Package leaflet: Information for the patient

Tamsulosine HCl Sandoz retard capsule 0,4 mg, capsules met gereguleerde afgifte, hard

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 [Nationally completed name] is and what it is used for
The active substance of [Nationally completed name] is tamsulosin. This is an alpha-1-receptor blocker that reduces the ability to contract the muscles in the prostate and urethra. As a result, the urethra, which runs through the prostate, is less constricted so that urinating is easier. In addition, it diminishes sensations of urge.

[Nationally completed name] is used by men for the treatment of complaints in the lower urinary tract that occur in benign prostate enlargement. 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 [Nationally completed name]
Do not take [Nationally completed name]
- if you are allergic to tamsulosin or any of the other ingredients of this medicine (listed in section 6)
- if you have serious liver problems if you 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 [Nationally completed name].
- Periodic medical examinations are necessary to monitor the development of the condition you are being treated for.

- If you suffer from a serious kidney problems
- In rare cases during the use of [Nationally completed name], fainting may occur on sitting up straight or standing. If you start to feel dizzy or weak you must lie down or sit down until it has passed.
- Before therapy with [Nationally completed name] is initiated, you should be evaluated by your doctor in order to exclude the presence of other conditions which can cause the same symptoms as benign (harmless) prostate enlargement. Your doctor will likely to examine your prostate gland manually (done by hands) to detect abnormalities and may measure a chemical substance produced by the prostate (prostate specific antigen, PSA) in your blood before treatment and at regular intervals afterwards.
- In rare occasions, severe allergic reaction with swelling of the face, lips, tongue and throat which may cause difficulty in breathing, speaking or swallowing (angio-oedema) may occur. If this happens, you should stop taking [Nationally completed name] immediately and contact your doctor.
- If you are undergoing or have been scheduled for eye surgery because of cataract (cloudiness of the lens) or increased pressure in the eye (glaucoma), please inform your eye specialist before the operation that you have previously used, are using, or are planning to use tamsulosin. This is because [Nationally completed name] may cause complications during the surgery which can be managed if your specialist is prepared in advance.

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 [Nationally completed name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines,.

In particular, tell your doctor or pharmacist if you are taking:
• Medicines that lower your blood pressure such as verapamil and diltiazem
• Medicines to treat HIV such as ritonavir or indinavir
• Medicines to treat a fungal infection such as ketaconazole or itraconazole
• Other alpha blockers such as doxazosin, indoramin, prazosin or alfuzosin
• Erythromycin, an antibiotic used to treat infections

[Nationally completed name] with food and drink
You should take the capsule after breakfast, or the first meal of the day.

Pregnancy, breast-feeding and fertility
[Nationally completed name] 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 [Nationally completed name] affects the ability to drive or to operate machinery or equipment.You should take into account the possibility that [Nationally completed

name] may cause dizziness. In that case you should not drive vehicles and/or operate machinery that requires concentration.

[Nationally completed name] contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per hard modified-release capsule, that is to say essentially 'sodium-free'.

3. How to take [Nationally completed name]
Always take this medicine exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure. The recommended dose is one capsule per day taken orally. Take the capsule after breakfast, or the first meal of the day. Swallow the capsule whole with some water while standing or sitting (not lying down). Do not chew or break the capsule.
Usually, [Nationally completed name] is prescribed for long periods of time. The effects on the bladder and on urination are maintained during long-term treatment with [Nationally completed name].
Follow these instructions unless otherwise indicated by your doctor. Remember to take your medication. Your doctor will indicate the duration of your treatment with [Nationally completed name].

If you take more [Nationally completed name] than you should
If you take more [Nationally completed name] than you should, consult your doctor or pharmacist or go to the local hospital accident and emergency department immediately and take this leaflet and any other remaining capsules.
Symptoms of [Nationally completed name] overdose may include dizziness, fainting and headache.

If you forget to take [Nationally completed name]
If you forget to take your daily [Nationally completed name] after breakfast or first meal of the day, you can take it later the same day after another meal. If you miss a whole day, just continue to take your normal daily dose the next day after breakfast or first meal of the day. Do not take a double dose to make up for a forgotten dose.

If you stop taking [Nationally completed name]
If the treatment with [Nationally completed name] is stopped earlier than recommended, then the original symptoms may return. For this reason, use [Nationally completed name] for the duration of your treatment, as recommended by your doctor even though your symptoms may, have disappeared. Always consult your doctor if you are considering to stop taking the medicine.

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.

Contact your doctor or hospital immediately if you notice any of the following rare serious side effects (it may be an allergic reaction):
rash, itching, inflamed or reddened skin (especially affecting the whole body); swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing (angio-oedema).

The following side effects have been reported during the use of tamsulosin hydrochloride:

Common (may affect up to 1 in 10 people)
- dizziness, abnormal ejaculation

Uncommon (may affect up to 1 in 100 people)
- headache
- feeling your heart beet
- orthostatic hypotension (experience dizziness caused by low blood pressure after sitting or standing up)
- runny or blocked nose (rhinitis)
- feeling sick and being sick, diarrhoea and constipation
- allergic reactions such as skin rash, itching and local inflammation
- weakness

Rare (may affect up to 1 in 1,000 people)
- fainting
- generalized hives

Very rare (may affect up to 1 in 10,000 people)
- priapism (persistent and painful erection of the penis without sexual stimulus which requires immediate medical attention)
- serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome)

Not known (Frequency cannot be estimated from the available data):
Vision blurred, visual impairment, bleeding from the nose, rash, inflammation and blistering of the skin (erythema multiforme, dermatitis exfoliative), irregular heart beat, faster heart beat, shortness of breath , dry mouth

If you may undergo a cataract or glaucoma surgery while you are taking or have taken [Nationally completed name], your pupil may not correctly dilate and the iris (the coloured part of the eye) may become floppy (see also section “Take special care with [Nationally completed name]”.

Reporting of side effects
If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. 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 [Nationally completed 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 blister and carton after “EXP”. The expiry date refers to the last day of that month.

Store below 30ºC.

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 [Nationally completed name] contains

- The active substance is tamsulosin hydrochloride. Each hard modified-release capsule contains 0.4 mg of tamsulosin hydrochloride.
- The other ingredients are: microcrystalline cellulose (E 460), polyacrylate dispersion 30%, metacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30%, polysorbate 80 (E 433), sodium laurilsulfate, talc (E 553b), colloidal anhydrous silica (E 551) in the content of the capsule; gelatin (E 441), patent blue V (E 131), titanium dioxide (E 171), yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172) in the capsule shell.

What [Nationally completed name] looks like and contents of the pack

Light green/yellow hard modified-release capsules filled with white to slightly yellowish pellets.

The hard modified-release capsules are packed in ALU/PVC/TE/PVDC blisters and inserted in a carton.

Pack sizes:
10, 20, 28, 30, 50, 56, 60, 90, 100 hard modified-release capsules

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:
Sandoz B.V., Veluwezoom 22, Almere

Fabrikanten:
Lek Pharmaceuticals d.d.
Verovškova 57,
1526 Ljubljana
Slovenië

Salutas Pharma GmbH
Otto-von-Guericke Allee 1
39179 Barleben
Duitsland

Lek S.A.
Ul. Domaniewska 50C
02-672 Warzawa
Polen

In het register ingeschreven onder:
Tamsulosine HCl Sandoz retard capsule 0,4 mg - RVG 33747

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:
Nederland: Tamsulosine HCl Sandoz retard capsule 0,4 mg, capsules met gereguleerde afgifte, hard
Denemarken: Miktosan
Noorwegen: Miktosan
Verenigd Koninkrijk: Morvesin 400 microgram SR capsules

Deze bijsluiter is voor het laatst goedgekeurd in juli 2020.