TAMSULOSIN HYDROCHLORIDE 400 micrograms MR CAPSULES tamsulosin hydrochloride

Package leaflet: Information for the user

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

1 What Tamsulosin Hydrochloride is and what it is used for

Tamsulosin Hydrochloride is the brand name of your medicine. It is sometimes known by the name of the active ingredient, tamsulosin hydrochloride.

The active ingredient in Tamsulosin Hydrochloride 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.

Tamsulosin Hydrochloride 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 Hydrochloride

Do not take Tamsulosin Hydrochloride :
- 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 (angiooedema).
- if you suffer from fainting due to reduced blood pressure when changing posture (e.g. when sitting up from lying down or when standing up)
- if you suffer from severe liver problems.

Warnings and precautions
Talk to your doctor or pharmacist before taking Tamsulosin Hydrochloride:
- Because periodic medical examinations are necessary to monitor the development of the condition you are being treated for
- Because, rarely, fainting can occur during the use of Tamsulosin Hydrochloride 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
- 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).

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

Talk to your doctor if you are taking any of the following:
- other medicines from the same class e.g. alfuzosin, doxazosin or terazosin, because concurrent administration with tamsulosin may cause an unwanted decrease in blood pressure.
- diclofenac (an anti-inflammatory painkiller)
- warfarin (used to prevent blood clotting)
- It is especially important to inform your doctor if you are being treated with medicines that may decrease the removal of tamsulosin from your body, for example ketoconazole (used to treat fungal infections) and erythromycin.

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

Pregnancy, breast-feeding and fertility
Tamsulosin Hydrochloride 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 Hydrochloride 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.

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

3 How to take Tamsulosin Hydrochloride

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

The recommended dose is one capsule per day, to be taken after breakfast or the first meal of the day
The capsule must be swallowed whole and not be crunched or chewed
Usually, Tamsulosin Hydrochloride is prescribed for a long period of time. The effects on the bladder and on urination are maintained during long-term treatment with Tamsulosin Modified-Release Capsules.

If you take more Tamsulosin Hydrochloride than you should
Taking too many Tamsulosin Hydrochloride 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 many Tamsulosin Modified-Release Capsules.

If you forget to take Tamsulosin Hydrochloride
You may take your daily Tamsulosin Hydrochloride 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. Never take a double dose to make up for a forgotten dose.

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GENERAL INFORMATION	
INN	Tamsulosin Hydrochloride
Destination Markets	UNITED KINGDOM (GB)
Component Type	Leaflet
Packing Plant	SYNTHON B V ,
Dimensions	170x240 mm

ARTWORK CREATION	
Studio Artworker	Denitsa Atanasova
Origination Date	24-09-2026

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PRINT COLOURS

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If you stop taking Tamsulosin Hydrochloride
When treatment with Tamsulosin Hydrochloride is stopped prematurely, your original complaints may return. Therefore use Tamsulosin Modified-Release Capsules 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 the capsules and tell your doctor immediately or go to the casualty department at your nearest hospital if the following happens:
- an allergic reaction with sudden local swelling of the lips, face, tongue or throat leading to severe difficulty in breathing and/or itching and rash (angiooedema) (rare, may affect up to 1 in 1000 people).
- a serious illness with rash, inflammation and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals called Stevens-Johnson syndrome (very rare, may affect up to 1 in 10 000 people).

These are very serious but rare side effects. You may need urgent medical attention or hospitalisation.
The following side effects have been reported. If you experience any of these effects, and they are troubling you, contact your doctor.

Common (may affect up to 1 in 10 people)
- dizziness, particularly when going to sit or stand up.
- 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 (ejaculation failure). This phenomenon is harmless.

Uncommon (may affect up to 1 in 100 people)
- headache
- the heart beats more rapidly than normal and it is also noticeable (palpitations)
- reduced blood pressure e.g. when getting up quickly from a sitting or lying position
- runny or blocked nose (rhinitis)
- diarrhoea, constipation, nausea (feeling sick), vomiting
- rashes, itching and hives (urticaria)
- feeling of weakness (asthenia).

Rare (may affect up to 1 in 1000 people)
- fainting

Very rare (may affect up to 1 in 10 000 people)
- prolonged and painful erection that can last from several hours up to a few days (priapism).

Not known (frequency cannot be estimated from the available data)
- abnormal irregular heart rhythm (atrial fibrillation, arrhythmia, tachycardia)
- difficult breathing (dyspnoea)
- blurred vision
- impaired vision
- nosebleed (epistaxis)
- serious skin rashes (erythema multiforme, dermatitis exfoliative)
- dry mouth.

If you are undergoing eye surgery because of cloudiness of the lens (cataract) or increased pressure in the eye (glaucoma) 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”).

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 Hydrochloride

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

Blister packs: Store in the original package.
HDPE container: Store in the original container and keep the container tightly closed. Do not transfer to another container.

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.
Do not use this medicine after the expiry date which is stated on the carton and bottle label 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 Hydrochloride capsules contains
- The active ingredient is tamsulosin hydrochloride.
  Each capsule contains 0.4 mg tamsulosin hydrochloride.
- The other ingredients are microcrystalline cellulose, methacrylic acid-ethyl acrylate copolymer, polysorbate 80, sodium laurilsulfate, triethyl citrate, talc, gelatine, indigotin (E 132), titanium dioxide (E 171), yellow iron oxide (E 172), red iron oxide (E 172), black iron oxide (E 172).

What Tamsulosin Hydrochloride capsule looks like and contents of the pack
- The Tamsulosin Hydrochloride Modified-Release Capsules are hard gelatin capsules with orange coloured body and olive coloured cap. The capsule is filled with white to off-white pellets.
- The product is available
  in cardboard boxes with 10, 14, 20, 28, 30, 50, 56, 60, 90, 100, 180 or 200 modified-release capsules in PVC/PE/PVDC/ Aluminium blister packs and
  in HDPE tablet container with PP child-resistant closures containing 10, 14, 20, 28, 30, 50, 56, 60, 90, 100, 2x100, 180 or 200 modified-release capsules.
  Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Company Responsible for Manufacture:
Synthon Hispania S.L., Sant Boi de Llobregat, Barcelona, Spain.

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