

Package leaflet: Information for the patient

Tamzelto 400 micrograms

prolonged-release tablets

tamsulosin hydrochloride

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. See section 4.

What is in this leaflet

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

1. What Tamzelto is and what it is used for

The active ingredient in Tamzelto is tamsulosin. This is a selective $\alpha_{1A/1D}$ -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.

Tamzelto 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 Tamzelto

Do not take Tamzelto if you:

- are allergic to tamsulosin or any of the other ingredients of this medicine (listed in section 6). Hypersensitivity may present a sudden local swelling of the soft tissues of the body (e.g. the throat or tongue), difficult breathing and/or itching and rash (angioedema);
- suffer from severe liver problems;
- 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 Tamzelto.

- 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 Tamzelto, 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) or increased pressure in the eye (glaucoma). Please inform your eye specialist that you are using or have previously, are using or planning to use Tamzelto. 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 (cataract) or increased pressure in the eye (glaucoma).

You may observe a remnant of the tablet in your faeces. Since the active ingredient of the tablet has been released already, there is no risk of the tablet being less effective.

Children

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

Other medicines and Tamzelto

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Taking Tamzelto together with other medicines from the same class (α_1 -adrenoceptor blockers) 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 Tamzelto from the body (for example, ketoconazole, erythromycin).

Tamzelto with food and drink

Tamsulosin can be taken with or without of food.

Pregnancy, breast-feeding and fertility

This section is not relevant, because Tamzelto is intended for male patients only.

In men, abnormal ejaculation has been reported (ejaculation disorder). This means that the semen does not leave the body via the urethra, but instead goes into the 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 tamsulosin affects the ability to drive and use machines. You should take into account that tamsulosin may cause dizziness and light-headedness. Only drive or use machines if you feel alright.

3. How to take Tamzelto

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

The recommended dose is one tablet per day. You can take tamsulosin with or without food, preferably at the same time of each day.

Swallow the tablet **whole**. It is important that you **do not crunch or chew the tablet** as this may influence how well tamsulosin works.

Usually, Tamzelto is prescribed for long periods of time. The effects on the bladder and on urination are maintained during long-term treatment with Tamzelto.

If you take more Tamzelto than you should

Taking too many Tamzelto tablets 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 Tamzelto.

If you forget to take Tamzelto

You may take your daily tamsulosin tablet later the same day if you have forgotten to take it as recommended. If you have missed a day, just take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Tamzelto

When treatment with tamsulosin is stopped prematurely, your original complaints may return. Therefore use tamsulosin 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.

Serious reactions are rare. **Contact your doctor immediately** if you experience **a serious allergic reaction which causes swelling of the face or throat** (angio-oedema).

Common (may affect up to 1 in 10 people)

- dizziness, particularly when going to sit or stand up,
- Abnormal ejaculation (ejaculation disorder). This means that semen does not leave the body via the urethra, but instead goes into the bladder (retrograde ejaculation) or the ejaculation volume is reduced or absent (ejaculation failure). This phenomenon is harmless.

Uncommon (may affect up to 1 in 100 people)

- headache,
- palpitations (the heart beats more rapidly than normal and it is also noticeable),

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PhC that comes out of the middle of leaflet must be visible!/
- **blackU**


Article No.: xxxxxx
Article name.: PL. Tamzelto 400mcg IE
Dimension: 148 ± 0,5 mm x 420 ± 0,8 mm
Material: Woodfree paper 50 g/m ²
PhC No.: /
Measure: 1:1
Date: 03.10.2019
Prepared by: A. Mohorič
Checked by: N. Regina
Packaging Design

130 mm ± 0,5 mm

direction of reading PhC



- 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 (may affect up to 1 in 1,000 people)

- faintness,
- 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 (may affect up to 1 in 10,000 people)

- 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 from the available data)

- blurred vision, visual impairment,
- nosebleed,
- dry mouth,
- a severe form of rashes (erythema multiforme, dermatitis exfoliative).
- Abnormal irregular heart rhythm (atrial fibrillation, arrhythmia, tachycardia), difficult breathing (dyspnoea).

If you are undergoing eye surgery because of cloudiness of the lens (cataract) or increased pressure in the eye (glaucoma) and are already taking or have previously taken Tamzeltos, the pupil may dilate poorly and the iris (the coloured circular part of the eye) may become floppy during the procedure.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tamzeltos

Keep this medicine out of the sight and reach of children.

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

Store in the original package in order to protect from light. This medicine does not require any special temperature storage conditions.

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

6. Contents of the pack and other information

What Tamzeltos contains

- The active substance is tamsulosin hydrochloride. Each prolonged-release tablet contains 400 micrograms tamsulosin hydrochloride.
- The other ingredients are:
Inner tablet: hypromellose (E464), microcrystalline cellulose (E460), carbomer, colloidal anhydrous silica (E551), red iron oxide (E172), magnesium stearate (E470b)
Outer tablet: hypromellose (E464), microcrystalline cellulose (E460), carbomer, colloidal anhydrous silica (E551), magnesium stearate (E470b)

What Tamzeltos looks like and contents of the pack

Tamzeltos 400 micrograms prolonged-release tablets are white, unscored, round, with a diameter of 9 mm, debossed on one side with "T9SL" and "0.4" on the other side.

Tamzeltos is available in boxes containing 30 and 90 prolonged-release tablets in blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Krka, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer

TAD Pharma GmbH, Heinz-Lohman Straße 5, 27472 Cuxhaven, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of the Member State	Name of the medicinal product
Netherlands, Belgium,	Tamsulosine HCl Krka
Spain	Tamsulosina Krka
France	TAMSULOSINE KRKA LP
Ireland	Tamzeltos

This leaflet was last revised in



direction on fibre

420 mm ± 0,8 mm

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direction of reading PhC

148 mm ± 0,5 mm