

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

This medicine is dispensed with a doctor's prescription only

Promnix® 0.4 **Hard modified release capsules**

Active ingredient:

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.

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: alpha 1 adrenoreceptor antagonist

Promnix 0.4 acts by relaxing the muscles in the prostate gland and urethra (the tube that carries urine to the outside), and lets urine pass more readily through the urethra and aids urination.

In the prostate gland, urinary bladder and urethra there are specialised cells containing alpha1A-receptors that cause the muscles in the urethra to tighten. Promnix 0.4 is an alpha1A-adrenoceptor blocker, which reduces the action of these specialised cells and relaxes the muscles making it easier to pass water.

Promnix 0.4 is used to treat the symptoms associated with benign prostatic hyperplasia (BPH) which is enlargement of the prostate gland. These symptoms include difficulty in starting to pass water, more frequent urination, a feeling of partial emptying of the bladder and having to get up several times in the night to pass water.

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to tamsulosin or to any of the other ingredients in Promnix 0.4 (see section 6).
- you are suffering from a severe liver disorder
- you have ever fainted or felt dizzy when suddenly sitting or standing up. Dizziness can sometimes occur when taking Promnix 0.4, particularly if you are also taking other alpha1- blockers. If you feel weak or dizzy, make sure you sit or lie down straight away until the symptoms have disappeared.

Special warnings about using this medicine:

Before using Promnix 0.4, tell your doctor if:

- you have kidney problems

- you are undergoing or have been scheduled for eye surgery because of cloudiness of the lens (cataract) or increased pressure in the eye (glaucoma).

Inform your ophthalmologist that you have previously used, are using or are planning to use tamsulosin hydrochloride. The ophthalmologist can then take appropriate precautions with respect to medication and surgical techniques they will use. Ask your doctor whether you should postpone or temporarily stop taking this medicine when undergoing eye surgery because of a cloudy lens (cataract) or increased pressure in the eye (glaucoma).

Children and adolescents

Do not give this medicine to children and adolescents under 18 years, because it is not effective in this population.

Tests and follow up

Your doctor may want to examine you from time to time whilst you are taking this medicine.

Interactions with other medicines

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or Interactions pharmacist.

Particularly if you are taking:

- Medicines to lower your blood pressure such as verapamil and diltiazem
- Medicines to treat HIV such as ritonavir or indinavir
- Medicines to treat a fungal infection such as ketoconazole or itraconazole
- Other alpha blockers such as doxazosin, indoramin, prazosin or alfuzosin
- Erythromycin, an antibiotic used to treat infections
- Warfarin – anticoagulant
- Diclofenac - nonsteroidal anti-inflammatory drug

Inform your doctor that you are taking Promnix 0.4 before any operation or dental procedure as the medicine may interfere with the effects of the anaesthetic.

Pregnancy, breastfeeding and fertility

Promnix 0.4 is not intended for use in women.

In men, ejaculation dysfunction has been reported (ejaculation disorder). This means that the semen does not leave the body via the urethra, but instead goes 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 information available regarding the possible effect of Promnix 0.4 on the ability to drive or to operate machines or equipment. However, it is known that Promnix 0.4 may cause drowsiness, blurred vision, dizziness and fainting. If you suffer from these effects, do not drive or operate machinery.

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 standard 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 a severe drop in blood pressure, dizziness and malaise.

If you have taken too many capsules, immediately see a doctor or go to the nearest hospital emergency room and bring the medicine package and patient information leaflet with you.

If you forget to take the medicine

You may take the capsule later the same day if you have forgotten to take it earlier. If you have missed a day, continue to take your daily capsule the next day. Do not take a double dose to make up for a missed dose.

Adhere to the treatment as recommended by your doctor.

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

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

4. Side effects

As with any medicine, using Promnix 0.4 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 consult your doctor as soon as possible if you experience any of the following effects – you may need medical treatment.

Rare side effects – effects that occur in less than 1 in 1,000 users:

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

Very rare side effects – effects that occur in less than 1 in 10,000 users:

- Persistent painful erection usually unrelated to sexual activity.
- Rash, inflammation and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (Stevens-Johnson syndrome).
- Abnormal irregular heart rhythm (atrial fibrillation, arrhythmia, tachycardia), difficult breathing (dyspnoea).

Additional side effects

Common side effects – effects that occur in less than 1 in 10 users:

- dizziness
- ejaculation disorder. This means that the semen is not secreted from the body via the urethra, but instead goes 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 less than 1 in 100 users:

- weakness

- headache
- runny or blocked nose
- dizziness as you sit or stand up
- palpitations (rapid or irregular heartbeat)
- gastro-intestinal symptoms such as nausea and vomiting, diarrhoea or constipation
- hypersensitivity reactions such as rash, itching, redness, local swelling and breathing problems

Rare side effects – effects that occur in less than 1 in 1,000 users:

- fainting

Side effects of unknown frequency (the frequency of these effects has not been established yet):

- blurred vision
- impaired vision
- nosebleeds
- severe skin rash (erythema multiforme), inflammation of the skin accompanied by peeling (exfoliative dermatitis))
- dry mouth

As with other medicines of this type, drowsiness or swelling of the hands and feet can occur.

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 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use 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 your 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.

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:

An orange/olive green capsule. A Promnix 0.4 pack contains 30 capsules in blisters or 60 capsules in a bottle. Not all pack types and 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 July 2024.

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

For further information about the medicinal product and for updated patient leaflets in Hebrew, Arabic and English, please scan the code:



Promnix® 0.4

<https://israel drugs.health.gov.il/#!/medDetails/137%2008%2031452%2000>

For a printed copy of the patient information leaflet in English, please contact the registration holder by email info@taro.com or by phone 1-800-464-664.