B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Tamsulosin Viatris 400 microgram modified release capsules, 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 Tamsulosin Viatris is and what it is used for

The active ingredient in Tamsulosin Viatris is tamsulosin. This is a selective α 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.

Tamsulosin Viatris 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 Tamsulosin Viatris

Do not take Tamsulosin Viatris
- If you are allergic 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 suffer from severe 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 Tamsulosin Viatris
- Periodic medical examinations are necessary to monitor the development of the condition you arebeing treated for.
- Rarely, fainting can occur during the use of Tamsulosin Viatris as 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 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), please inform your eye specialist that you have previously used, are using , or are planningto use Tamsulosin Viatris. The specialist can then take appropriate precautions with respect to medication andsurgical 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) .

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

Taking Tamsulosin Viatris 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 Tamsulosin Viatris from the body (for example, ketoconazole, erythromycin).

Tamsulosin Viatris with food and drink
Tamsulosin Viatris must be taken after breakfast or the first meal of the day.

Pregnancy, breast-feeding and fertility
This section is not relevant, because Tamsulosin Viatris is intended for male patients only.
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 Viatris 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.

3. How to take Tamsulosin Viatris

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 is 1 capsule per day to be taken after breakfast or the first meal of each day. The capsule must be swallowed whole and not be crunched or chewed. Usually, Tamsulosin Viatris is prescribed for long periods of time. The effects on the bladder and on urination are maintained during long- term treatment with Tamsulosin Viatris.

If you takemore Tamsulosin Viatris than you should
Taking too many Tamsulosin Viatris may lead to an unwanted decrease in blood pressure and an increase in heartrate, with feelings of faintness. Contact your doctor immediately if you have taken too much Tamsulosin Viatris.

If you forget to take Tamsulosin Viatris
You may take your daily Tamsulosin Viatris later the same day if you have forgotten to take it as recommended. If you have missed a day, just continue to take your daily capsule as prescribed.
Do not take a double dose to make up for a forgotten capsule.

If you stop taking Tamsulosin Viatris
When treatment with Tamsulosin Viatris is stopped prematurely, your original complaints may return. Therefore use Tamsulosin Viatris 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.

Stop taking your medicine and seek medical help immediately, if you have any of the following allergic reactions:
- Difficulties in breathing
- Swollen face, tongue or throat (angioedema)
- Itch and rash

Common (may affect up to 1 in 10 people)
- dizziness
- abnormal ejaculation (ejaculation disorders). 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 (failure of ejaculation). This phenomenon is harmless.

Uncommon (may affect up to 1 in 100 people)
- headache
- rapid or irregular heart beat
- dizziness especially when standing up (orthostatic hypotension)
- runny or blocked nose
- constipation
- diarrhoea
- nausea (feeling of being sick)
- vomiting
- rash
- itching and hives (urticaria)
- feeling of weakness

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

Very rare (may affect up to 1 in 10,000 people)
- painful, prolonged, unwanted erection (priapism)
- a severe inflammatory eruption of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals, which is an allergic reaction to drugs or other substances called Stevens-Johnson syndrome

Not known (frequency cannot be estimated from the available data)
- nose bleeding
- vision blurred, visual impairment
- dry mouth
- serious skin rashes (erythema multiforme, dermatitis exfoliative)

If you are undergoing eye surgery because of cloudiness of the lens (cataract) and are already taking or have previously taken tamsulosin hydrochloride, the pupil may dilate poorly and the iris (the coloured

circular part of the eye) may become floppy during the procedure (see section 2 “Warnings and precautions”).

In addition to the adverse events listed above,

- very rapid uncoordinated contractions of the heart
- irregular rhythm of the heartbeat
- abnormally rapid heart rate and

difficulty in breathing have been reported in association with tamsulosin hydrochloride use. Because these spontaneously reported events are from the worldwide post-marketing experience, the frequency of events and the role of tamsulosin hydrochloride in their causation cannot be reliably determined

Reporting of side effects
If you get any side effects, talk to your doctor pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tamsulosin Viatris

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage condition
Do not use this medicine after the expiry date which is stated on the blister pack, bottle and carton after EXP. The expiry date refers to the last day of that month.

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 Viatris contains
Each capsule contains 0.4 mg of tamsulosin hydrochloride.

The other ingredients are:
Pellets: Metacrylic acid – ethyl acrylate copolymer (1:1) dispersion 30 per cent*, cellulose microcrystalline, dibutyl sebacate, polysorbate 80 (E433)
Coating layer: Metacrylic acid – ethyl acrylate copolymer (1:1) dispersion 30 per cent*, dibutyl sebacate, polysorbate 80 (E433), silica, colloidal hydrated
Calcium stearate

- *Hard capsule of gelatin:* Red iron oxide (E172), Titanium dioxide (E171), Yellow iron oxide (E172), Black iron oxide (E172), Indigotine - FD&C Blue2 (E132), Gelatin*the dispersion contains 0.7 % Sodium Laurylsulfate Ph. Eur. / NF and 2.3 % Polysorbate 80 Ph. Eur. / NF on solid substance, as emulsifiers.

What Tamsulosin Viatris looks like and contents of the pack

Tamsulosin Viatris are hard capsules, approximately 15.6 – 16.2 mm closed, opaque, orange body and olive green cap. Tamsulosin Viatris are packed in PVC/PVdC-Al blisters or HDPE bottles that are supplied in a cardboard box.
PVC/PVDC-aluminium blister packs contain 10, 20, 30, 50, 90 or 100 capsules.
PVC/PVDC-aluminium perforated unit dose blisters containing 10 x 1, 20 x 1, 30 x 1, 50 x 1, 90 or 100 x 1 capsules.
HDPE Bottles contain 30, 35, 50, 60, 90, 100, 112 or 200 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Viatris Limited, Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland.

Manufacturer
LABORATORIOS LICONSA, S.A., Avda. Miralcampo, No. 7, Pol. Ind. Miralcampo, 19200, Azuqueca de Henares, Guadalajara, Spain.

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