

Consumer Medicine Information

TAMSULOSIN Capsules

Tamsulosin hydrochloride *400 micrograms*

This leaflet contains the information about the use of Tamsulosin capsules. Please read all the instructions carefully before you start to take your medicine. Keep the leaflet, as you may want to read it again. The information in this leaflet answers some common questions. Your doctor or pharmacist will have more information. This leaflet is not to replace the discussion with your doctor about Tamsulosin.

Always talk to your doctor or pharmacist if there is anything that is worrying you or you do not understand any of the information.

WHAT IS Tamsulosin

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.

WHAT IS Tamsulosin USED FOR

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

Your Doctor will prescribe Tamsulosin to you for symptoms caused by an enlarged prostate gland. This occurs only in men. BPH is common in men over the age of 50 years.

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.

HOW DOES Tamsulosin WORK

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 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.

WHEN YOU SHOULD NOT TAKE Tamsulosin

Only MEN use Tamsulosin. If you are a child or a woman, do not take Tamsulosin. If you are not sure whether you should start taking Tamsulosin you should contact your doctor.

You should not take Tamsulosin if:

- you are allergic to any of the ingredients in the capsule (see "WHAT DOES Tamsulosin CONTAIN?").
 - 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 serious problems with your liver.
 - you have serious kidney function problems.
 - you are taking other medication which relaxes the smooth muscle (some of the tradenames are Minipress, Prasig, Hytrin).
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BEFORE YOU TAKE Tamsulosin

You should only use Tamsulosin if your doctor has prescribed it for you.

All the medicines have benefits and risks. When deciding to prescribe Tamsulosin for you, your doctor has weighed the risk of taking Tamsulosin against the benefit it is expected to have for you.

Your doctor has prescribed Tamsulosin for BPH and not for prostate cancer. These two separate conditions can have similar symptoms. A man can have prostate cancer and BPH at the same time. You should be checked for prostate cancer before you start Tamsulosin. It is recommended that the men be checked for prostate cancer once a year, from 50 years of age onwards. These checks should continue while you are on Tamsulosin.

Before you start taking Tamsulosin capsules you should tell your doctor if:

- you have an allergy to Tamsulosin or any of its ingredients (see "WHAT DOES Tamsulosin CONTAIN?").
 - you are taking any other medicines and what they are. This includes medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You must tell your doctor if you are taking cimetidine, a medicine, which is generally used to treat stomach ulcers or reflux.
 - 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.
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HOW MUCH Tamsulosin SHOULD I TAKE

The 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 on an empty stomach as the risk of feeling faint or dizzy on standing up (orthostatic hypotension) is increased.

Do not take Tamsulosin 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 missed.

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

SIDE EFFECTS

Although most men prescribed Tamsulosin benefit, but as with any medicines, some side effects may occur. Usually Tamsulosin does not usually cause any problems.

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 squirted out but most of it runs back into the bladder. Retrograde ejaculation is painless.

Other side effects reported by people when taking Tamsulosin are dizziness, headache, itching, weakness, dizziness on standing, nausea, vomiting, diarrhoea, constipation, rash, fast heart beats, increase in coughing, blocked nose and infection.

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.

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.

This is not a complete listing. Other unwanted effects may occur in some men. Tell your doctor if you notice any other effects.

You should always tell your doctor about any problems you have whilst taking Tamsulosin.

OVERDOSAGE

If you know or think that you or anyone else may have taken too much Tamsulosin, contact your doctor or go to the emergency department of your nearest hospital, or call the New Zealand National Poison Centre on 0800 POISON or 0800 764 766. 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.

WHAT DOES Tamsulosin CONTAIN

Each Tamsulosin capsule contains 400 micrograms of tamsulosin hydrochloride. The capsule is specially designed so that it gradually releases Tamsulosin into 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.

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

There are 30 capsules in each pack.

HOW TO STORE Tamsulosin

Keep Tamsulosin capsules in the original pack until you use them.

Store Tamsulosin capsules below 30°C. Keep the pack in a cool dry place. Do not store Tamsulosin in the bathroom or near the sink, or in a car on a hot day. Do not use after the expiry date on the package. Keep Tamsulosin out of reach of children.

This is not all the information available on Tamsulosin. If you have any more questions or are unsure about anything, ask your doctor or pharmacist.

Tamsulosin is distributed in New Zealand by:

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Tamsulosin is manufactured by:

Ranbaxy Laboratories

Dewas-455001, Madhya Pradesh, India

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