What is in this leaflet

Please read this leaflet carefully before you start using Tamsulosin Hydrochloride Capsule.

This leaflet answers some common questions about Tamsulosin Hydrochloride Capsule. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Tamsulosin Hydrochloride Capsule against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Tamsulosin Hydrochloride Capsule is used for

Tamsulosin is a medicine used by MEN only. It is used in men who have noncancerous enlargement of the prostate gland. This is a medical condition called benign prostatic hyperplasia, also known as BPH.

Tamsulosin is from a group of medicines called alpha-blockers.

Tamsulosin is used for symptoms caused by an enlarged prostate gland. This occurs only in men. BPH is common in men over the age of 50 years.

How does Tamsulosin work

The prostate gland lies deep in your pelvis, below your bladder. As your prostate has become bigger than it should be, it would affect how well you are able to pass your urine. This causes some, or all of the following symptoms; they usually start gradually and can increase in severity:
• You feel an urgency to pass urine as soon as you first feel the need to do so
• Urine flow is slow and the stream is poor.
• You feel that you cannot empty your bladder completely.
• You may dribble at the end of passing urine.
• The urine stream may become a trickle, or it may stop and start.
• You find a delay when you try to pass urine, and you have to strain to do so.
• You need to pass urine often during the day.
• You need to pass urine often during the night as well.

When passing urine, it travels from the bladder through a channel in the tissues of the prostate. When the gland becomes large, it presses on this channel, making it narrow. The channel can become completely blocked and no urine can be passed. This is a medical emergency.

Tamsulosin Hydrochloride Capsule is a medicine that relaxes the smooth muscle. Particularly the smooth muscle in the prostate. Tamsulosin works with BPH by widening the channel through the prostate gland, which then allows the urine to flow easily.

Your doctor may have prescribed Tamsulosin Hydrochloride Capsule for another reason.

Ask your doctor if you have any questions about why Tamsulosin Hydrochloride Capsule has been prescribed for you.

This medicine is available only with a doctor’s prescription.

____________________________

**Before you use Tamsulosin Hydrochloride Capsule**

**When you must not use it**

Do not use Tamsulosin Hydrochloride Capsule if:

• you have an allergy to Tamsulosin or any of the ingredients in Tamsulosin Hydrochloride Capsules (see Product description)
• you become dizzy or light-headed or have low blood pressure when you stand up, after sitting or lying down. This is called orthostatic hypotension.
• you have severe liver problems
• you have severe kidney function problems
• the medication is not prescribed for you

Only **MEN** use Tamsulosin. If you are a child or a woman, do not take Tamsulosin Hydrochloride Capsule. If you are not sure whether you should start using Tamsulosin Hydrochloride Capsule, talk to your doctor.
**Before you start to use it**

Tell your doctor if:

- you have angina (severe pain in the chest, usually on exertion) or have had a heart attack during the last six months;
- your blood pressure is too high or too low, or it is controlled by medication
- you have ever had ejaculation problems;
- you are suffering from any other illness

If you have not told your doctor about any of the above, tell them before you start using Tamsulosin Hydrochloride Capsule.

**Taking other medicines**

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Tamsulosin Hydrochloride Capsule.

Some medicines may interfere with Tamsulosin Hydrochloride Capsule. These include:

- Other alpha-blockers or medicines that reduce blood pressure. Tamsulosin Hydrochloride Capsules may lower blood pressure when taken with these medicines.
- The elimination of Tamsulosin may be reduced by ketoconazole (an antifungal medication), paroxetine (an antidepressant medication), cimetidine (for treatment of stomach ulcers or reflux) and other drugs. Reduced elimination may lead to increased side effects of Tamsulosin.

These medicines may be affected by Tamsulosin Hydrochloride Capsule, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Tamsulosin Hydrochloride Capsule.

**How to use Tamsulosin Hydrochloride Capsule**

**How much to take**

The prescriber’s instructions on how much and when to take the medicine should be followed. The label should be carefully read.
The usual dose is one capsule a day. Take the capsule about thirty minutes after breakfast or first meal of the day. You must swallow the capsule whole, preferably with a glass of water. Never bite or chew the capsule, as this stops it being absorbed at the desired rate. Do not take Tamsulosin Hydrochloride Capsule on an empty stomach as the risk of feeling faint or dizzy on standing up (orthostatic hypotension) is increased.

Do not take Tamsulosin Hydrochloride Capsule if the packaging is torn or shows signs of tampering, or if the capsules show visible signs of deterioration.

**If you forget to take it**

- If you forget to take your daily Tamsulosin after breakfast or first meal of the day, you can take it later the same day after another meal
- If you miss a whole day, just continue to take your normal daily dose the next day after breakfast or first meal of the day
- Do not take a double dose to make up for the dose that you have missed.

If you have trouble remembering to take Tamsulosin Hydrochloride Capsule, ask your pharmacist for some hints.

### While you are using Tamsulosin Hydrochloride Capsule

**Things you must do**

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Tamsulosin Hydrochloride Capsule.

**Things you must not do**

Do not give Tamsulosin Hydrochloride Capsule to anyone else, even if they have the same condition as you.

Do not stop the medicine without seeking advice from your doctor.

**Things to be careful of**

Tamsulosin can occasionally cause people to feel faint and dizzy. You should get up slowly from the sitting or lying position to reduce the risk of dizziness or light-headedness. If you do feel faint on standing up, you should lie down for a short while. If the dizziness persists you should contact your doctor.

You must not drive a car or operate machinery if you feel dizzy.
In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Tamsulosin Hydrochloride Capsule.

Do this even if there are no signs of discomfort or poisoning.

Symptoms of overdose may include vomiting, diarrhoea, and low blood pressure leading to dizziness or fainting. This is a serious condition and medical attention should be sought immediately.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Tamsulosin Hydrochloride Capsule.

Although most men prescribed Tamsulosin benefit, but as with any medicines, some side effects may occur. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

A few people may be allergic to some medicines. If you develop a skin rash, itchiness or swelling of the face, lips or tongue, tell your doctor immediately, as you may be having an allergic reaction to Tamsulosin. Swelling of the face, lips or tongue may cause difficulty in swallowing or breathing.

One of the side effects of Tamsulosin is known as "retrograde ejaculation". When this happens, the ejaculation fluid is not ejaculated out but most of it runs back into the bladder. Retrograde ejaculation is painless.

Medicines similar to Tamsulosin have very rarely caused prolonged painful erection of the penis, unrelated to sexual activity. While taking Tamsulosin, if you experience a prolonged erection, immediately contact your doctor or go to the emergency department of your nearest hospital.

Other side effects reported by people when taking Tamsulosin are dizziness, headache, itching, weakness, dizziness on standing, nausea, vomiting, diarrhoea, dry mouth, blurred vision, skin peeling, rash, constipation, fast heart beats, increase in coughing, blocked nose, nosebleed and infection.
Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

---

**After using Tamsulosin Hydrochloride Capsule**

**Storage**

Store Tamsulosin Hydrochloride Capsules below 25 °C. Keep the pack in a cool dry place. Do not store Tamsulosin Hydrochloride Capsules in the bathroom or near the sink, or in a car on a hot day. Keep Tamsulosin Hydrochloride Capsules in the original pack until you use them.

Do not use after the expiry date on the package.

Keep Tamsulosin Hydrochloride Capsules out of reach of children.

**Disposal**

Return to a pharmacy for disposal of any unused medicine and any medicine past its expiry date shown on the dispensing label or on the packaging, and any medicine past its expiry date as shown on the dispensing label or on the packaging.

---

**Product description**

**What it looks like**

Tamsulosin Hydrochloride Capsule is made of hard gelatin; it has a surface marking for identification purposes in black edible ink (‘R’ on Cap and ‘TSN400’ on the body).

The colours of the capsule are brown cap and orange body. The colouring agents in the capsule shell are indigo carmine, titanium dioxide and red and yellow iron oxides.

**Ingredients**

Active ingredient:

Each Tamsulosin Hydrochloride Capsule contains 400 micrograms (0.4 mg) of tamsulosin hydrochloride.
Inactive ingredients:

The capsule also contains cellulose, methacrylic acid copolymer, polysorbate 80, sodium lauryl sulphate, glycerol triacetate, magnesium stearate, colourants and talc.

Sponsor Details

Tamsulosin Hydrochloride Capsule is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd
PO Box 45 027
Auckland 0651
NEW ZEALAND

Phone: 09 835 0660

Date of Preparation

This leaflet was revised on 8 August 2014.