Package leaflet: information for the patient

Tamsulosine HCl ratiopharm 0,4 mg, tabletten met verlengde afgifte

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 <Invented name> is and what it is used for

The active ingredient in <Invented name> 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.

<Invented name> is prescribed in men to alleviate urinary symptoms caused by an enlarged prostrate (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 <Invented name>

Do not take <Invented name>
- if you are **allergic (hypersensitive) to tamsulosin or 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 have a history of a fall in blood pressure on standing up, which causes **dizziness, light-headedness or fainting**.
- if you have **severe liver problems**

Warnings and precautions
Talk to your doctor or pharmacist before taking <Invented name>
- 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 in the eye (glaucoma). 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 in the eye (glaucoma).

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

<Invented name> is a specially designed tablet from which the active ingredient is gradually released once the tablet has been ingested. 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 adolescents under 18 years because it does not work in this population.

Other medicines and <Invented name>
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use 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 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.
- 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 tamsulosin hydrochloride from the body (for example, **ketoconazole, erythromycin**).

<Invented name> with food and drink
Tamsulosin can be taken independently of food.

Pregnancy, breast-feeding and fertility
<Invented name> 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. However, you should bear in mind that tamsulosin may cause dizziness and light-headedness. Only drive or use machines if you feel alright.

3. How to take <Invented name>

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 tablet per day. You can take <Invented name> 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, <Invented name> is prescribed for long periods of time. The effects on the bladder and on the urination are maintained during long-term treatment with <Invented name>.

Use in children and adolescents
Tamsulosin is not intended for use in children and adolescents.

If you take more <Invented name> than you should
Taking too many <Invented name> 0.4 mg prolonged-release 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 tamsulosin hydrochloride 0.4 mg.

If you forget to take <Invented name>
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 <Invented name>
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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, tamsulosin 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** (angioedema).

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
- 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 or being sick (nausea or vomiting)

- Rashes, itching and hives (urticaria)
- Feeling of weakness (asthenia)

Rare (may affect up to 1 in 1,000 people)
- Fainting (syncope)
- Skin rash or hives on the whole body with swelling of the face, lips, tongue or throat, which may cause difficulty swallowing or breathing (angioedema)

Very rare (may affect up to 1 in 10,000 people)
- Priapism (painfulprolonged unwanted erection for which immediate medical treatment is required)
- Serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome)

Not known (frequency cannot be estimated from the available data)
- Abnormal irregular heart rhythm (atrial fibrillation, arrythmia, tachycardia)
- Difficulty breathing (dyspnoea)
- Visual disorders (blurred vision, impaired vision)
- Nosebleed (epistaxis)
- Dry mouth
- Inflammatory skin disease, reddish itchy blotches (erythema multiforme)
- Redness and scaling of the skin (dermatitis exfoliative)

During eye surgery a condition called Floppy Iris Syndrome (IFIS) may occcur: 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, 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 Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

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 to protect the environment.

6. Contents of the pack and other information

What <Invented name> contains
- The active substance is 0.4 mg of tamsulosin hydrochloride, equivalent to 0.367 mg tamsulosin.
- The other ingredients are:
  Inner tablet: cellulose microcrystalline, hypromellose, carbomer, silica colloidal anhydrous, iron oxide red (E 172), magnesium stearate

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

What <Invented name> looks like and contents of the pack
White, round tablets with the inscription "T9SL" on one side 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.

Houder van de vergunning voor het in de handel brengen en fabrikant
Houder van de vergunning voor het in de handel brengen
Ratiopharm GmbH
Graf-Arco-Str. 3
89079 Ulm
Duitsland

Fabrikant
Synthon BV
Microweg 22
6545 CM Nijmegen
Nederland

Synthon Hispania S.L.
C/ Castelló, no 1, Pol. Las Salinas
08830 Sant Boi De Llobregat
Spanje

Merckle GmbH
Graf Arco Strasse 3
89079 Ulm
Duitsland

Dit geneesmiddel is geregistreerd in de lidstaten van de Europese Economische Ruimte onder de volgende namen:

Nederland	Tamsulosine HCl ratiopharm 0,4 mg, tabletten met verlengde afgifte
Spanje	Tamsulosina ratiopharm 0,4 mg comprimidos de liberación prolongada EFG

Deze bijsluiter is voor het laatst goedgekeurd in september 2023.