Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Promnix® 0.4

Modified release capsules

Active ingredient and its quantity per dosage unit:
Tamsulosin Hydrochloride 0.4 mg/capsule

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

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your 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 below the age of 18.

1. What is this medicine intended for?

The medicine is intended for the treatment of functional disorders caused by benign prostatic hyperplasia (BPH).

Therapeutic group: Selective alpha 1A,1D adrenoreceptor antagonist.

2. Before using this medicine

☒ Do not use this medicine if:

- you are sensitive (allergic) to tamsulosin or to any of the other ingredients contained in the medicine. For the list of inactive ingredients in the medicine, see section 6 "Additional information". Hypersensitivity may be manifested as sudden local swelling of the soft tissues of the body (such as throat or tongue), difficulty breathing and/or itching and rash (angioedema).
- you are suffering from severe liver failure.
- you are suffering, or have suffered in the past, from hypotension, dizziness or fainting resulting from a drop in blood pressure, for example, when suddenly transitioning from lying position to standing or sitting position (orthostatic hypotension).

Special warnings about using this medicine:

- Do not use the medicine without consulting the doctor before starting treatment if you are suffering, or have suffered in the past, from impaired function of the kidney/urinary system.
- Before starting treatment and during the course of treatment with this medicine, you must undergo a kidney function test, a rectal examination and if necessary, a test to determine prostate-specific antigen (PSA).
- If you are sensitive to any food or medicine, you must inform the doctor before taking the medicine.
- This medicine may occasionally cause orthostatic hypotension and fainting; therefore, if dizziness or weakness develop, the patient should sit or lie down until the condition resolves.
- If you plan to undergo eye surgery for cataract removal, or if you suffer from increased intraocular pressure (glaucoma), inform the ophthalmologist about current or past use of the medicine. When necessary, the ophthalmologist will take prophylactic measures (medicinal or surgical). Consult the attending doctor about stopping treatment with the medicine before cataract surgery or surgery to treat increased intraocular pressure.

Children and adolescents

The medicine is not intended for children and adolescents below the age of 18, since there is no relevant indication for its use in this age group and its efficacy in this population has not been established.

Tests and follow up

You should perform periodic medical tests necessary for monitoring your medical condition.

Drug interactions

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

- Anticoagulants (warfarin)
- Antihypertensives of the alpha blocker group – the combination may cause an undesirable decrease in blood pressure
- Anti-inflammatory medicines – diclofenac
- Medicines which may reduce the clearance of Promnix from the body – such as: ketoconazole, erythromycin

Using this medicine and food

Take Promnix after breakfast or after the first meal of the day.

Pregnancy, breastfeeding and fertility

Promnix is not intended for women.
In men, cases of abnormal ejaculation have been reported (ejaculation disorder). This means that the semen does not leave the body via the urethra, but passes into the urinary bladder (retrograde ejaculation), or the ejaculation volume is reduced or absent (ejaculation failure). This phenomenon is harmless.

Driving and using machines

Promnix may cause dizziness, and therefore, caution must be exercised when driving and/or operating machines which require alertness.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine. The usual dosage is generally one capsule per day after breakfast or after the first meal of the day, preferably at the same time every day.
Do not exceed the recommended dose.
Swallow the medicine whole, with water. Do not chew or crush.

If you have accidentally taken a higher dose, this may cause an unexpected drop in blood pressure, increase in heart rate and fainting.
If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately contact a doctor or proceed to a hospital emergency room and bring the medicine package with you**.**

If you forget to take the medicine at the scheduled time, take the forgotten capsule on the same day, but do not take a double dose. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor or pharmacist.
If you discontinue taking the medicine prematurely, the symptoms may recur.
Always consult your doctor if you consider discontinuing the treatment.

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

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Promnix may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

- **Stop taking this medicine and contact a doctor immediately** if a sudden allergic reaction occurs (rare). Symptoms include swelling of the hands and/or feet, difficulties breathing, itching, skin rash.
- Side effects that occur frequently: dizziness, especially when suddenly transitioning to a sitting or standing position; abnormal ejaculation – this means that the semen does not leave the body via the urethra, but passes into the urinary bladder (retrograde ejaculation) or the ejaculation volume is reduced or absent (ejaculation failure) (this phenomenon is harmless).
- Side effects that occur infrequently: headache, fatigue, orthostatic hypotension, rapid or irregular pulse, rhinitis (runny nose) or stuffy nose, constipation, diarrhea, nausea, vomiting, rash, weakness, itching, hives (urticaria).
- Side effects that occur rarely: feeling of fainting and sudden swelling of the soft tissues of the body (such as throat,

tongue, around the mouth or in the mouth), difficulties breathing and/or itching and rash, sometimes as an allergic reaction (angioedema).
- Side effects that occur very rarely: prolonged and painful involuntary erection (priapism) - immediate medical help is required; rash, inflammation and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nose or genitals (Stevens-Johnson syndrome); heart rate disorders, shortness of breath.
- Side effects of unknown frequency (side effects the frequency of which has not yet been determined): blurred vision, impaired vision, nosebleeds, severe skin rash (erythema multiforme, exfoliative dermatitis), irregular heart rate (atrial fibrillation, arrhythmias, tachycardia), difficulties breathing, dry mouth.

If you plan to undergo eye surgery for cataract removal or surgery to treat increased intraocular pressure (glaucoma), and you are taking or have taken the medicine in the past, a condition of constricted pupil that does not dilate and floppy iris (IFIS) may develop during the surgery.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

Avoid poisoning! To avoid poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

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

6. Additional information

In addition to the active ingredient, this medicine also contains: Microcrystalline cellulose, methacrylic acid-ethyl acrylate copolymer, polysorbate 80, sodium lauryl sulphate, triethyl citrate, talc, gelatin, FD&C blue No. 2, titanium dioxide, yellow iron oxide, red iron oxide, black iron oxide.

What the medicine looks like and contents of the pack:
The Promnix 0.4 capsule is of orange/olive green color. Promnix 0.4 is packed in packs of 30 and 60 capsules per pack. Not all pack sizes may be marketed.

Registration holder's name and address: Taro International Ltd., 14 Hakitor St., Haifa Bay 2624761

Manufacturer's name and address:
Synthon BV, Nijmegen, Netherlands

This leaflet dated March 2020 is in the format determined by the Ministry of Health and its content is consistent with the leaflet of the original medicine, which was reviewed and approved by the Ministry of Health in October 2014.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 13708.31452