

Package Leaflet: Information for the user

Tamsulosin 400 micrograms 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 400 micrograms modified-release capsules, hard are and what they are used for
2. What you need to know before you take Tamsulosin 400 micrograms modified-release capsules, hard
3. How to take Tamsulosin 400 micrograms modified-release capsules, hard
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1. What Tamsulosin 400 micrograms modified-release capsules, hard are and what they are used for

Tamsulosin 400 micrograms modified-release capsules, hard are modified release capsules. It contains an active ingredient in the capsules which is a so-called alpha 1A-blocker that reduces muscle contraction in the prostate and urethra. This facilitates the flow of urine through the urethra and aids urination.

Tamsulosin 400 micrograms modified-release capsules, hard are used for the treatment of urination symptoms caused by benign prostatic hyperplasia (BPH - enlarged prostate).

2. What you need to know before you take Tamsulosin 400 micrograms modified-release capsules, hard

Do not take Tamsulosin 400 micrograms modified-release capsules, hard

- If you are allergic to tamsulosin hydrochloride or any of the other ingredients of this medicine (listed in section 6). Hypersensitivity or allergy to tamsulosin hydrochloride can express itself as sudden swelling of hands or feet, difficulties in breathing and/or itch and rash swollen lips, tongue or throat, (angio-oedema).
- If you have experienced dizziness or have fainted from lowered blood pressure (e.g. when suddenly sitting or standing up).
- If you have been found to suffer from severe liver problems.

Warnings and precautions

Talk to your doctor before taking Tamsulosin 400 micrograms modified-release capsules, hard:

- 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, swollen lips, tongue or throat, difficulties in breathing and/or itch and rash, caused by an allergic reaction (angio-oedema) during the use of tamsulosin.
- If you are about to have an operation on your eye for cloudiness of the lens (cataract)

Please consult your doctor, even if these statements were applicable to you at any time in the past.

You should have your prostate examined by a doctor before taking Tamsulosin 400 micrograms modified-release capsules, hard and at regular intervals thereafter

Children and adolescents

Tamsulosin 400 micrograms modified-release capsules, hard are not indicated for use in the paediatric population (patients below 18 years of age).

Other medicines and Tamsulosin 400 micrograms modified-release capsules, hard

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

- Tamsulosin 400 micrograms modified-release capsules, hard may lower blood pressure when taken with other alpha 1A-blockers e.g. doxazosin, prazosin and indoramin.
- Diclofenac (an anti-inflammatory painkiller) and warfarin (used to prevent blood clotting) may have an influence on how fast Tamsulosin 400 micrograms modified-release capsules, hard are removed from the body.
- Medicines which lower you blood pressure such as verapamil and diltiazem.
- Medicines which are used to suppress your immune system e.g. ciclosporin
- Antibiotics to treat infection e.g. erythromycin, clarithromycin.
- Medicines to treat fungal infections e.g. ketoconazole, itraconazole, fluconazole, voriconazole.
- Medicines used to treat HIV e.g. ritonavir, saquinavir

Please note that these statements may also apply to products used some time ago or at some time in the future.

Tamsulosin 400 micrograms modified-release capsules, hard with food and drink

Tamsulosin should be taken after the first meal of the day. Taking tamsulosin on an empty stomach may increase the number of side effects or increase the severity of a side effect.

Pregnancy, breast-feeding and fertility

Tamsulosin 400 micrograms modified-release capsules, hard are not indicated for use in women.

Tamsulosin 400 micrograms modified-release capsules, hard may cause ejaculation disorders including inability to ejaculate.

Driving and using machines

Up until now, there is no evidence that tamsulosin affects the ability to drive or use machines. Patients should nevertheless be aware that dizziness may occur.

3. How to take Tamsulosin 400 micrograms modified-release capsules, hard

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 capsule a day after the first meal of the day.

The capsule should be taken while standing or sitting upright (not lying down) and should be swallowed whole with a glass of water.

The capsule must not be chewed.

Your physician has prescribed a suitable dose for you and your illness, and has specified the duration of the treatment.

The dose should not be independently changed.

If you have the impression that the effect of tamsulosin is too strong or too weak, talk to your doctor or pharmacist.

If you take more Tamsulosin 400 micrograms modified-release capsules, hard than you should

If you may have taken more tamsulosin than you should, talk to your doctor or pharmacist immediately.

If you forget to take Tamsulosin 400 micrograms modified-release capsules, hard

If you have forgotten to take tamsulosin after the first meal of the day, it can be taken later the same day after food. 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 forgotten individual doses.

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.

Serious side effects:

If you have any of the following symptoms, stop taking this medicine and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

- sudden swelling of hands or feet, difficulties in breathing and/or itch and rash, swollen lips, tongue or throat (angio-oedema)

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

- a widespread rash with severe blisters, peeling skin and bleeding in the lips, eyes, mouth, nose and genitals (Stevens-Johnson syndrome)

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

- a severe inflammation of the skin with pale-red, pale centred blotches known as erythema multiforme.

The following other side effects may also occur:

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

dizziness, ejaculation disorders including inability to ejaculate and ejaculation into the bladder (retrograde ejaculation)

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

headache, a sensation of abnormal heart beat (palpitations), dizziness especially when sitting or standing up, common cold, constipation, diarrhoea, nausea, vomiting, rash, itching, hives, 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)

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

an irregular heartbeat (atrial fibrillation), abnormal heart rhythm (arrhythmia), accelerated heart beat (tachycardia), shortness of breath (dyspnoea), blurred vision, impaired vision, nose bleed, scaly skin rash (dermatitis exfoliative), dry mouth.

In some occasions possible complications in connection to cataract operations have been observed.

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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; Email: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tamsulosin 400 micrograms modified-release capsules, hard

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

Store in the original package.

Keep the container tightly closed.

Do not use after the expiry date which is stated on the label 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 400 micrograms modified-release capsules, hard contain:

One modified-release capsule contains 400 micrograms of tamsulosin hydrochloride as the active substance.

The other ingredients are: microcrystalline cellulose, methacrylic acid-ethyl acrylate copolymer (1:1), polysorbate 80, sodium laurilsulfate, triethyl citrate and talc.

The capsule body ingredients are gelatine, indigo carmine (E 132), titanium dioxide (E 171), yellow iron oxide (E 172), red iron oxide (E 172) and black iron oxide (E 172).

What Tamsulosin 400 micrograms modified-release capsules, hard look like and contents of the pack

The Tamsulosin 400 micrograms modified-release capsules, hard are orange/olive-green in colour.

They are available in blister packaging or in containers of 10, 14, 20, 28, 30, 50, 56, 60, 90, 100 or 200 modified-release capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturers:

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Generics UK Ltd., Station Close, Potters Bar, Hertfordshire EN6 1TL, United Kingdom.
Mylan Hungary Kft., H-2900 Komárom, Mylan utca. 1, Hungary.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Tamsulosin Arcana retard 0,4 mg - Kapseln
Belgium: Tamsulosine Mylan 0,4 mg capsules met gereguleerde afgifte, hard
Czech Republic: Tamsulosin HCl Mylan 0,4 mg, tvrdé tobolky s řízeným uvolňováním
Finland: Tamsulogen 0.4 mg Säädellisesti vapauttava kapseli, kova
Germany: Tamsulosin-dura 0,4 mg Hartkapseln mit veränderter Wirkstofffreisetzung
Greece: Tamsulosin/Generics CR. CAP 0.4 mg/CAP
Hungary: Tamsugen 0,4 retard kemény kapszula
Iceland: Tamsulogen 0,4 mg forðahylki, hörð
Ireland: Tamsulosin 400 micrograms modified-release capsules, hard
Italy: Tamsulosin Mylan Generics
Norway: Tamsulosin Mylan kapsel med modifisert frisetting, hard 0.4mg
Poland: TAMSUGEN 0.4 mg kapsułki o zmodyfikowanym uwalnianiu, twarde
Portugal: Tansulosina Mylan
Slovakia: Tamsulosin HCl Mylan 0,4mg
Spain: Tamsulosina Mylan 0, 4 mg cápsulas duras de liberación modificada EFG
The Netherlands: Tamsulosine HCL Retard Mylan 0,4mg, harde capsules met gereguleerde afgifte
United Kingdom: Prosurin XL 400 microgram Capsules

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