

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor or pharmacist. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.



**TAZIN 0,4 mg**  
**prolonged-release hard capsules**  
*Tamsulosin*

**What is in this leaflet**

1. What **TAZIN** is and what it is used for
2. What you need to know before you take **TAZIN**
3. How to take **TAZIN**
4. Possible side effects
5. How to store **TAZIN**
6. Contents of the pack and other information

**1. What TAZIN is and what it is used for**

The active ingredient in **TAZIN** is tamsulosin. This is a selective alpha1A/1D-adrenoceptor antagonist. It reduces tension of the smooth muscles in the prostate and the urethra, enabling urine to pass more readily through the urethra and facilitating urination. In addition, it diminishes sensations of urge.

**TAZIN** is used in men for the treatment of the complaints of the lower urinary tract associated with an enlarged prostatic gland (benign prostatic hyperplasia). These complaints may include difficulty urinating (poor stream), dribbling, urgency and having to urinate frequently at night as well as during the day.

**2. What you need to know before you take TAZIN**  
**Do not take TAZIN:**

- if you are allergic to tamsulosin hydrochloride or to any of the other ingredients of this medicine (listed in section 6). Hypersensitivity may present as sudden local swelling of the soft tissues of the body (e.g. the throat or tongue), difficult breathing and/or itching and rash (angioedema).
- if you suffer from severe liver problems.
- if you suffer from fainting due to reduced blood pressure when changing posture (going to sit or stand up).

**Warnings and precautions**

Talk to your doctor or pharmacist before taking **TAZIN**.

- Periodic medical examinations are necessary to monitor the development of the condition you are being treated for.

- Rarely, fainting can occur during the use of **TAZIN** as with other medicinal products of this type.

At the first signs of dizziness or weakness you should sit or lie down until they have disappeared.

- if you suffer from severe kidney problems, tell your doctor.
- if you are undergoing or have been scheduled for eye surgery because of cloudiness of the lens (cataract), please inform your eye specialist that you have previously used, are using, or are planning to use **TAZIN**. The specialist can then take appropriate precautions with respect to medication and surgical techniques to be used. Ask your doctor whether or not you should postpone or temporarily stop taking this medicine when undergoing eye surgery because of a cloudy lens.

**Children**

Do not give this medicine to children or adolescent under 18 years because it does not work in this population.

**Other medicines and TAZIN**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Taking **TAZIN** together with other medicines from the same class ( $\alpha$ 1-adrenoceptor antagonists) may cause an unwanted decrease in blood pressure.

It is especially important to inform your doctor if you are being treated at the same time with medicines that may decrease the removal of **TAZIN** from the body (for example, ketoconazole, erythromycin).

**TAZIN with food, drink or alcohol**

**TAZIN** must be taken after breakfast or the first meal of the day.

**Pregnancy, breast-feeding and fertility**

This section is not relevant, because **TAZIN** is not indicated for use in women.

Impaired sexual functions in males have been reported with **TAZIN**.

**Driving and using machines**

There is no evidence that **TAZIN** affects the ability to drive or to operate machinery or equipment. However, you should bear in mind that dizziness can occur, in which case you should not undertake activities that require attentiveness.

**TAZIN contains sucrose.**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

**3. How to take TAZIN**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The dosage is one capsule per day to be taken after breakfast or the first meal of each day. The capsule must be swallowed whole and not be crunched or chewed. Usually, **TAZIN** is prescribed for long periods of time. The effects on the bladder and on urination are maintained during long-term treatment with **TAZIN**.

**If you take more TAZIN than you should**

Taking too many capsules of **TAZIN** may lead to an unwanted decrease in blood pressure and an increase in heart rate, with feelings of faintness. Contact your doctor immediately if you have taken too much **TAZIN**.

**If you forget to take TAZIN**

You may take your daily **TAZIN** later the same day if you have forgotten to take it as recommended. If you have missed a day, just continue to take your daily capsule as prescribed. Do not take a double dose to make up for a forgotten capsule.

**If you stop taking TAZIN**

When treatment with **TAZIN** is stopped prematurely, your original complaints may return. Therefore use **TAZIN** as long as your doctor prescribes, even if your complaints have disappeared already. Always consult your doctor, if you consider stopping this therapy.

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

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Common** (less than 1 in 10, more than 1 in 100 (1-10%)):

- Dizziness, particularly when going to sit or stand up.
- Ejaculation disorders
- Retrograde ejaculation; this means that semen does not leave the body via the urethra, but instead goes into the bladder. This phenomenon is harmless.
- Ejaculation failure.

**Uncommon** (more than 1 in 1000, less than 1 in 100 (0,1-1%)):

- Headache, palpitations (the heart beats more rapidly than normal and it is also noticeable), reduced blood pressure e.g. when getting up quickly from a seating or lying position sometimes associated with dizziness; runny or blocked nose (rhinitis), diarrhoea, feeling sick and vomiting, constipation, weakness (asthenia), rashes, itching and hives (urticaria).

**Rare** (more than 1 in 10,000, less than 1 in 1000 (0,01-0,1%)):

- Faintness and sudden local swelling of the soft tissues of the body (e.g. the throat or tongue) difficult breathing and / or itching and rash, often as an allergic reaction (angioedema).

**Very rare** (less than 1 in 10,000 (<0,01%)):

- Priapism (painful prolonged unwanted erection for which immediate medical treatment is required).
- Rash, inflammation and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (Stevens-Johnson syndrome)
- Not known (frequency cannot be estimated based on available data)
- Vision blurred, visual impairment
- Nose bleed
- Severe condition of the skin that may affect the mouth and other parts of the body
- Skin disease
- Dry mouth
- Abnormal irregular heart rhythm (atrial fibrillation, arrhythmia, tachycardia), difficult breathing (dyspnoea).

If you are undergoing eye surgery because of cloudiness of the lens (cataract) and are already taking or have previously taken **TAZIN**, the pupil may dilate poorly and the iris (the coloured circular part of the eye) may become floppy during the procedure (Intraoperative Floppy Iris Syndrome (IFIS)).

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

#### 5. How to store TAZIN

**Do not store above 25°C. Store in the original pack to protect from moisture.**

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer use. These measures will help to protect the environment.

#### 6. Contents of the pack and other information

##### What TAZIN contains

The active substance is tamsulosin hydrochloride. One prolonged release hard capsule contains 400 micrograms of tamsulosin hydrochloride.

The other ingredients are: starch, sucrose, copovidone, ethyl cellulose, hypromellose, povidone, hypromellose phthalate, cetyl alcohol, diethyl phthalate, purified talc, polysorbate 80, isopropyl alcohol, acetone, purified water, hard gelatin capsules.

##### Contents of the pack

Box containing 30 ( 3 x 10 ) capsules with 0.4 mg tamsulosin hydrochloride in blister packs.

##### Marketing Authorisation Holder and Manufacturer:

ZADA Pharmaceuticals d.o.o.

Donji Bistarac bb

75300 Lukavac, Bosnia and Herzegovina.

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