

1.3.1 Package Leaflet

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tamsulosine HCl Zentiva 0,4 mg, tabletten met verlengde afgifte tamsulosine 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.

In this leaflet:

1. What <Tamsulosin hydrochloride 0.4 mg> is and what it is used for
2. What you need to know before you take <Tamsulosin hydrochloride 0.4 mg>
3. How to take <Tamsulosin hydrochloride 0.4 mg>
4. Possible side effects
5. How to store <Tamsulosin hydrochloride 0.4 mg>
6. Contents of the pack and other information

1 What <Tamsulosin hydrochloride 0.4 mg> is and what it is used for

Tamsulosin relaxes the muscles in the prostate and urinary tract. By relaxing the muscle tamsulosin enables a more easily pass of urine and helps urination. In addition, it diminishes sensations of urge.

Tamsulosin is prescribed in men to alleviate urinary symptoms caused by an enlarged prostate (benign prostatic hyperplasia). These symptoms 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 <Tamsulosin hydrochloride 0.4 mg>

Do not take <Tamsulosin hydrochloride 0.4 mg> 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).

- have a history of a fall in blood pressure on standing up, which causes **dizziness, light-headedness or fainting**.
- have **severe liver problems**

Warnings and precautions

Talk to your doctor or pharmacist before using <Tamsulosin hydrochloride 0.4 mg>

- if you experience **dizziness or light-headedness**, especially after standing up. Tamsulosine may lower your blood pressure, causing these symptoms. You should sit or low down until the symptoms have gone.
- 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 of the eye (glaucoma). An eye condition called Intraoperative Floppy Iris Syndrome may occur (see section 4, Possible side effects). Please inform your eye specialist that you have previously used, are using, or are planning to use tamsulosin hydrochloride. 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 of the eye (glaucoma).

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

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 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 hydrochloride 0.4 mg>

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 tamsulosine 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 tamsulosine is effective.
- **another α_{1A} -adrenoreceptor blocker**. The combination may lower your blood pressure, causing dizziness or light-headedness.
- **ketoconazole**, a medicine to treat fungal skin infections. This medicine may increase the effect of tamsulosin.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

<Tamsulosin hydrochloride 0.4 mg> with food, drink and alcohol

Tamsulosin can be taken independently of food.

Pregnancy, breast-feeding and fertility

Tamsulosin is not indicated for use in 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 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 <Tamsulosin hydrochloride 0.4 mg>

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

The **usual 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.

Tamsulosin is not intended for use in children.

If you take more <Tamsulosin hydrochloride 0.4 mg> than you should

Your blood pressure may suddenly drop if you take more tamsulosin than you should. You may experience dizziness, weakness, vomiting, diarrhoea and fainting. Lie down to minimise the effects of low blood pressure and then contact your doctor.

If you forget to take <Tamsulosin hydrochloride 0.4 mg>

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 <Tamsulosin hydrochloride 0.4 mg>

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 side effects (may affect up to 1 in 10 people)

Dizziness

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 side effects (may affect up to 1 in 100 people)

Headache • Feeling your heart beat (palpitations) • a Fall in blood pressure on standing up, which causes dizziness, 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 side effects (may affect up to 1 in 1,000 people)

Fainting (syncope)

Very rare side effects (may affect up to 1 in 10,000 people)

Painful erection (priapism) • Serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome)

Not known side effects (frequency cannot be estimated from the available data)

Blurred vision • Vision loss • Nose bleed • Dry mouth

Serious skin rashes (erythema multiform, dermatitis exfoliative)

Abnormal heart rhythm • Irregular heart beat • Faster heart beat • Difficulty breathing

During eye surgery because of cloudiness of the lens (cataract) or increased pressure in the eye (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, Warnings and precautions.

Reporting of side effects

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

You can also report side effects directly via <to be completed nationally>. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store <Tamsulosin hydrochloride 0.4 mg>

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 packaging after 'EXP'. The first two digits indicate the month and the last four digits indicate the year. The expiry date refers to the last day of that month.

Store the blisters in the original package to protect from light.

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 ourther information

What <Tamsulosin hydrochloride 0.4 mg> contains

- The active substance is 0.400 mg400 microgram of tamsulosin hydrochloride, equivalent to 0.367 mg367 microgram tamsulosin.
- The other ingredients are:

Inner tablet: cellulose microcrystalline, hypromellose, carbomer, silica colloidal anhydrous, iron oxide red (E172), magnesium stearate

Outer tablet: cellulose microcrystalline, hypromellose, carbomer, silica colloidal anhydrous, magnesium stearate

What <Tamsulosin hydrochloride 0.4 mg> looks like and contents of the pack

White, un-scored, round tablets with a diameter of 9 mm, debossed on one side with "T9SL" and "0.4" on the other side.

They are supplied in blister packs with 10, 18, 20, 28, 30, 50, 60, 90, 98 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Houder voor het in de handel brengen:

ZENTIVA, k.s.

U Kabelovny 130, 102 37

Praag 10

Tsjechië

Fabrikanten:

Synthon BV

Microweg 22

6545 CM Nijmegen

Nederland

Synthon Hispania SL

Castelló 1, Polígono Las Salinas

08830 Sant Boi de Llobregat

Spanje

In het register ingeschreven onder: RVG 114204

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

Deze bijsluiter is voor het laatst goedgekeurd in februari 2015