

Package leaflet: information for the user**Tamsulosin hydrochloride Zentiva
400 microgram prolonged-release hard capsules**

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

1. What tamsulosin capsules are and what they are used for

Tamsulosin hydrochloride Zentiva 400 microgram prolonged-release hard capsules (called tamsulosin capsules throughout this leaflet) contains the active substance tamsulosin, which reduces the tension in muscles of the prostate and urethra. Thus an easier flow of urine through the urethra and subsequently easier urination are facilitated. Tamsulosin capsules are used in men for the treatment of difficulties associated with benign enlargement of the prostate such as: difficult urination, urinary dribbling, strong urge to urination, frequent urination during the night as well as during the day.

2. What you need to know before you take tamsulosin capsules**Do not take tamsulosin capsules**

- if you are allergic to tamsulosin or any of the other ingredients of this medicine (listed in section 6).
- if angioedema (swelling due to allergic reaction) occurs after using of some drugs.
- if you suffer from a serious infection of the liver.
- if you suffer from dizziness when you want to sit up or stand up from the lying position.

Warnings and precautions

Talk to your doctor or pharmacist before taking tamsulosin capsules.

On long-term use of this product regular medical examinations are necessary.

Infrequently, drop in blood pressure has been reported during the use of the product tamsulosin capsules. On first feeling of dizziness, it is necessary to sit down or lay down until disappearance of these signs.

Caution should be paid if you have severely impaired renal function as there is not sufficient data from clinical studies about patients with severe renal impairment.

Angioedema (swelling due to allergic reaction) has been rarely reported after the use of tamsulosin. In case of angioedema seek immediate medical assistance and discontinue use of tamsulosin capsules. The product should not be re-administered.

If you are planning to undergo cataract or glaucoma surgery, please inform your doctor that you are taking or have recently taken tamsulosin capsules. 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).

Caution should be exercised if you have already had malaise while you urinate or after urinating (micturition syncope).

Children and adolescents

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

Other medicines and tamsulosin capsules

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

Other medicines may be affected by tamsulosin. They, in turn, may affect how well tamsulosin works. Tamsulosin can interact with:

- **diclofenac**, a pain killer and anti-inflammatory medicine. This medicine can speed up the removal of tamsulosin from your body, thereby shortening the time tamsulosin is effective.
- **warfarin**, a medicine to prevent blood clotting. This medicine can speed up the removal of tamsulosin from your body, thereby shortening the time tamsulosin is effective.
- **another α_{1A} -adrenoceptor blocker**. The combination may lower your blood pressure, causing dizziness or light-headedness.
- medicines that may decrease the removal of tamsulosin capsules from the body (for example, ketoconazole, erythromycin).

Tamsulosin capsules with food and drink

Take tamsulosin capsules after breakfast or after the first daily meal. Swallow whole, while sitting or standing, and follow with a glass of water. Do not open, crush or chew.

Pregnancy, breast-feeding and fertilityPregnancy and breast-feeding

Tamsulosin capsules are designed only for the treatment of men therefore information on pregnancy and breast-feeding is not relevant.

Fertility

Difficulties with ejaculation have been reported in association with tamsulosin use (see section 4).

Driving and using machines

Dizziness can occur during the treatment. Therefore activities requiring enhanced alertness should be performed only if allowed by the doctor.

Important information about some of the ingredients of tamsulosin capsules

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

3. How to take tamsulosin capsules

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is one capsule a day. Take tamsulosin capsules after breakfast or after the first daily meal. Swallow whole, while sitting or standing, and follow with a glass of water. Do not open, crush or chew.

If you take more tamsulosin capsules than you should

Drop in blood pressure can occur after overdosage. Blood pressure and heart rate will return to normal by lying the patient down.

If you take more tamsulosin capsules than you should, or in case of an accidental ingestion of the product by a child, immediately seek your doctor's advice.

If you forget to take tamsulosin capsules

If you have forgotten to take tamsulosin capsules at the scheduled time, take it anytime later during the day. If you realize this fact only on the next day, continue with the usual dosage scheme. Do not take a double dose to make up for a forgotten capsule.

If you stop taking tamsulosin capsules

Do not stop taking without medical advice from your doctor.

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

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4. Possible side effects

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

If dizziness or weakness occurs, it is necessary to sit down or lay down until disappearance of these signs.

Discontinue use of this product and seek immediate medical assistance if you get:

- Hypersensitivity reaction with purplish spots or patches on the skin, blisters on the skin, peeling of the skin, (high) fever, joint pain and/or eye inflammation (Stevens-Johnson syndrome).*
- Serious allergic reaction which causes swelling of the face or throat (angioedema).**

The side effects which may occur are listed below in groups according to the frequency:

- *Common (may affect up to 1 in 10 people):* Dizziness (can occur especially on an abrupt alteration of the position – when sitting up or standing up from the lying position), difficulties with ejaculation, little or no semen ejaculated at sexual climax, cloudy urine following sexual climax.
- *Uncommon (may affect up to 1 in 100 people):* Headaches, feeling your heartbeat (palpitations), light-headedness or fainting (orthostatic hypotension), swelling and irritation inside the nose (rhinitis), constipation, diarrhoea, feeling sick (nausea), vomiting, rash, itching, hives (urticaria), feeling of weakness (asthenia).
- *Rare (may affect up to 1 in 1,000 people):* Short-term loss of consciousness (syncope), angioedema**.
- *Very rare (may affect up to 1 in 10,000 people):* Painful long-lasting unwanted erection which requires immediate medical assistance (priapism), Stevens-Johnson syndrome*.
- *Not known (frequency cannot be estimated from the available data):* Disturbances of vision, blurred vision, bleeding from the nose (epistaxis), rash with red irregular spots (erythema multiforme), erythema and scaling of the skin (dermatitis exfoliative), abnormal irregular heart rhythm (atrial fibrillation, arrhythmia, tachycardia), difficult breathing (dyspnoea), dry mouth.

During eye surgery (cataract or glaucoma) a condition called Floppy Iris Syndrome (IFIS) may occur: The pupil may dilate poorly and the iris (the coloured circular part of the eye) may become floppy during surgery. For more information see section 2.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store tamsulosin capsules

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 below 25 °C.

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 tamsulosin capsules contain

The active substance is tamsulosin hydrochloride at an amount of 400 microgram in each capsule (equivalent to 367 microgram of tamsulosin).

The other ingredients are:

Capsule content: Cellulose microcrystalline; metacrylic acid – ethyl acrylate copolymer (1:1) dispersion 30% (contains sodium laurilsulfate, polysorbate 80); dibutyl sebacate; silica, colloidal hydrous; polysorbate 80; calcium stearate.

Capsule shell: Gelatin; titanium dioxide (E171); yellow iron oxide (E172); red iron oxide (E172); black iron oxide (E172); indigotine – FD&C Blue2 (E132).

What tamsulosin capsules look like and contents of the pack

Tamsulosin capsules are hard gelatin capsules, no. 3 with orange body and olive cap containing white to off-white pellets.

Each package contains 10, 20, 30, 50, 90 or 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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