

Package leaflet: Information for the user

Tamsulosin Teva 400 micrograms modified-release capsules

(Tamsulosin hydrochloride)

The name of your medicine is **Tamsulosin Teva 400 micrograms modified-release capsules** which will be referred to as Tamsulosin throughout this leaflet

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

1. -What Tamsulosin is and what it is used for

The active ingredient in your capsules, tamsulosin hydrochloride, belongs to a group of medicines known as alpha-1A-adrenoceptor blockers.

The capsules are used to treat the symptoms of Benign Prostatic Hyperplasia (BPH) which is caused by enlargement of the prostate gland in men which can cause difficulty in passing urine and/or frequent passing of urine. Tamsulosin works by relaxing muscle around the bladder and prostate gland so urine can be passed more easily.

2. What you need to know before you take Tamsulosin

Do not take Tamsulosin

- If you are allergic (hypersensitive) to tamsulosin hydrochloride or any of the other ingredients of this medicine (listed in section 6).

- If you have ever suffered from low blood pressure causing dizziness or fainting (e.g. when suddenly sitting or standing up).
- If you have taken tamsulosin before and had swelling of parts of your body e.g. lips, mouth, tongue, hands or feet.
- If you have serious liver disease

Warnings and precautions

Talk to your doctor or pharmacist before taking Tamsulosin

- If you have been found to suffer from severe kidney problems.
- If you experience dizziness or fainting during the use of Tamsulosin. Please sit or lie down straight away until the symptoms disappear.
- If you experience sudden swelling of hands or feet, difficulties in breathing and/or itch and rash, caused by an allergic reaction (angio-oedema) during the use of Tamsulosin.
- If you have been scheduled for cataract surgery

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

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

Please tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines:

- diclofenac (a drug used to treat pain and inflammation e.g. arthritis or gout).
- warfarin (a drug used to thin the blood).
- cimetidine (a drug used to treat excess stomach acid)
- furosemide (a diuretic)
- doxazosin, indoramin, prazosin and terazosin (drugs used to treat a number of conditions e.g. high blood pressure, BPH, heart failure)
- ketoconazole (a drug used to treat fungal infections).

Tamsulosin with food and drink

You should take your capsule after breakfast or the first meal of the day. You should stand or sit up when taking the capsule and swallow the capsule whole with a glass of water. Do not chew or break open the capsule.

Pregnancy, breast-feeding and fertility

Tamsulosin is not indicated for use in women.

Ejaculation problems (e.g ejaculation failure or retrograde ejaculation) have been reported with use of tamsulosin

Driving and using machines

Tamsulosin may cause dizziness. If you do feel dizzy, you should not drive or operate machinery.

3. How to take Tamsulosin

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

Adult males including the older people

- The recommended dose is one capsule a day.
- You should take your capsule after breakfast or the first meal of the day. You should stand or sit up when taking the capsule and swallow the capsule whole with a glass of water.
- Do not chew or break open the capsule.

If you take more Tamsulosin than you should

It is important to stick to the dose on the label of your medicine. If you or someone else swallows several of these capsules all together, or a child takes any of these tablets contact your doctor, pharmacist or hospital emergency department immediately. Always take the box and any left over capsules with you as this will make identification of the capsules quicker. Symptoms of overdose include feeling light-headed or dizzy due to a drop in your blood pressure, being sick and diarrhoea.

If you forget to take Tamsulosin

If you forget to take a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. Do not take a double dose to make up for a forgotten dose.

If you stop taking Tamsulosin

Do not stop taking Tamsulosin without talking to your doctor first, even if you feel better. If you have any further questions on the use of this product, ask your doctor or pharmacist.

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 (swelling of the lips, face or neck leading to severe difficulty in breathing, skin rash or hives)
- serious illness with blistering of the skin, mouth, eyes and genitals called Stevens-Johnson syndrome (may affect up to 1 in 10 000 people)

This is a very serious side effect. You may need urgent medical attention or hospitalisation.

The following side effects have also been reported:

Common (may affect up to 1 in 10 people):

- Dizziness
- Abnormal ejaculation, retrograde ejaculation, ejaculation failure.

Uncommon (may affect up to 1 in 100 people):

- Headache.
- A fast heart rate
- Feeling your heart beat
- Faintness or dizziness on standing up.
- Stuffy nose.
- Constipation, diarrhoea, feeling or being sick.
- Rash, itching and hives.
- Muscle weakness.

Rare (may affect up to 1 in 1 000 people):

- Fainting.
- Swelling of parts of your body e.g. lips, mouth, tongues, hands or feet.

Very rare (may affect up to 1 in 10 000 people):

- Persistent and usually painful erection.
- Possible complications in connection to cataract operations

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

- Chest pain or irregular heart beat
- Shortness of breath
- Blurred vision
- Nosebleed
- Dry mouth

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

5. -How to store Tamsulosin

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 carton after 'EXP'. The expiry date refers to the last day of that month.

Blister pack: Store in the original package.

Bottle: Keep the container tightly closed.

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 contains

- The active substance is tamsulosin hydrochloride 400 micrograms
- The other ingredients are microcrystalline cellulose, methacrylic acid-ethyl acrylate copolymer, polysorbate 80, sodium laurilsulfate, triethyl citrate, talc, gelatine, indigotine (E132), titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172), shellac and propylene glycol.

What Tamsulosin looks like and contents of the pack

Tamsulosin capsules are orange/olive green, modified release capsules marked with TSL 0.4 and a black stripe at both ends. The capsules contain white to off-white pellets. The capsules have been specially formulated to release tamsulosin slowly. Tamsulosin is available in blister packs or bottles of 10, 14, 20, 28, 30, 50, 56, 60, 90, 100 or 200 capsules though not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is:

Teva Pharma B.V., 2031GA Haarlem, Swensweg 5, The Netherlands.

The product is manufactured by

Synthon BV, Microweg 22, 6545 CM Nijmegen, Netherlands

Synthon Hispania S.L, Castello, 1, Polgono Las Salinas, Sant Boi de Llobregat, Spain.

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