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:
tamsulosin hydrochloride 0.4 mg

Inactive ingredients and allergens - see section 6 'Additional information".

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 (see section 6). 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 from dizziness or fainting resulting from a drop in blood pressure when changing position (transitioning from a lying to a sitting or standing position (orthostatic hypotension)).

Special warnings about using this medicine:

- In rare instances, this medicine can cause fainting. At the first signs of dizziness or weakness, the patient should sit or lie down until the condition resolves.
- **Before using Promnix, tell your doctor if:**
  - you suffer or have suffered in the past from severe kidney problems.
  - you are about 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 medicinal or surgical measures. Consult the attending doctor about stopping treatment with the medicine before cataract surgery or surgery to treat increased intraocular pressure (glaucoma).

Children and adolescents
The medicine is not intended for children and adolescents below the age of 18, as it is not effective in this population.

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 nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- Antihypertensives of the alpha blocker group – the combination may cause an undesirable decrease in blood pressure
- 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
There is no evidence that Promnix affects the ability to drive or to operate machines that require alertness. However, 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.
How to take
Swallow the medicine whole, with water. Do not chew or crush.

If you have accidentally taken a higher dose, this may cause an unwanted 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 see a doctor or go to a hospital emergency room and bring the medicine package with you**.**

If you forget to take the medicine at the scheduled time, 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 stop 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 every time 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.

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

- dizziness, especially when suddenly transitioning to a sitting or standing position;
- abnormal ejaculation (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.

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

- headache, palpitations (the heart beats faster than usual in a noticeable manner), fatigue, low blood pressure (sometimes experienced as dizziness when getting up quickly from a sitting or lying position), runny or stuffy nose (rhinitis), constipation, diarrhea, nausea, vomiting, rash, weakness, itching, hives (urticaria).

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

- feeling of fainting and sudden swelling of the soft tissues of the body (such as throat, tongue), difficulties breathing and/or itching and rash, sometimes as an allergic reaction (angioedema).

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

- prolonged and painful involuntary erection (priapism) for which immediate medical treatment is required.
- rash, inflammation and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nose or genitals (Stevens-Johnson syndrome).

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 (dyspnea).
- if you are undergoing 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.
- dry mouth.

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, or by using this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent 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, gelatin, methacrylic acid-ethyl acrylate copolymer, talc, triethyl citrate, titanium dioxide, yellow iron oxide, polysorbate 80, sodium lauryl sulphate, red iron oxide, black iron oxide, FD&C blue No. 2.

What the medicine looks like and contents of the pack:
The Promnix 0.4 capsule is orange/olive green. Promnix 0.4 contains 30 or 60 capsules. 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, Microweg 22, 6545 CM, Nijmegen, Netherlands

Revised in December 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 137-08-31452-00