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 regarding 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.
This medicine is not intended for use in children and adolescents under the age of 18.

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-1A, alpha-1D adrenoceptor blocker.

2. Before using the medicine:

Do not use this medicine if:

- You are sensitive (allergic) to tamsulosin or to any of the other ingredients the medicine contains. Hypersensitivity can appear as sudden local swelling in the soft tissues of the body (e.g., throat or tongue), breathing difficulties and/or itching and rash (angioedema).
- You have serious liver problems.
- You have or have had in the past low blood pressure, dizziness or fainting due to fall in blood pressure, for example when suddenly changing from a lying position to sitting or standing (orthostatic hypotension).

Special warnings regarding the use of the medicine

- Consult with your doctor before taking this medicine.
- Like other medicines from the same group, Tamsu P.R. Teva can cause fainting on rare occasions. When you feel dizzy or faint, you should sit or lie down until the signs disappear.
- Before starting treatment with Tamsu P.R. Teva, inform the doctor if:
  - You have severe kidney problems.
  - If you are undergoing or have been scheduled cataract surgery or surgery for treatment of increased intraocular pressure (glaucoma), you should tell the eye specialist that you are using this medicine, are planning to use it or have used it in the past. The eye specialist will take preventive measures (pharmacological or surgical) as necessary. Consult with the treating doctor about stopping the medicine before undergoing cataract surgery or surgery for treatment of 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 food supplements, tell the doctor or the pharmacist. Especially inform the doctor or pharmacist if you are taking:

- Medicines for lowering blood pressure of the same class (alpha adrenoceptor blockers). This combination may cause an unwanted drop in blood pressure.
- Medicines that may decrease the elimination of Tamsu P.R. Teva from the body (e.g., ketoconazole and erythromycin).

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, abnormal ejaculation (ejaculation disorder) has 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 phenomenon is harmless.

Driving and operating machinery

There is no evidence that Tamsu P.R. Teva affects the ability to drive or to operate machinery that requires alertness.
However, Tamsu P.R. Teva may cause dizziness; therefore, you should be careful when driving and/or operating machinery that requires alertness.

3. How should you use the medicine?

Always use 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.

Do not chew, halve or crush! The tablet 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 swallowed this medicine by mistake, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.
If you have forgotten to take this medicine at the required time, you can take Tamsu P.R. Teva later that day. If you have forgotten 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 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 the medicine. Wear glasses if you need them.
If you have any other questions regarding 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.

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

- Dizziness, especially upon sitting or standing up.
- Abnormal ejaculation - 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 phenomenon is harmless.

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

- Headache.
- Palpitations (awareness of faster-than-usual heartbeats).
- Lower blood pressure, e.g., when standing up quickly from a sitting or lying position, accompanied by dizziness.
- Runny nose or nasal congestion (rhinitis).
- Constipation, diarrhea, nausea, vomiting.
- Weakness (asthenia).
- Rash, itching, hives (urticaria).

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

- Feeling of faintness and sudden swelling in 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 - side effects that occur in less than one out of 10,000 users:

- Priapism (unwanted, prolonged and painful erection that requires immediate medical attention).
- Rash, inflammation and blisters in the skin and/or the mucosa of the lips, eyes, mouth, nose or genitals (Stevens-Johnson syndrome); heart arrhythmias, shortness of breath.

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

- Blurry vision.
- Impaired vision.
- Nose bleeds (epistaxis).
- Severe skin rash (erythema multiforme, exfoliative dermatitis).
- Irregular heartbeat (atrial fibrillation, arrhythmia, accelerated heartbeat), difficulty breathing (shortness of breath).
- If you are undergoing cataract surgery or surgery for treatment of increased intraocular pressure (glaucoma), and you are taking Tamsu P.R. Teva or have taken it in the past, a phenomenon of a constricted pupil that does not dilate as well as intra-operative floppy iris syndrome (IRIS) may occur during the surgery.
- 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 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.

License holder and address

Abic Marketing Ltd., P.O. box 8077, Netanya.

Name and address of the manufacturer

Teva Pharmaceutical Industries Ltd., P.O. box 3190, Petah Tikva.
The leaflet was revised in April 2021 in accordance with the Ministry of Health guidelines.

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

TAMSU PIL MW0621

teva