

Package leaflet: Information for the patient

TANYZ 400 micrograms

hard modified-release capsules

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

1. What TANYZ is and what it is used for

What is TANYZ

The active ingredient in TANYZ is tamsulosin hydrochloride. 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.

TANYZ 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 TANYZ

Do not take TANYZ

- if you are **allergic to tamsulosin or any of the other ingredients of this medicine** (listed in section 6). Hypersensitivity or allergy to tamsulosin hydrochloride can express itself as sudden swelling of hands or feet, swollen lips, tongue or throat causing difficulties in breathing and/or itch and rash (angio-oedema);
- if you have a **severe liver condition**;
- if you suffer from fainting due to reduced blood pressure when changing posture (going to sit or standing up).

Warnings and precautions

Talk to your doctor or pharmacist before taking TANYZ.

- 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 TANYZas 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 have 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 have previously used, are using, or are planning to use TANYZ. 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).

Children

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

Other medicines and TANYZ

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

Taking TANYZ together with other medicines from the same class (α 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 TANYZ from the body (for example, ketoconazole, erythromycin).

Taking TANYZ with food and drink

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

Pregnancy, breast-feeding and fertility

TANYZ is not intended for use by women.

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 TANYZ 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.

TANYZ contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially "sodium-free".

3. How to take TANYZ

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

Dosage

For adults and the elderly, the dose is one capsule each day. It should be taken after breakfast or the first meal of the day. Swallow the capsule whole. Do not crunch or chew.

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

If you take more TANYZ than you should

Taking too many TANYZ 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 TANYZ.

If you forget to take TANYZ

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

If you stop taking TANYZ

When treatment with TANYZ is stopped prematurely, your original complaints may return. Therefore use TANYZ 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)
- 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)

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- PMS-433U-KRKA


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Article name.: XX PL. TANYZ IE
Dimension: 148 ± 0,5 mm x 420 ± 0,8 mm
Material: Woodfree paper 50 g/m ²
PhC No.: /
Measure: 1:1
Date: 05.06.2019
Prepared by: A. Mohorič
Checked by: N. Regina
Packaging Design

130 mm ± 0,5 mm

direction of reading PhC

**Rare (may affect up to 1 in 1,000 people)**

- fainting
- 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)

- dry mouth
- blurred vision, visual impairment,
- nosebleed,
- 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 TANYZ, 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 TANYZ

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.

This medicine does not require any special 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 TANYZ contains**

- The active substance is tamsulosin hydrochloride. Each hard modified-release capsule contains 400 micrograms tamsulosin hydrochloride.

- The other ingredients are microcrystalline cellulose (E460), methacrylic acid – ethyl acrylate copolymer (1:1) dispersion 30 per cent, polysorbate 80 (E433), sodium laurilsulfate, triethyl citrate (E1505) and talc (E553b) in the capsule core and gelatin (E441), indigo carmine (E132), titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172) and black iron oxide (E172) in the capsule shell.
- See section 2 "TANYZ contains sodium".

What TANYZ looks like and contents of the pack

TANYZ 400 micrograms hard modified-release capsules are orange/olive-green in colour. The capsules contain white to off-white pellets. The capsule size is 19.3 mm x 6.4 mm.

TANYZ is available in boxes containing 20, 30, 90 and 100 hard modified-release capsules in blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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

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
Denmark	Tamsulosin Krka
Spain, Italy	Tamsulosina Krka
France	TAMSULOSINE KRKA LP
Ireland	TANYZ
Norway	Tamsulosin Krka

This leaflet was last revised in

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