Flomaxtra contains active substance called tamsulosin and belongs to the group of alpha-blockers intended for use in the treatment of benign prostatic hypertrophy. It selectively binds to the alpha-1A and alpha-1D receptors which are found in the prostate. This binding to receptors reduces tension and relax the muscle tissue in the prostate and consequently produces alleviation of symptoms of prostate enlargement (weak or slow urine stream and frequent urination).

**Precautions**

Flomaxtra is contraindicated in the following conditions:

- If you suffer from orthostatic hypotension or have ever had blackouts due to the application of a drug. Flomaxtra can (although very rarely, as it selectively binds only to the alpha receptors in the prostate tissue) bind to the alpha receptors in the arterioles, which reduces peripheral resistance and consequently blood pressure. Because of that, sudden drop in blood pressure may occur when rapid standing up from a sitting or lying position.
- If you have liver disease. Cases of acute pseudoangiocholitic hepatitis induced by this drug have been reported, and therefore use of this drug in patients with liver damage should be avoided.

Flomaxtra should be administered with caution in patients who are planning for cataract eye surgery because there are reported cases of so-called intraoperative floppy iris syndrome (IFIS), which can cause complications during surgery.

There are no data from the use of this drug in patients with severe renal impairment and caution is recommended in administering this drug to patients with impaired renal function.
This medicine can occupy in a very small percentage alpha-1B receptors found in the arterioles and cause a reduction of peripheral resistance in the blood vessels and consequently a sudden fall in blood pressure. Cases of sudden, transient loss of consciousness (so-called syncope), in patients who are treated with this drug have been rarely (in less than 0.1% of patients) reported. The risk of syncope increases if you're suddenly getting up from a sitting or lying position.

For this reason, this drug must be administered cautiously in patients who are taking antihypertensive drugs or have heart problems.

### Flomaxtra, pregnancy and lactation

Flomaxtra is intended only for use in men.

### Dosage instructions

The recommended dose is 400 micrograms (one tablet) daily. You need to take a pill after breakfast or after the first main meal of the day. Swallow the tablet whole with a glass of water.

### Interactions

Flomaxtra should not be taken concomitantly with potent CYP3A4 inhibitors because of an increased risk of orthostatic hypotension:

- **Clarithromycin** and telithromycin - antibiotics used for the treatment of numerous bacterial infections
- **Atazanavir**, amprenavir, indinavir, saquinavir, fosamprenavir and darunavir - drugs used for the treatment of AIDS
- **Boceprevir** - used for the treatment of hepatitis C.
- **Ketoconazole**, posaconazole, itraconazole and **fluconazole** - drugs used for the treatment of numerous fungal infections
- **Tizanidine** - used for the treatment of muscle spasticity

Concurrent use with following drugs should also be avoided:

- **Non-steroidal anti-inflammatory drugs** (e.g. *diclofenac*). This drug may accelerate the elimination and reduce the effectiveness of Flomaxtra.
- **Oral anticoagulants** (e.g. *warfarin*). This drug may accelerate the elimination and reduce the effectiveness of Flomaxtra.

Although clinical studies have shown no interactions with antihypertensive drugs, due to the potential impact on blood pressure, extra precaution is necessary when Flomaxtra is used concurrently with antihypertensive agents.

### Side effects

Flomaxtra may cause the following side effects:

- Gastrointestinal adverse reactions
  - nausea
  - vomiting
- diarrhea
- constipation

- Syncope
- Dizziness
- Headache
- Inflammation of the mucous membranes of the nose
- An abnormally prolonged erection (*priapism*)
- Ejaculation disorders
- Extreme fatigue or tiredness
- Orthostatic hypotension
- Stevens-Johnson syndrome