**Package leaflet: Information for the patient**

**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 is and what it is used for

Tamsulosin contains the active ingredient tamsulosin hydrochloride which belongs to a group of medicines called alpha-adrenoreceptor antagonists (alpha 1A-blockers). These medicines are used to reduce muscle contraction in the prostate and urethra. This facilitates the flow of urine through the urethra and aids urination.

Tamsulosin is used for the treatment of lower urinary tract symptoms caused by an enlarged prostate, known as benign prostatic hyperplasia (BPH).

## 2. What you need to know before you take Tamsulosin

**Do not take Tamsulosin:**
- If you are allergic to tamsulosin or any of the other ingredients of this medicine (listed in section 6). Allergy to tamsulosin can express itself as sudden swelling of hands or feet, difficulties in breathing and/or itch and rash swollen lips, tongue or throat, (angioedema).
- If you have experienced dizziness or have fainted due to lowered blood pressure (e.g. when suddenly sitting or standing up).
- If you have severe liver problems.

**Warnings and precautions**
Talk to your doctor or pharmacist before taking Tamsulosin
- If you have severe kidney problems.
- If you are undergoing or about to have an operation on your eye for cloudiness of the lens (cataract) or increased pressure in the eye (glaucoma).
  An eye condition called Intraoperative Floppy Iris Syndrome may occur (see section 4, 'Possible side effects'). Please tell your eye specialist that you have previously taken, are taking, or are planning to take tamsulosin. 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).

During treatment
Talk to your doctor or pharmacist

- If you experience dizziness or fainting during the use of tamsulosin. If you experience these signs of orthostatic hypotension, 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 (angioedema) during the use of tamsulosin.

You should have your prostate or urinary system examined by a doctor before taking Tamsulosin and at regular intervals thereafter.

**Children and adolescents**
Do not give this medicine to children or adolescents under the age of 18 years because it does not work in this population.

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

- tamsulosin 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 is removed from the body.
- medicines which lower your 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.

**Pregnancy, breast-feeding and fertility**
Tamsulosin is not indicated for use in women.

Tamsulosin may cause ejaculation disorders including ejaculation of the semen into the urinary bladder (retrograde ejaculation) and inability to ejaculate (ejaculation failure).

**Driving and using machines**
No studies on the effects of tamsulosin on the ability to drive or use machines have been performed. However, patients should nevertheless be aware that dizziness may occur.

**Tamsulosin 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

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 breakfast or the first meal of the day.
The capsule should be swallowed whole.
The capsule must not be crunched or chewed as this will affect how the medicine gets into the body.

**If you take more Tamsulosin than you should**

If you may have taken more tamsulosin than you should, talk to your doctor or pharmacist immediately. You may get symptoms of low blood pressure such as dizziness, lightheadedness, fainting, blurred vision, irregular heartbeat, confusion, or being weak. If any of these symptoms occur, you should sit or lie down.

**If you forget to take Tamsulosin**
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 a forgotten individual capsule.

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 (angioedema)

**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)
- irregular and abnormal fast heartbeat (atrial fibrillation).

**Other possible side effects:**

**Common** (may affect up to 1 in 10 people)
- dizziness
- ejaculation disorders including inability to ejaculate and ejaculation of semen into the urinary bladder (retrograde ejaculation)

**Uncommon** (may affect up to 1 in 100 people)
- headache
- a sensation of abnormal heart beat (palpitations)
- dizziness especially when suddenly sitting or standing up (orthostatic hypotension)
- runny or blocked nose (rhinitis)
- constipation
- diarrhoea
- feeling sick
- being sick
- rash
- itching
- feeling of weakness (asthenia).

**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)
- widespread inflammation of the skin with pale-red, pale centred blotches known as erythema multiforme
- abnormal heart rhythm (arrhythmia)
- accelerated heart beat (tachycardia)
- shortness of breath (dyspnoea)
- blurred or reduced vision (impaired vision)
- nose bleed
- scaly skin rash (dermatitis exfoliative)
- dry mouth.

In some occasions possible complications in connection to cataract or glaucoma operations have been observed. During eye surgery a condition called Floppy Iris Syndrome (IFIS) may occur: the pupil may dilate poorly and the iris (the coloured circular part of the eye) may become floppy during surgery. For more information, 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 HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Tamsulosin

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

Store in the original package.
Keep the container tightly closed.

Do not use this medicine 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 contains:**

The active substance is tamsulosin hydrochloride.

Each modified-release capsule contains 400 micrograms of tamsulosin hydrochloride.
The other ingredients are: microcrystalline cellulose, methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 per cent, polysorbate 80, sodium laurilsulfate, triethyl citrate and talc.
The capsule shell ingredients are gelatin, 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 looks like and contents of the pack**

Tamsulosin are orange body/olive-green cap in colour. The capsules contain white to off-white spheres.

They are available in blister packaging of 10, 14, 20, 28, 30, 50, 56, 60, 90, 100, 200, and in a multipack of 200 comprising 2 cartons, each containing 100 modified-release capsules, 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**
Viatris Limited, Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland
**Manufacturers**
McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.
Mylan Hungary Kft, H-2900 Komárom, Mylan út. 1, Hungary.

**This medicine is authorised in the Member States of the European Economic Area under the following names:**

Austria: Tamsulosin Arcana retard 0,4 mg - Kapseln
Belgium: Tamsulosine Viatris 0,4 mg harde capsules met gereguleerde afgifte
Czech Republic: Tamsulosin HCl Mylan
Finland: Tamsulogen 0.4 mg säädellysti vapauttava kapseli, kova
Germany: Tamsulosin-dura 0,4 mg Hartkapseln mit veränderter Wirkstofffreisetzung
Greece: Tamsulosin/Mylan C.R. Capsules 0.4 mg/CAP
Iceland: Tamsulosin Viatris 0,4 mg hart hylki með breyttan losunarhraða
Ireland: Tamsulosin 400 micrograms Modified-release Capsules, Hard
Italy: Tamsulosin Mylan Generics
Norway: Tamsulosin Viatris
Poland: TAMSUGEN 0.4 mg kapsułki o zmodyfikowanym uwalnianiu, twarde
Portugal: Tansulosina Mylan
Slovakia: Tamsulosin HCL Viatris 0,4 mg
Spain: Tamsulosina Viatris 0,4 mg cápsulas duras de liberación modificada EFG
The Netherlands: Tamsulosine HCl Retard Mylan 0,4 mg, harde capsules met gereguleerde afgifte

**This leaflet was last revised in 02/2024.**