

APO- Prazosin Tablets

Contains the active ingredient, prazosin hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about this medicine. 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, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

The name of your medicine is APO-Prazosin. It contains the active ingredient, prazosin (as prazosin hydrochloride).

It is used to treat:

- high blood pressure (hypertension)
- prostate problems, such as benign prostatic hyperplasia (BPH) in men waiting for prostate surgery
- Raynaud's disease, where the fingers become white and very painful when cold
- certain types of heart failure

Prazosin belongs to a group of medicines called alpha blockers.

It works by relaxing the muscles in the walls of blood vessels and making it easier for blood to flow.

They also relax the muscles in the prostate gland and increase the flow of urine.

When used to treat high blood pressure or heart failure, prazosin is often used together with other medicines.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription

There is no known evidence to show that this medicine is addictive.

There is not enough information to recommend the use of this medicine in children under the age of 12 years.

Before you take this medicine

When you must not take it

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

- prazosin
- related medicines called quinazolines
- 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

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy. Your doctor can discuss with you the risks and benefits involved.

Do not breastfeed if you are taking this medicine.

Prazosin passes into breast milk and there is a possibility that your baby may be affected. Your doctor can discuss with you the risks and benefits involved.

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

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

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

- heart problems such as heart failure or angina or recent heart attack
- kidney or liver problems.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are planning to have cataract surgery.

If you are taking or have previously taken prazosin, then the eye surgeon needs to be aware of this to avoid complications during the operation.

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 interact with prazosin. These include:

- medicines used to lower blood pressure or for other heart conditions
- fluid tablets (diuretics), also used to lower blood pressure
- medicines to treat impotence (erectile dysfunction)

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

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

Other medicines not listed above may also interact with prazosin.

How to take this medicine

Follow carefully all directions given to you by your doctor.

Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Prazosin is usually started at a low dose of 0.5 mg (half a 1 mg tablet). Your doctor may gradually increase this dose as required. Starting with a low dose reduces the risk of too great a drop in your blood pressure which can make you dizzy, light-headed or faint.

Hypertension (high blood pressure):

The usual starting dose is 0.5 mg twice a day, increasing to 1 mg two or three times a day. Your doctor may increase this up to 20 mg a day, taken as divided doses.

Heart failure:

The usual starting dose is 0.5 mg increasing to 4 mg a day, divided into three or four doses. This may be increased by your doctor up to 20 mg a day, taken in divided doses.

Raynaud's disease:

The usual starting dose is 0.5 mg twice a day. Your doctor may increase this up to 1 mg or 2 mg twice a day.

Benign prostatic hyperplasia (BPH):

The usual starting dose is 0.5 mg twice a day. Your doctor may increase this gradually up to a maximum of 2 mg twice a day.

How to take it

Swallow the tablets with a glass of water.

The tablets can be broken in half, if your doctor has prescribed this.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Take your very first dose last thing at night, just before going to bed. Be very careful if you need to get up during the night, because you may feel dizzy and could fall.

If your doctor increases your dose, take the first of that increased dose

last thing at night. Again, be especially careful if you must get up in the night.

It does not matter if you take it before, with or after food.

How long to take it for

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

Prazosin helps control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

If you are taking prazosin for high blood pressure, heart failure or Raynaud's disease, you may need to take it for a long time.

If you are taking prazosin for prostate problems, you will only have to take it until your operation.

If you forget to take it

If it is almost time for your next dose (within 3 hours), skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

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

If you miss two doses or more, you will need to restart at a low dose and build up again gradually to your usual dose.

Ask your doctor how to do this.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 for Australia) for advice or go to the Accident and

Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much prazosin.

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

You may need urgent medical attention.

If you take too much prazosin, you may feel lightheaded, dizzy, have a fast or irregular heartbeat, or you may faint.

While you are taking this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery (especially eye surgery), tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

Get up slowly after you have been sitting or lying down.

Prazosin can cause dizziness, light-headedness and fainting, particularly if you get up too quickly. This effect is more likely to occur if you have just started prazosin, if the dose has just been increased or you have started taking another blood pressure medicine as well.

These symptoms can be dangerous, especially in people aged 65 years or older with heart or blood vessel disease.

If you feel dizzy or light-headed, lie down so that you do not faint, then sit for a few moments before

standing to prevent the dizziness from returning. Make sure the area around you is clear so that you do not injure yourself if you fall.

If these symptoms continue, tell your doctor.

A change in your dose may be needed.

See your doctor immediately if you experience painful erections or if your erection continues for longer than four hours.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give your 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 driving or operating machinery until you know how prazosin affects you.

Prazosin may cause dizziness, light-headedness or fainting in some people, especially after the first dose or a dose increase. Blurred vision or drowsiness may also occur. Make sure you know how you react to prazosin before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy, light-headed or not alert. If this occurs do not drive.

Limit the amount of alcohol you drink while taking prazosin.

Combining prazosin with alcohol can make you more dizzy or light-headed.

Make sure you drink enough water in hot weather, during exercise and

when you must stand for long periods of time, while you are taking prazosin. This is because dizziness, light-headedness and fainting are more likely to occur in these situations.

If you continue to feel unwell, tell your doctor.

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, but most of the time they are not.

Do not be alarmed by the following list of side effects. You may not experience any of them.

If you are over 65 years of age you may have an increased chance of getting side effects.

Tell your doctor if you notice any of the following:

- nausea, vomiting or feeling sick
- dry mouth
- constipation or diarrhoea
- weakness or lack of energy
- headache
- drowsiness
- pain or fever
- hair loss or thinning
- poor bladder control
- impotence
- painful joints
- ringing in the ears (tinnitus)
- stuffy nose
- problems getting to sleep
- breast enlargement

Tell your doctor immediately if you notice any of the following:

- dizziness, spinning sensation or light-headedness when standing up
- fast or pounding heart beat

- skin problems such as rash, itching or hives
- blurred vision or painful or red eyes
- painful, continual erection
- tingling or numbness in the hands or feet
- swelling of the hands, feet or ankles
- feelings of nervousness or depression
- severe chest pain, that may also spread to the shoulders, arms and neck

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- sharp pain in the stomach or back
- fast or slow heart beat
- chest pain
- fainting or passing out
- hallucinations (seeing, hearing or feeling things that aren't there)
- 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.

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

Other side effects not listed above may occur in some patients.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C. Protect it from light.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.

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 medicine that is left over.

Product description

What APO-Prazosin looks like

1 mg tablets:

Capsule-shaped, white, flat-faced, bevelled edge tablets, scored and engraved "APO P1" on one side, the other side plain. AUST R 73858.

2 mg tablets:

Round, white biconvex tablets, scored and engraved "APO" over "P2" on one side, the other side plain. AUST R 73862.

5 mg tablets:

Diamond-shaped, white biconvex tablet, scored and engraved "APO" over "P5" on one side, the other side plain. AUST R 73866.

Each tablet strength is available in a blister pack containing 100 tablets.

Ingredients

Each tablet contains 1 mg, 2 mg or 5 mg of prazosin as the active ingredient.

It also contains the following inactive ingredients:

- lactose monohydrate
- polysorbate 80
- microcrystalline cellulose
- croscarmellose sodium
- magnesium stearate.

This medicine is gluten-free, tartrazine-free and free of other azo dyes.

Sponsor

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park, NSW 2113

Australia

APO and APOTEX are registered trademarks of Apotex Inc.

This leaflet was prepared in August 2019.