

APO-Prazosin Tablets

Contains the active ingredient, prazosin hydrochloride

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about prazosin. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine.

You may want 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.

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

How it works

Prazosin 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.

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

Use in children

There is not enough information to recommend the use of this medicine in children.

Care when driving

Be careful driving or operating machinery until you know how prazosin affects you.

It may cause dizziness, light-headedness, drowsiness, blurred vision or fainting in some people, especially after the first dose or a dose increase. Make sure you know how you react to prazosin before you do anything that could be dangerous if you get the above side effects. If any of these occur do not drive.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to prazosin or to related medicines called quinazolines, or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: 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; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency Department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - heart problems such as heart failure or angina or recent heart attack
 - kidney or liver problems.
3. You are currently pregnant or plan to become pregnant.
Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breast-feeding or plan to breastfeed.
Prazosin may appear in breast milk. Do not take this medicine whilst breast-feeding until you and your doctor have discussed the risks and benefits involved.
5. **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 so he can be extra careful to avoid complications during the operation.

6. You are planning to have surgery or an anaesthetic.
7. You are currently receiving or are planning to receive dental treatment.
8. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Taking other medicines

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).

If you are taking any of these you may need a different dose or you may need to take different medicines.

Your doctor and pharmacist can tell you if you are taking any of these medicines. They may also have more information on medicines to be careful with or avoid while taking prazosin.

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.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

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 this medicine at the same time each day. Taking this medicine at the same time each day will have the best effect and 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 have to get up in the night.

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

How long to take it for

Prazosin helps control your condition, but does not cure it. Therefore you must take your medicine every day.

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.

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

Make sure you have enough to last over weekends and holidays.

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 light-headed, dizzy, have a fast or irregular heartbeat, or you may faint.

While you are taking this medicine

Things you must do

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.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breast-feeding or are planning to breastfeed
- you are about to have any blood tests or urine tests
- **you are going to have surgery or an anaesthetic or are going into hospital. You are about to have eye surgery (for example cataract surgery).**

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Go to your doctor regularly for a check-up.

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

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first 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 have to 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.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking prazosin or if you have any questions or concerns.

Do not be alarmed by the following list of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious, but most of the time they are not.

If you are 65 years or older, you should be especially careful while taking prazosin. Report any side effects promptly to your doctor.

Tell your doctor if you notice any of the following:

- nausea, vomiting, feeling sick
- dry mouth
- constipation or diarrhoea
- weakness, 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:

These may be serious side effects and you may need medical attention:

- dizziness, spinning sensation or light-headedness when standing up
- fast or pounding heartbeat
- 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.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency Department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

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

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

Allergic reactions

If you think you are having an allergic reaction to prazosin, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency Department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- 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
- fainting
- hay fever-like symptoms.

This leaflet was prepared in December 2015.

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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

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.

2 mg tablets:

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

5 mg tablets:

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

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

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

Australian Registration Numbers

APO-Prazosin 1 mg tablets:

AUST R 73858

APO-Prazosin 2 mg tablets:

AUST R 73862

APO-Prazosin 5 mg tablets:

AUST R 73866

Sponsor

Apotex Pty Ltd
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Australia

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