

APO-Tamsulosin SR

Contains the active ingredient tamsulosin (tam-su-lo-sin) 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 benefits and risks. Your doctor has weighed the risks of you taking APO-TAMSULOSIN SR 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 APO-TAMSULOSIN SR is used for

APO-TAMSULOSIN SR is a medicine for use by MEN only. APO-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.

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

Your doctor has prescribed APO-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; they usually start gradually and increase in severity:

- 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 have to 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.

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

APO-TAMSULOSIN SR is available only with a doctor's prescription.

Before you take APO-TAMSULOSIN SR

When you must not take it

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

Do not take APO-TAMSULOSIN SR if you are allergic to medicines containing tamsulosin

hydrochloride or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not take APO-TAMSULOSIN SR if you have:

- 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 (some of the tradenames are Minipress, Prasig, Hytrin).

Do not take APO-TAMSULOSIN SR if the expiry date (Exp.) printed on the pack has passed.

Do not take APO-TAMSULOSIN SR if the packaging is torn or shows signs of tampering.

Before you start to take it

Use APO-TAMSULOSIN SR only if your doctor has prescribed it for you.

All medicines have benefits and risks. In deciding to prescribe APO-TAMSULOSIN SR for you, your doctor has weighed the risk of taking APO-TAMSULOSIN SR against the benefit it is expected to have for you.

Your doctor has prescribed APO-TAMSULOSIN SR for BPH.

APO-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 APO-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 APO-TAMSULOSIN SR.

Tell your doctor if you have allergies to:

- any other medicines including APO-TAMSULOSIN SR
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you have, any medical conditions, especially the following:

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

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 APO-TAMSULOSIN SR. (see "Side Effects").

Your doctor will discuss the risks and benefits of using APO-TAMSULOSIN SR.

If you have not told your doctor about any of the above, tell them before you start taking APO-TAMSULOSIN SR.

Taking other medicines

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

Some medicines may be affected by APO-TAMSULOSIN SR or may affect how well it works. These include:

- cimetidine, a medicine generally used to treat stomach ulcers or reflux.

Taking these medicines with APO-TAMSULOSIN SR may increase the risk of possible side effects (see Side Effects).

Other medications can also interfere with APO-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 APO-TAMSULOSIN SR.

How to take APO-TAMSULOSIN SR

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 or not you are taking any other medicines. It is important that you take this medicine as directed by your doctor.

The dose is one tablet a day. Patients with severe liver problems should not take these tablets. Patients with severe kidney problems should not take these tablets.

Follow all directions given to you by your doctor and pharmacist carefully.

How to take APO-TAMSULOSIN SR

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

Do not crush, bite or chew the tablet, as this changes how APO-TAMSULOSIN SR works.

If you forget to take APO-TAMSULOSIN SR

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.

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

If you miss a whole day, just continue to take your normal daily dose the next day.

If you take too much APO-TAMSULOSIN SR (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 APO-

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 APO-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 APO-TAMSULOSIN SR

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking APO-TAMSULOSIN SR.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking APO-TAMSULOSIN SR.

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 APO-TAMSULOSIN SR (see "Side Effects").

Things you must not do

Do not use APO-TAMSULOSIN SR to treat any other conditions unless your doctor tell you to.

Do not give APO-TAMSULOSIN SR to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful when driving or operating machinery until you know how APO-TAMSULOSIN SR affects you.

APO-TAMSULOSIN SR 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 APO-TAMSULOSIN SR.

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:

Common:

- "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

Uncommon:

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

Rare:

- faintness

APO-TAMSULOSIN SR 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 APO-TAMSULOSIN SR, 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 APO-TAMSULOSIN SR.

APO-TAMSULOSIN SR 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.

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

You should always tell your doctor about any problems you have whilst taking APO-TAMSULOSIN SR.

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

- extremely rarely, medications similar to APO-TAMSULOSIN SR have caused prolonged painful erection of the penis, which is unrelated to sexual activity. If you have a prolonged erection, call your doctor or go to the Emergency Room as soon as possible.
- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to APO-TAMSULOSIN SR. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using APO-TAMSULOSIN SR

Storage

Keep APO-TAMSULOSIN SR 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.

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 APO-TAMSULOSIN SR or any other medicine in the bathroom or near a sink.

Do not leave APO-TAMSULOSIN SR in a car or on window sill.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking APO-TAMSULOSIN SR, 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 are 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.

Each pack contains 30 tablets.

Ingredients

The active ingredient in APO-TAMSULOSIN SR is tamsulosin hydrochloride. Each APO-TAMSULOSIN SR tablet contains 400 micrograms of tamsulosin hydrochloride.

The tablets also contain:

- microcrystalline cellulose
- polyethylene oxide
- magnesium stearate

The tablets do not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Supplier

This medicine is supplied in Australia by:

Arrotex Pharmaceuticals

15 - 17 Chapel St

Cremona VIC 3121

Australian registration numbers: APO-TAMSULOSIN SR – AUST R 313161

This leaflet was prepared in November 2023