

APO-Tamsulosin SR

Contains the active ingredient tamsulosin hydrochloride

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about APO-TAMSULOSIN SR.

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 taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

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

What this medicine is used for

APO-TAMSULOSIN SR is a medicine for use by men only. Tamsulosin SR is used in men who have a medical condition called benign prostatic hyperplasia (also known as BPH). In BPH the prostate gland is bigger than normal. BPH is NOT prostate cancer.

Tamsulosin SR belongs to a group of medicines called alpha-blockers.

Your doctor has prescribed Tamsulosin SR for you because you have symptoms caused by an enlarged prostate gland. BPH occurs only in men. It is common in men over the age of 50 years.

The prostate gland is at the outlet of your urinary bladder. Because your prostate has become bigger than it should be, it is affecting how well you are able to pass your urine.

This causes some, or all of the following symptoms:

- urine flow is slow
- 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 must strain to do so
- you feel that you cannot empty your bladder completely
- you may dribble at the end of passing urine

- you need to pass urine often during the day
- you need to get up often during the night to pass urine
- you feel an urgency to pass urine as soon as you first feel the need to do so

These symptoms usually start gradually and increase in severity.

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

Tamsulosin SR is available only with a doctor's prescription.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- medicines containing tamsulosin hydrochloride
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Tamsulosin SR is for use by MEN only. If you are a woman or a child, do not take Tamsulosin SR. If you are not sure whether you should start taking Tamsulosin SR you should contact your doctor.

Do not take this medicine if you have or have had any of the following medical conditions:

- 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 liver problems
- you have serious kidney function problems
- you are taking other medication which relaxes the smooth muscle of blood vessels (e.g. prazosin).

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tamsulosin SR does not treat prostate cancer. BPH and prostate cancer may 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 SR. It is recommended that men be checked for prostate cancer once a year, from 50 years of age onwards.

These checks should continue while you are on Tamsulosin SR.

Tell your doctor if you have allergies to any other medicines, foods, preservatives, or dyes including medicines containing sulfa.

Tell your doctor if you have or have had any of the following medical conditions:

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

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you plan to have surgery.

If you are going to have eye surgery for cataracts or glaucoma, please tell your surgeon that you are taking or have taken Tamsulosin SR.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by this medicine or may affect how well it works. These include:

- cimetidine, used to treat stomach ulcers or reflux.

Taking these medicines with Tamsulosin SR may increase the risk of possible side effects.

Other medications can also interfere with Tamsulosin SR and make you feel drowsy.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take this medicine

How much to take

Your doctor will tell you how many tablets you need to take each day and when to take them. This depends on your

condition and whether you are taking any other medicines. It is important that you take this medicine as directed by your doctor.

The usual dose is one tablet a day.

Patients with severe liver or kidney problems should not take these tablets.

Continue taking your medicine for as long as your doctor tells you.

How to take this medicine

Swallow the tablets whole, preferably with a glass of water.

Do not crush, bite or chew the tablet, as this changes how this medicine works.

If you forget to take this medicine

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Tamsulosin SR. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many Tamsulosin SR tablets, this may result in vomiting, diarrhoea and low blood pressure leading to dizziness or fainting.

If you experience any of these symptoms, seek urgent medical attention.

While you are taking this medicine

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking this medicine.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking this medicine.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise your doctor may think it is not working effectively and change your treatment unnecessarily.

If you are going to have eye surgery for cataracts or glaucoma, please tell your surgeon that you are taking or have taken this medicine.

Things you must not do

Do not use this medicine to treat any other conditions unless your doctor tell you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

This medicine may cause dizziness and may impair your reactions.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- "retrograde ejaculation" – when this happens, the ejaculation fluid is not squirted out, most of it runs back into the bladder. Retrograde ejaculation is painless.
- dizziness

Tell your doctor as soon as possible if you notice any of the following:

- headache
- skin rash (red spots or patches), itching, hives
- weakness
- dizziness on standing
- nausea, vomiting, diarrhoea, constipation
- fast heart beats

- blocked nose
- faintness

This medicine 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.

If you are having an operation on your eyes because of cataracts or glaucoma and are already taking or have taken this medicine, the pupil may dilate poorly and the iris (the coloured part of the eye) may become floppy during the procedure.

This can be managed if your surgeon knows before carrying out the operation. If you are going to have eye surgery for cataracts or glaucoma, please tell your surgeon that you are taking or have taken this medicine.

This medicine may also occasionally cause blurred or reduced vision, inflammation and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals, or nose bleeds.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- prolonged painful erection of the penis, which is unrelated to sexual activity
- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using this medicine

Storage

Keep your tablets in the blister pack until it is time to take them.

Keep your tablets in a cool, dry place where the temperature stays below 25°C.

Do not store this medicine or any other medicine in the bathroom or near a sink.

Do not leave this medicine in a car or on windowsill.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine, or the expiry date has passed, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

APO-TAMSULOSIN SR tablets

White to off-white round tablets with a diameter of approximately 9 mm, debossed with “TSLN” on one side and “0.4” on the other side. AUST R 313161.

Each pack contains 30 tablets.

Ingredients

This medicine contains 400 micrograms of tamsulosin hydrochloride as the active ingredient.

This medicine also contains the following:

- microcrystalline cellulose

- polyethylene oxide
- magnesium stearate

This medicine does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Supplier

This medicine is supplied in Australia by:

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

Tel: (02) 8877 8333

Web: www1.apotex.com/au

This leaflet was last updated in May 2020.