since it is ineffective in this population.

Tests and follow-up:

Periodic medical examinations, necessary for monitoring your medical condition should be performed.

Drug interactions:

If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell the doctor or pharmacist. Especially inform the doctor or pharmacist if you are taking:

- Medicines to prevent blood clotting (warfarin).
- Medicines for lowering blood pressure of the alpha blocker group (e.g. doxazosin, prazosin), other medicines that lower blood pressure: concomitant use could cause undesirable lowering of blood pressure.
- Diclofenac.
- Medicines that may reduce the clearance of Tamsulim from the body, for example: ketoconazole, erythromycin.
- Medicines for the treatment of HIV, for example: ritonavir, indinavir.

Use of this medicine and food:
Take Tamsulin after breakfast or after the first meal of the day.

Pregnancy, breastfeeding and fertility:
Tamsulin is not intended for women.
In men, cases of abnormal ejaculation (ejaculation disorders) have been reported; meaning that the semen does not exit from the body through the urethra, but rather passes into the bladder (retrograde ejaculation) or the ejaculation volume decreases or disappears (non-ejaculation). This phenomenon is not harmful.

Driving and use of machinery:
There is no evidence that Tamsulin affects the ability to drive or operate machinery which requires alertness.
Nevertheless, Tamsulin may cause dizziness, and therefore you need to be careful when driving and/or operating machinery that requires alertness.

3. How to use this medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure regarding the dosage and the manner of treatment.
The dosage and the manner of treatment will be determined by the doctor only.
The standard dosage is usually: one capsule daily. It is recommended to take the capsule at the same time every day.

Do not exceed the recommended dosage.

How to take: swallow the capsule whole, with a glass of water, standing or sitting straight (not lying down). Do not chew or crush the capsule or its contents, since this impairs the release mechanism of the active ingredient from the capsule.

For those with swallowing difficulties, the capsule can be opened and the granules in it swallowed immediately without chewing them.

If you accidentally took a higher dosage, this can cause an undesirable lowering of the blood pressure, increase in heart rate and fainting.
If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or a hospital emergency room and bring the medicine package with you.

If you forgot to take this medicine at the set time, do not take a double dose. Take the next dose at the usual time and consult the doctor.
Adhere to the treatment as recommended by the doctor.
Even if your state of health improves, do not stop the treatment with the medicine without consulting the doctor.

If you stop taking the medicine too soon, the symptoms may return.
Always consult with the doctor if you are considering discontinuing the treatment.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take a medicine. Wear glasses if you need them.

If you have further questions concerning the use of the medicine, consult the doctor or pharmacist.

4. Side effects

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

Stop the use and refer to the doctor immediately if a sudden allergic reaction appears (rare). The symptoms include swelling of the hands and/or the feet, breathing difficulties, itching, skin rash.

<u>Additional side effects:</u>

Common side effects (appear in 1-10 users out of 100):
Dizziness, especially in the sudden transition to sitting or standing; abnormal ejaculation (ejaculation disorder) - meaning that the semen does not exit the body through the urethra, but rather passes into the bladder (retrograde ejaculation) or the ejaculation volume decreases or disappears (non-ejaculation), this phenomenon is not harmful.

Uncommon side effects (appear in 1-10 users out of 1,000):
Headache; palpitations (the heart is noticeably beating faster than usual), low blood pressure (felt at times 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; hives (urticaria).

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

Very rare side effects (appear in less than 1 user out of 10,000):
Priapism (painful prolonged unwanted erection, which requires immediate medical attention); rash, inflammation and blisters on the skin and/or in the 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; bleeding from the nose (epistaxis); severe skin rash (erythema multiforme), scaling skin inflammation (dermatitis exfoliative); irregular heart beat (atrial fibrillation, arrhythmia, accelerated heartbeat); breathing difficulties (shortness of breath); If you are undergoing eye cataract surgery or surgery for treatment of increased pressure in the eye (glaucoma) and you are taking or have taken the medicine in the past, during the course of the surgery, pupil constriction which does not dilate as well as the colored part of the eye becoming floppy (IFIS) may occur; dry mouth.

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

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects or by entering the link:
https://sideeffects.health.gov.il/

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or babies, 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. date) stated on the package. The expiry date refers to the last day of that month.

Storage conditions: Store in the original package, below 25°C.

6. Additional information

In addition to the active ingredient, the medicine also contains:
Methacrylic acid - ethyl acrylate copolymer, gelatin, glyceryl dibehenate, maltodextrin, sodium alginate, purified water, macrogol 6000, sodium lauryl sulphate, polysorbate 80, titanium dioxide (E-171), yellow iron oxide (E-172), colloidal anhydrous silica, sodium hydroxide, red iron oxide (E-172), simethicone emulsion 30%.

What does the medicine look like and what does the package contain?
Orange colored capsules, containing white-yellowish granules, in blister packs of 30 capsules.

Registration Holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301, Israel.

Manufacturer: Bluepharma Industria Farmaceutica S.A., Sao Martino Do Bispo, 3045-16 Coimbra, Portugal

Medicine registration number in the National Medicines Registry of the Ministry of Health:
138-43-31538

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