

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS
(PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

Tamsulin[®]
Controlled release capsules

Active ingredient:

Each capsule of Tamsulin contains:
0.4 mg tamsulosin hydrochloride.

For a list of 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 to treat 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 the treatment of functional symptoms caused by benign prostate enlargement.

Therapeutic group: Alpha_{-1A, 1D} adrenoreceptor selective antagonist.

Tamsulin works by relaxing the muscles in the prostate gland and urethra (the duct conveying urine out of the body), allows easier flow of urine through the urethra and assists urination.

In the prostate gland, the urinary bladder and the urethra, there are specialized cells containing alpha_{-1A} receptors, which cause contraction of the muscles in the urethra. Tamsulin blocks alpha_{-1A} adrenoreceptors, reducing the activity of these specialized cells and relaxing the muscles, making urination easier.

Tamsulin is intended for the treatment of symptoms relating to benign prostatic hyperplasia (BPH), i.e. enlargement of the prostate gland. These symptoms include difficulty starting urination, increased urination frequency, feeling of partial emptying of the urinary bladder and a need to wake up several times a night to urinate.

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 disorder.
- You ever fainted or felt dizziness when suddenly changing to a sitting or standing position, as a result of a drop in blood pressure.

Special warnings regarding the use of the medicine

- Before, and at fixed time intervals throughout the treatment with the medicine, periodic medical tests need to be carried out to monitor the development of the medical condition for which you are being treated.
- Rarely, this medicine can cause fainting. If you feel weak or dizzy, sit down or lie down immediately, until the symptoms disappear.

Before treatment with Tamsulin tell the doctor if:

- You suffer from kidney problems.
- You are undergoing or have been scheduled for eye surgery due to cloudiness of the lens (cataract) or increased pressure in the eye (glaucoma).
Inform the eye doctor if you have used the medicine in the past, you are currently using it or are planning to use tamsulosin hydrochloride. The eye doctor can then take appropriate precautionary measures regarding medicines or the surgical methods he will use.
Consult the attending doctor whether you need to postpone or temporarily discontinue treatment with the medicine when you undergo eye surgery due to cloudiness of the lens (cataract), or 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 not effective in this population.

Tests and follow-up

You are to undergo periodic medical tests, necessary for monitoring your medical condition.

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:

- Warfarin (medicine to prevent blood clotting). This medicine may accelerate the clearance of Tamsulin from the body and thereby shorten the duration of its effect.
- Medicines to lower blood pressure, such as verapamil and diltiazem.
- Other alpha blockers, such as doxazosin, indoramin, prazosin or alfuzosin. Concomitant use could lead to a drop in the blood pressure and cause dizziness or feeling faint.
- Diclofenac, an analgesic and anti-inflammatory medicine. This medicine may accelerate the clearance of Tamsulin from the body and thereby shorten the duration of its effect.
- Medicines that may reduce the clearance of Tamsulin from the body, for example: ketoconazole or itraconazole (medicines for treatment of a fungal infection), erythromycin (antibiotic used for treatment of infections).
- Medicines for treatment of HIV, for example ritonavir or indinavir.

Before any surgery or dental treatment, tell the doctor you are taking Tamsulin, as the medicine may interfere with the effects of the anesthetic.

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 use in women.

In men, an ejaculation disorder has been reported. This means that the semen is not excreted from the body through the urethra but rather passes into the bladder (retrograde ejaculation), or the ejaculation volume decreases or a lack of ejaculation (ejaculation failure). This phenomenon is not harmful.

Driving and use of machinery

There is no available information about a possible effect of Tamsulin on the ability to drive or operate machinery or equipment.

Nevertheless, it is known that Tamsulin may cause drowsiness, blurred vision, dizziness and fainting. If you suffer from these effects, do not drive or operate machinery.

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about 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.

It is recommended to take the capsule at the same time every day.

Do not exceed the recommended dosage.

Swallow the capsule whole, with a glass of water, standing up or sitting up 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, you can open the capsule and swallow the granules in it immediately without chewing them.

If you accidentally took a higher dosage, there may be a severe drop in blood pressure, increase in heart rate, dizziness, fainting and generally feeling unwell.

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 package of the medicine and the patient leaflet with you.

If you forgot to take this medicine at the set time, you can take the capsule later the same day. If you missed a day, continue to take your daily capsule the next day at the usual time. Do not take a double dose to make up for a forgotten dose.

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.

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 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 taking the medicine and consult the doctor immediately if one of the following side effects appears - you may require medical treatment:

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

Swelling of the face, throat or tongue, accompanied by allergy-related breathing problems

(angioedema).

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

Painful extended erection, usually unrelated to sexual activity; rash, inflammation and blisters on the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (Stevens-Johnson syndrome).

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

Abnormal irregular heart beat (atrial fibrillation, arrhythmia, tachycardia), difficulties breathing (shortness of breath).

Additional side effects:

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

Dizziness; ejaculation disorder - namely, the semen is not excreted from the body through the urethra but rather passes into the bladder (retrograde ejaculation), or the ejaculation volume decreases or a lack of ejaculation (ejaculation failure). This phenomenon is not harmful.

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

Weakness (asthenia); headache; runny or congested nose (rhinitis); palpitations (rapid or irregular heartbeat); dizziness when sitting up or standing up (postural hypotension); digestive symptoms such as constipation or diarrhea, nausea, vomiting; hypersensitive reactions such as rash, itching, redness, local swelling and breathing difficulties - hives (urticaria).

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

Fainting.

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), inflammation of the skin accompanied by peeling (dermatitis exfoliative)]; dry mouth.

During eye cataract surgery or surgery for treatment of increased pressure in the eye (glaucoma), an effect called IFIS may occur: pupil constriction which does not dilate, as well as the iris (the colored part of the eye) becoming floppy, which is related to the treatment with tamsulosin hydrochloride. This effect may increase the risk of eye complications during and after the surgery.

As with other medicines of this kind, there may be drowsiness, blurred vision or swelling of the hands and feet.

If a side effect appears, if any of the side effects worsens, or 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 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 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 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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