Patient Leaflet According to the Pharmacists' Regulations (Preparations) - 1986

This medicine is sold with a doctor's prescription only

Tamsulin®

Modified-Release Capsules

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

For the list of additional ingredients, please see section 6.

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

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

1. What is the medicine intended for?

The medicine is intended to treat functional symptoms of benign enlargement of the prostate.

Therapeutic group: Selective Alpha $_{1A,\ 1D}$ adrenergic receptor blocker.

2. Before you take the medicine:

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient, or to any of the additional ingredients this medicine contains (for the list of the additional ingredients, please see section 6).
- You suffer from severe liver insufficiency.
- You suffer or have suffered in the past from low blood pressure, dizziness or fainting as a result of a decrease in blood pressure, for example during a sudden transition from lying to standing or sitting (orthostatic hypotension).

Special warnings regarding the use of this medicine:

- Do not use this medicine without consulting your doctor before starting treatment: if you suffer or have suffered in the past from impaired function of: the kidney/urinary system.

- Before the start of treatment and during the treatment period with this medicine, a kidney function test, rectal examination and, if necessary, testing to determine the PSA should be performed.
- If you are sensitive to any food or medicine, you are to inform your doctor before taking this medicine.
- This medicine may seldomly cause a decrease in blood pressure while standing (even leading to fainting). Thus, in the event that dizziness or weakness develops, the patient should sit or lie down until the phenomenon passes.
- If you are about to undergo eye cataract surgery, or if you suffer from an increase in intraocular pressure (glaucoma), inform your ophthalmologist of current or past use of this medicine. If necessary, the ophthalmologist will take preventative measures (medicinal or surgical). Consult your attending doctor about discontinuing treatment with the medicine before eye cataract surgery, or surgery for the treatment of an increase in intraocular pressure.
- This medicine is not intended for children and adolescents under the age of 18, since it is ineffective in this population.

Drug interactions:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements.
You should especially inform your doctor or pharmacist if you take:

- Medicines against blood clotting (warfarin).
- Medicines to reduce blood pressure from the alpha-blockers group (for example doxazosin, prazosin), medicines that reduce blood pressure: the combination may cause an unwanted decrease in blood pressure.
- Diclofenac.
- Medicines that may decrease the clearance of Tamsulin from the body, for example: ketoconazole, erythromycin.
- Medicines for the treatment of HIV, for example: ritonavir, indinavir.

Use of the 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, instances of abnormal ejaculation (ejaculation disorders) have been reported; meaning that the semen does not exit the body through the urethra, but rather passes into the urinary bladder (retrograde ejaculation) or the volume of ejaculate decreases or

disappears (ejaculation failure). This phenomenon is not harmful.

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

3. How should this medicine be used?
Always use the medicine according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure regarding the dosage and manner of treatment.
The dosage and manner of treatment will be determined by the doctor only.
The standard dosage is usually: one capsule daily, recommended to be taken at the same time each day.
Do not exceed the recommended dose.
Swallow the capsule whole with water (while standing or sitting upright to prevent choking). Do not chew or crush the capsule or its contents since this compromises the release mechanism of the active ingredient from the capsule.

For those with difficulty swallowing, the capsule may be opened and the granules within swallowed immediately without chewing them.

Tests and follow up
Periodic medical tests needed in order to monitor your medical condition should be performed. Also see section 'Special warnings regarding the use of this medicine.'

If you have accidentally taken a higher dosage: a higher dosage may cause an unwanted decrease in 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 hospital emergency room and bring the medicine package with you.
If you forgot to take the medicine at the designated time, do not take a double dose. Take the next dose at the regular time and consult with your doctor.
Be consistent with the treatment as recommended by your doctor.
Even if your condition improves, do not stop treatment with this medicine without consulting your
doctor.
If you stop taking the medicine before the designated time, the symptoms may return. Always consult with your doctor if you consider stopping the treatment.

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

If you have any further questions regarding the use of this 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 while reading the list of side effects. You may not suffer from any of them.

Discontinue use and refer to your doctor immediately if a sudden allergic reaction appears (rare).

The symptoms include: swelling of the hands and/or feet, difficulty breathing, itchiness, skin rash.

Additional side effects:

Common side effects (appear in 1-10 users out of 100):

Dizziness, especially in the sudden transition to sitting or standing; abnormal ejaculation – meaning that the semen does not exit the body through the urethra, but rather passes into the urinary bladder (retrograde ejaculation), or the volume of ejaculate decreases or disappears (ejaculation failure), (this phenomenon is not harmful).

Uncommon side effects (appear in 1-10 users out of 1,000):

Headache, exhaustion, low blood pressure while standing, rapid or irregular pulse, rhinitis (runny nose), nasal congestion, constipation, diarrhea, nausea, vomiting, rash, weakness, itchiness, hives (urticaria).

Rare side effects (appear in 1-10 users out of 10,000):

Feeling faint and sudden swelling in the body's soft tissue (for example: throat, tongue), breathing difficulties and/or itchiness and rash, at times as an allergic reaction (angioedema).

Very rare side effects (appear in less than 1 user out of 10,000):

Prolonged erection (priapism); rash, inflammation and blisters on the skin and/or on the mucosa of the lips, eyes, mouth, nose or genitals (Stevens-Johnson syndrome), heart rate disturbances, shortness of breath.

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Blurred vision, impaired vision, nose bleeds, severe skin rash (erythema multiform, dermatitis exfoliative), irregular heart beat (atrial fibrillation, arrythmia, accelerated heart rate), breathing difficulties.
- If you undergo eye cataract surgery or surgery to treat an increase in intraocular pressure (glaucoma), and you take the medicine or have taken it in the past, pupil constriction which does not dilate during the course of the surgery as well as intraoperative floppy iris (IFIS) syndrome may occur.
- Dryness in the mouth.

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

Side effects may be reported to the Ministry of Health by clicking on the link "Report on

side effects following medicinal treatment" found on the homepage of the Ministry of Health website (www.health.gov.il) which leads to the 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 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. date) stated on the package. The expiry date refers to the last day of that month.

Storage conditions: Store below 25^{O}C in the original package.

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

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

Registration holder: Rafa Laboratories Ltd., P.O.Box 405, Jerusalem 9100301.
Manufacturer: Bluepharma, Portugal

This leaflet from June 2020 is in the format determined by the Ministry of Health and its content is in accordance with the innovative medicine's leaflet that was checked and approved by the Ministry of Health in October 2014.

Medicine registration number in the National Medicine Registry of the Ministry of Health: 1384331538

B-931003