The format of this leaflet was determined by the Ministry of Health and its content was checked and approved

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

The medicine is dispensed with a doctor's prescription only

Tamsu P.R. Teva

Prolonged-release tablets

Composition

Each film-coated, prolonged-release tablet contains:

Tamsulosin hydrochloride 0.4 mg

For information about inactive ingredients see section 6 "Additional information".

Read the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for 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.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for treatment of disturbances of the lower urinary system associated with a benign prostatic tumor.

Therapeutic class: a selective alpha $_1$ adrenoceptor blocker.

Tamsu P.R. Teva contains the active ingredient tamsulosin hydrochloride. It works by relaxing the muscles of the prostate and urethra (the tube that leads the urine out), which allows for easier passage of urine through the urethra and helps in urinating.

In the prostate, bladder and urethra, there are special cells that contain alpha $_{1A}$ receptors, which cause muscle contraction in the urethra. Tamsulosin is an alpha $_{1A}$ receptor blocker, which reduces the activity of these special cells and relaxes the muscles, which makes it easier to urinate.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to tamsulosin or to any of the other ingredients the medicine contains, see section 6 – "Additional information".
- You have serious liver problems.
- You have fainted or felt dizzy upon sitting or standing up suddenly. Dizziness can sometimes occur while taking Tamsu P.R. Teva, especially if you are also taking other alpha 1 blockers. If you feel weak or dizzy, make sure to sit or lay down immediately until the symptoms resolve.

Special warnings regarding the use of the medicine

Before starting treatment with Tamsu P.R. Teva, inform the doctor if:

- You have kidney problems
- You are undergoing or have been scheduled for an eye surgery due to clouding of the lens (cataract) or due to increased intraocular pressure (glaucoma). Inform the eye specialist that you are using the medicine, are planning to use it or have used it in the past. In such a case, the eye specialist can take appropriate safety measures with respect to the medicines and surgical techniques that should be used. Consult the treating doctor about postponing or temporary stopping treatment with the medicine before undergoing cataract surgery or surgery to treat increased intraocular pressure.

Children and adolescents

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

Tests and follow-up

Periodic medical tests that are required to follow your medical condition should be performed.

Drug interactions

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

- Medicines for lowering blood pressure such as: verapamil, diltiazem.
- Medicines for treatment of HIV, such as: ritonavir, indinavir.
- Medicines for treatment of fungal infection, such as: ketoconazole, itraconazole.
- Other alpha blockers, such as: doxazosin, indoramin, alfuzosin, prazosin.
- Erythromycin, an antibiotic for treatment of infections.

Inform the doctor that you are being treated with Tamsu P.R. Teva before any surgery or dental procedure, because of the medicine's potential to interfere with the effect of the anesthetic.

Use of the medicine and food

Tamsu P.R. Teva may be taken with or without food.

Pregnancy, breastfeeding and fertility

Tamsu P.R. Teva is not intended for use in women.

In men, cases of abnormal ejaculation (ejaculation disorder) have been reported. This means that semen does not leave the body via the urethra, but instead goes into the bladder (retrograde ejaculation) or the ejaculation volume is reduced or absent (ejaculation failure). This effect is harmless.

Driving and operating machinery

There is no information indicating that Tamsu P.R. Teva affects the ability to drive or to operate machinery or equipment.

However, Tamsu P.R. Teva may cause drowsiness, blurry vision, dizziness and fainting. If you suffer from any of these effects, do not drive and/or operate machinery.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The dosage and treatment regimen will be determined only by the doctor.

The generally accepted dosage is: one tablet per day, recommended to be taken at the same time every day.

Do not exceed the recommended dose.

Crushing/halving/chewing

Do not chew, halve or crush! The medicine should be swallowed whole with some water.

Tablet residues may appear in the stool. Since the active ingredient has already been released, efficacy is not reduced.

If you accidentally took a higher dosage, this may cause an undesired drop in blood pressure, increased heart rate and a feeling of faintness.

If you took an overdose or if a child accidently swallowed this medicine, go to the doctor or to a hospital emergency room immediately and take the package of the medicine with you.

If you forgot to take this medicine at the required time, you can take Tamsu P.R. Teva later that 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 in order to compensate for a forgotten dose.

Persist with the treatment as recommended by the doctor, even if your medical issues have resolved.

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 what the doctor has recommended to you, your medical issues may return.

Always consult with the doctor if you are considering to stop the treatment.

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

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, using Tamsu P.R. Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Stop using this medicine and refer to a doctor immediately if you experience any of the following conditions, you may require medical treatment:

Rare side effects – effects that occur in 1-10 users out of 10,000:

- Swelling of the face, throat or tongue with allergy-related breathing problems.

Very rare side effects – effects that occur in less than one user out of 10,000:

- Continuous and painful erection, usually not related to sexual activity
- Rash, inflammation and blisters in the skin and/or mucosal membranes of the lips, eyes, mouth, nose or genitals (Stevens Johnson syndrome)
- Abnormal irregular heart rate (atrial fibrillation, arrhythmias, tachycardia), difficulty breathing (shortness of breath)

Additional side effects

Common side effects – effects that occur in 1-10 users out of 100:

- Dizziness
- Abnormal ejaculation (ejaculation disorders) – this means that semen does not leave the body via the urethra, but instead goes into the bladder (retrograde ejaculation) or the ejaculation volume is reduced or absent (ejaculation failure). This effect is harmless

Uncommon side effects – effects that occur in 1-10 users out of 1,000:

- Weakness
- Headache
- Runny nose or nasal congestion
- Dizziness when sitting or standing up
- Palpitations (fast or irregular heartbeat)
- Gastrointestinal symptoms such as: nausea and vomiting, diarrhea or constipation
- Hypersensitivity reactions such as: rash, itch, redness, localized swelling and breathing difficulties

Rare side effects – effects that occur in 1-10 users out of 10,000:

- Fainting

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

- Blurry vision
- Impaired vision
- Nosebleeds (epistaxis)
- Severe skin rash (erythema multiforme, exfoliative dermatitis)
- Dry mouth

As with other medicines of this type, it may cause effects of drowsiness, blurred vision or swelling of the hands and feet.

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

Reporting side effects

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

5. HOW TO STORE THE MEDICINE?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

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

Store below 25°C.

6. ADDITIONAL INFORMATION

In addition to the active ingredient the medicine also contains:

Polyethylene oxide, Cellulose microcrystalline, Hypromellose, Silica colloidal anhydrous, Magnesium stearate, Titanium dioxide, Macrogol 8000, Iron oxide yellow, Iron oxide red.

What does the medicine look like and what are the contents of the package?

Yellow, oval tablets debossed with T04 on one side and plain on the other side.

Each package contains blisters of 10, 30, 50, 60, or 90 tablets.

Not all package sizes may be marketed.

Name and address of license holder and manufacturer

Teva Israel Ltd.

124 Dvora HaNevi'a St., Tel Aviv 6944020

The leaflet was revised in September 2024.

Registration number of the medicine in the national drug registry of the Ministry of Health: 165.28.35552

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