

PATIENT INFORMATION LEAFLET

UROMAX[®] 0.4 mg MR Modified Release Hard Gelatin Capsule

It is taken orally.

- **Active ingredient:** Tamsulosin hydrochloride.
Each capsule contains 0.4 milligrams of tamsulosin hydrochloride.
- **Excipients:** Microcrystalline cellulose, purified water, magnesium stearate, methacrylic acid-ethyl acrylate copolymer (1:1), sodium hydroxide, triacetin, talc, titanium dioxide, gelatin capsule (bovine gelatin).

Before you start using this medicine, carefully read this INSTRUCTIONS FOR USE, because it contains important information for you.

- *Keep this leaflet. You can need to read again.*
- *If you have other questions, please talk your doctor or pharmacist.*
- *This medicine has been prescribed for you personally, do not give it to others.*
- *When you go to the doctor or hospital during the use of this medicine, tell your doctor that you are using this medicine.*
- *Follow exactly what is written in this instruction. Do not use **high** or **low** doses other than the dose recommended to you about the drug.*

In this leaflet:

1. *What is UROMAX[®] and what is it used for?*
2. *Things to consider before using UROMAX[®]*
3. *How to use UROMAX[®]?*
4. *What are the possible side effects?*
5. *Storing condition for UROMAX[®]*

Headings are included.

1. What is UROMAX and what is it used for?

- UROMAX[®] is in the form of hard capsules.
UROMAX[®] is release to the market in PVC/PVDC Aluminum foil blister packages of 30 capsules.
- Tamsulosin hydrochloride, the active ingredient of UROMAX[®], is a member of a group of drugs called "alpha1-adrenoceptor antagonists". "Alpha1-adrenoceptors" are a type of sensory structures (receptors) found on the cell surface in various parts of the body. These structures perceive the messages coming to the cell and enable the cell to act in line with that message.
Tamsulosin hydrochloride selectively blocks alpha1-adrenoceptors. Blocking the activities of these structures relaxes the smooth muscles in the prostate and urinary tract. UROMAX[®] thus allows urine to pass more easily through the urinary tract, relieves urination and relieves the feeling of urinary urgency.
- UROMAX[®] is used for the treatment of lower urinary tract complaints in men that occur as a result of enlargement of the prostate gland. Benign enlargement of the prostate gland (benign prostatic hyperplasia) compresses the lower urinary tract, causing complaints such as difficulty urinating (decreased urine flow force), intermittent urination, dribbling of urine, frequent urination both at night and during the day, and urinary urgency. UROMAX[®] provides relief of these symptoms as a result of the effect mentioned above.

2. Things to consider before using UROMAX

DO NOT USE UROMAX[®] in the following conditions

- If you are hypersensitive (allergic) to tamsulosin or any of the other ingredients of this medicine. Hypersensitivity may manifest itself as sudden local swelling of the soft tissues of the body (e.g. throat or tongue), difficulty breathing and or itching and rash (angioedema),
- If you feel faint when you stand up from lying down or sitting (orthostatic hypotension),
- If you have severe liver disease.

UROMAX[®] should not be used together with the oral antifungal medicine called ketoconazole.

USE UROMAX[®] CAREFULLY in the following cases

- As with other medicines of this type, fainting may rarely occur while taking UROMAX[®]. Therefore, when symptoms of dizziness and fatigue begin, you should sit or lie down until they pass.
- Before starting treatment with UROMAX[®], your doctor will examine you thoroughly to make sure that you do not have other diseases that cause symptoms similar to benign prostatic hyperplasia (prostate cancer). These examinations may include rectal examination and laboratory determination of a substance called 'prostate specific antigen'. Your doctor may consider continuing these examinations at regular intervals during treatment.
- If you have severe kidney disease (creatinine clearance <10 ml/min), tell your doctor.
- In some patients who are currently taking tamsulosin or have taken it in the past, some problems have occurred during cataract and glaucoma surgeries that make the surgery difficult. If you are going to have surgery due to cataracts (cloudiness of the eye lens) or glaucoma (increased intraocular pressure), please inform your doctor that you are using UROMAX[®]. In this way, your doctor will be able to make the necessary preparations for the medications and surgical techniques to be used in your eye surgery. It is not recommended to start tamsulosin hydrochloride therapy in patients scheduled for carotid or glaucoma surgery.
- Caution should be exercised when using UROMAX[®] together with the antibiotic erythromycin; its effects may increase.

If these warnings apply to you, even at any time in the past, please consult your doctor.

Using UROMAX with food and drink

UROMAX[®] should be taken with a glass of water after breakfast or the first meal of the day.

Pregnancy

UROMAX[®] is not valid because it is only for male patients.

Breastfeeding

UROMAX[®] is not valid as it is intended for male patients only.

Vehicle and machine use

No studies have been conducted on the effects of UROMAX[®] on the ability to drive and use machines. However, keep in mind that dizziness, blurred vision, and syncope may occur. If such a situation occurs in you, you should avoid activities that require attention, such as driving and using machines.

Important information about some of the excipients contained in UROMAX[®]

This medicinal product contains less than 23 mg sodium per dose; in other words, it is essentially “sodium-free”.

Using with other drugs

UROMAX[®] should not be used together with ketoconazole (fungal infection medicine). Caution should be exercised when using UROMAX[®] together with erythromycin (antibiotic).

UROMAX[®] may accelerate the removal of atenolol, enalapril (these are medicines used for heart and vascular diseases), theophylline (a medicine for respiratory diseases/a medicine to prevent blood clotting), tamsulosin from the body.

Diclofenac (a type of painkiller) and warfarin (a blood thinner) can speed up the removal of tamsulosin from the body. Caution should be exercised when using UROMAX[®] together with these drugs.

Using UROMAX[®] together with other drugs from the same group (alpha1-adrenoreceptor blockers) may lead to an undesirable decrease in blood pressure.

If you are currently using or have recently used any prescription or non-prescription medication, please inform your doctor or pharmacist about them.

3. How to use UROMAX[®]?

Instructions for proper use and dose / frequency of administration:

Always take your medicine exactly as your doctor tells you. If you are not sure, check with your doctor or pharmacist.

The recommended dose is 1 capsule per day, to be taken after breakfast or the first meal of the day.

Application route and method:

Swallow the UROMAX[®] capsule whole. Do not crush or chew the capsule as this may affect the altered release of the active substance.

Different age groups

Use in children:

There is no indication for the use of UROMAX[®] in children.

Use in the elderly:

The safety and effectiveness of tamsulosin in patients over 65 years of age do not differ from those in patients under 65 years of age. However, it cannot be excluded that some elderly patients may be more sensitive.

Special use cases

Kidney failure:

No dose adjustment is necessary in patients with renal impairment.

Liver failure:

No dose adjustment is necessary in patients with mild to moderate hepatic impairment. However, it should not be used in patients with severe liver failure.

If you have the impression that the effect of UROMAX[®] is too strong or weak, talk to your doctor or pharmacist.

If you use more UROMAX[®] than you should

If you have used more UROMAX[®] than you should, talk to a doctor or pharmacist.

Taking too much UROMAX[®] may cause an undesirable drop in blood pressure.

If you forget to use UROMAX[®]:

If you forget to take your recommended daily UROMAX[®] capsule, take it as soon as you remember later on the same day. If you miss that day, continue using your medicine as prescribed.

Do not take a double dose to make up for forgotten doses.

Effects that may occur when treatment with UROMAX[®] is stopped:

If UROMAX[®] treatment is stopped prematurely, your initial symptoms may return. Therefore, even if your complaints have disappeared, continue using UROMAX[®] as long as your doctor prescribes. If you want to stop this treatment, be sure to consult your doctor.

If you have any other questions about the use of this medicine, ask your doctor or pharmacist.

4. What are the possible side effects?

Like all medicines, side effects may occur in people who are sensitive to the ingredients contained in UROMAX[®].

The following side effects have been reported during the use of UROMAX[®].

The frequencies given are as follows: Very common (1 in 10 patients or more); common (up to 1 in 10 patients); uncommon (up to 1 in 100 patients); rare (up to 1 in 1000 patients); very rare (less than 1 in 10000 patients); unknown (cannot be estimated with available data).

If any of the following occur, stop using UROMAX[®] and IMMEDIATELY inform your doctor or go to the emergency department of your nearest hospital:

- Severe allergic reactions, which may be accompanied by sudden local swelling of the soft tissues of the body (e.g. throat, tongue) and difficulty breathing (angioedema) and/or itching/rash on the skin

These are all very serious side effects.

If you have any of these, it means you have a serious allergy to UROMAX[®].

You may need emergency medical attention or hospitalization.

All of these very serious side effects are very rare.

Other side effects:

Common (Up to 1 in 10 patients):

- Dizziness
- Ejaculation disorders: This includes conditions where seminal fluid does not come out of the penis during ejaculation but goes into the bladder, or no ejaculation at all.

Uncommon (Up to 1 in 100 patients):

- Headache
- Palpitations
- Sudden drop in blood pressure, especially when standing up suddenly from sitting or lying down
- Inflammation of the nose (rhinitis)
- Constipation, diarrhea, nausea, vomiting
- Rash, itching, hives (urticaria)
- Unusual fatigue

Rare (Up to 1 in 1000 patients):

- Faint

Very Rare (Less than 1 in 10000 patients):

- Stevens-Johnson syndrome (a serious disease characterized by reddened, painful skin rashes and fluid-filled blisters)
- Unwanted, long-lasting and painful erection of the penis (priapism)

Unknown (cannot be estimated with available data):

- Blurred or impaired vision*
- Nose bleeding*
- Erythema multiforme*: It is a rare skin disease. Symmetrical, red and raised rashes usually occur on the arms and legs. The rashes resemble patches and have a center.
- Dermatitis exfoliative: It is a rare skin disease. Red rashes appear on a very large part of the body. The rash appears as flaking and peeling, and body temperature rises (fever).
- Dry mouth

* These are side effects that were not seen during clinical trials but were reported after the drug was introduced to the market.

Tamsulosin, like other drugs in its class, has rarely been associated with an unintentional, prolonged, and painful erection of the penis (priapism). If this occurs, you should definitely consult your doctor, as this condition can lead to permanent erectile dysfunction if left untreated.

As with other drugs in the same group, drowsiness and fluid retention in the tissues (edema) may occur.

In addition to the adverse events mentioned above, heart palpitations, heart rhythm disturbances, rapid heartbeat and shortness of breath have been reported in association with the use of tamsulosin after the drug was introduced to the market. Because these spontaneously reported events relate to post-marketing experience worldwide, the frequency of these events and the role played by tamsulosin in their cause cannot be reliably determined.

If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

5. Storing condition for UROMAX[®]

Keep UROMAX in its packaging and out of sight and reach of children.

Store at room temperature below 25°C. Protect from moisture.

Use in accordance with expiration dates.

Do not use UROMAX[®] after the expiration date on the packaging.

If you notice any defects in the product and/or its packaging, do not use UROMAX[®].

Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment, Urbanization and Climate Change.

License Holder:

Drogsan İlaçları San. ve Tic. A.Ş.
Oğuzlar Mahallesi 1370. Sokak No: 7/3
06520 Balgat- ANKARA
Tel: (0 312) 287 74 10

Manufacturing site:

Drogsan İlaçları San. ve Tic. A.Ş.
06760 Çubuk - ANKARA

These instructions for use were approved on 27/12/2017.