## **APO-PRAZOSIN**

## **Consumer Medicine Information (CMI) summary**

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

## 1. Why am I using APO-PRAZOSIN?

APO-PRAZOSIN contains the active ingredient prazosin. APO-PRAZOSIN is used to treat high blood pressure, also called hypertension, benign prostatic hyperplasia or BPH ('prostrate trouble') in men waiting for prostate surgery, Raynaud's disease where the fingers become white and painful when cold, and certain types of heart failure. For more information, see Section 1. Why am Lusing APO-PRAZOSIN? in the full CMI.

## 2. What should I know before I use APO-PRAZOSIN?

Do not use if you have ever had an allergic reaction to APO-PRAZOSIN or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use APO-PRAZOSIN? in the full CMI.

## 3. What if I am taking other medicines?

Some medicines may interfere with APO-PRAZOSIN and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

## 4. How do I use APO-PRAZOSIN?

Start with a low dose of 0.5 mg (half a 1 mg tablet) taken twice a day.

More instructions can be found in Section 4. How do I use APO-PRAZOSIN? in the full CMI.

## 5. What should I know while using APO-PRAZOSIN?

Things you should do	<ul> <li>Remind any doctor or dentist you visit that you are using APO-PRAZOSIN.</li> <li>If you experience continued dizziness, light headedness, painful erections, or become pregnant, tell your doctor immediately.</li> <li>Take care during exercise or hot weather or if you have to stand for a long time.</li> </ul>
Things you should not do	Do not stop taking this medicine or lower the dosage, without checking with your doctor.
Driving or using machines	Be careful driving or operating machinery until you know how APO-PRAZOSIN affects you.
Drinking alcohol	Be careful to limit the amount of alcohol you drink while taking APO-PRAZOSIN.
Looking after your medicine	Keep your tablets in a cool, dry place where the temperature stays below 30°C.

For more information, see Section 5. What should I know while using APO-PRAZOSIN? in the full CMI.

## 6. Are there any side effects?

Side effects include feeling sick, vomiting or dry mouth, constipation, diarrhoea, weakness or lack of energy, headache or drowsiness and stuffy nose. Serious side effects include fast or pounding heartbeat, chest pain, fainting, dizziness or light headedness when standing up, shortness of breath or difficulty breathing, blurred vision,

rash, itching or other skin problems, sharp pain in the stomach or back, persistent painful erection of the penis which occurs without sexual arousal, tingling or numbness of the hands or feet, swelling of the hands, feet or ankles and feelings of nervousness or depression.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

## **APO-PRAZOSIN**

Active ingredient: prazosin hydrochloride

## **Consumer Medicine Information (CMI)**

This leaflet provides important information about using APO-PRAZOSIN. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APO-PRAZOSIN.

#### Where to find information in this leaflet:

- 1. Why am I using APO-PRAZOSIN?
- 2. What should I know before I use APO-PRAZOSIN?
- 3. What if I am taking other medicines?
- 4. How do I use APO-PRAZOSIN?
- 5. What should I know while using APO-PRAZOSIN?
- 6. Are there any side effects?
- 7. Product details

## 1. Why am I using APO-PRAZOSIN?

## APO-PRAZOSIN contains the active ingredient prazosin.

APO-PRAZOSIN belongs to a family of medicines called alpha blockers. These medicines work by relaxing muscles in the walls of blood vessels and reducing the resistance to blood flow. They also relieve prostate problems by relaxing muscles in the prostate gland and increasing the flow of urine.

APO-PRAZOSIN is used to treat high blood pressure, also called hypertension, benign prostatic hyperplasia or BPH ('prostrate trouble') in men waiting for prostate surgery, Raynaud's disease, where the fingers become white and painful when cold, and certain types of heart failure.

When used to treat high blood pressure or heart failure, APO-PRAZOSIN is often used in combination with other medicines.

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

Your doctor may have prescribed it for another reason.

## 2. What should I know before I use APO-PRAZOSIN?

# Do not use this medicine if you have an allergy to:

- Prazosin
- Related medicines called Quinazolines
- Any of the ingredients listed at the end of this leaflet
- 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

## Tell your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- heart problems such as heart failure or angina or recent heart attack
- kidney or liver problems.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects?</u>

## Pregnancy and breastfeeding

**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.

# 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.

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

## 3. What if I am taking other medicines?

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

In particular, tell your doctor if you are taking:

- medicines used to lower blood pressure
- fluid tablets (diuretics)
- medicines to treat impotence (erectile dysfunction).

## Some medicines may interfere with APO-PRAZOSIN and affect how it works.

Other medicines that lower high blood pressure may have an additive effect with APO-PRAZOSIN and make your blood pressure too low. As a result, their dose may need to be changed when APO-PRAZOSIN is started.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-PRAZOSIN.

Your doctor or pharmacist has a complete list of medicines to be careful with or avoid while taking APO-PRAZOSIN.

## 4. How do I use APO-PRAZOSIN?

#### How much to take

- APO-PRAZOSIN is usually started at a low dose of 0.5 mg (half a 1 mg tablet) taken twice a day.
- Follow the instructions provided and use APO-PRAZOSIN until your doctor tells you to stop.

Starting with a low dose reduces the risk of too great a drop in your blood pressure which can make you dizzy, lightheaded or faint.

Your doctor may gradually increase this dose as required. This may depend on your age, your condition and whether or not you are taking any other medicines.

#### Hypertension (high blood pressure)

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

#### **Heart failure**

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

#### Benign prostatic hyperplasia (BPH)

The usual starting dose is 0.5 mg (half a 1 mg tablet) taken twice a day. Your doctor may increase this to 2 mg taken twice a day.

#### When to take APO-PRAZOSIN

 APO-PRAZOSIN should be taken at the same time each day.

## When you first start taking APO-PRAZOSIN or if your doctor

increases your dose, take the first dose last thing at night, just before going to bed.

Be especially careful if you need to get up during the night, because you may feel dizzy and could fall.

#### How to take APO-PRAZOSIN

- Swallow the tablets with a glass of water or other liquid.
- It does not matter if you take APO-PRAZOSIN before or after food.

## How long to take APO-PRAZOSIN Keep taking APO-PRAZOSIN every day until your doctor tells you to stop.

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

APO-PRAZOSIN will help control these conditions but will not cure them. Therefore, it must be taken every day.

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

## If you forget to use APO-PRAZOSIN

APO-PRAZOSIN should be used regularly at the same time each day. If you miss your dose at the usual time, and it is within 3 hours before your next dose,

skip the dose you missed and take the 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 the dose you missed.

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

If you miss two (2) 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 use too much APO-PRAZOSIN

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

If you think that you, a child or anyone else may have taken too much APO-PRAZOSIN, you may need urgent medical attention.

### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

## 5. What should I know while using APO-PRAZOSIN?

#### Things you should do

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

APO-PRAZOSIN can cause dizziness, light headedness and fainting, particularly if you get up too quickly. This is also more likely to occur if you have just started APO-PRAZOSIN or the dose of APO-PRAZOSIN has just been increased.

These symptoms can be dangerous, particularly if you are 65 years or older and have heart disease.

If you feel dizzy or lightheaded, lie down so that you do not faint. Then sit for a few moments before standing to prevent the dizziness from returning. If these symptoms continue, tell your doctor. A change in dose may be needed.

Call your doctor straight away if you:

- experience painful erections or if your erection continues for longer than four hours.
- become pregnant while taking APO-PRAZOSIN

- are about to start any new medicines, tell your doctor that you are taking APO-PRAZOSIN.
- Remind any doctor or dentist you visit that you are using APO-PRAZOSIN.

### Things you should not do

- Do not give APO-PRAZOSIN to anyone else, even if they have the same condition as you.
- Do not use APO-PRAZOSIN to treat any other complaints unless your doctor tells you to.
- Do not stop taking APO-PRAZOSIN, or lower the dosage, without checking with your doctor.

Your doctor will reduce your dose of APO-PRAZOSIN gradually if you are to stop taking this medicine.

## **Driving or using machines**

## Be careful before you drive or use any machines or tools until you know how APO-PRAZOSIN affects you.

APO-PRAZOSIN may cause dizziness, light headedness or fainting in some people, especially after the first dose or after a dose increase. Blurred vision or drowsiness may also occur.

Make sure you know how you react to APO-PRAZOSIN before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy, drowsy, or are not alert.

#### **Drinking alcohol**

## Tell your doctor if you drink alcohol.

Be careful to limit the amount of alcohol you drink while taking APO-PRAZOSIN. Also, take extra care during exercise or hot weather or if you have to stand for a long time.

Dizziness, light headedness, or fainting is more likely to occur if you drink alcohol, stand for a long time, exercise or the weather is hot.

### Looking after your medicine

- Keep your tablets in their pack until it is time to take them.
- Keep them in a cool, dry place where the temperature stays below 30°C.

# Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Do not use this medicine after the expiry date.
Keep it where young children cannot reach it.
When to discard your medicine
If your doctor tells you to stop taking APOPRAZOSIN, or the tablets have passed their expiry date.

#### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## **Side effects**

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

Side effects	What to do
<ul> <li>nausea, vomiting or feeling sick</li> <li>dry mouth</li> <li>constipation or diarrhoea</li> <li>weakness or lack of energy</li> <li>headache</li> <li>drowsiness</li> <li>pain or fever</li> <li>hair loss or thinning</li> <li>poor bladder control</li> <li>impotence</li> <li>painful joints</li> <li>ringing in the ears (tinnitus)</li> <li>stuffy nose</li> <li>breast enlargement</li> <li>problems getting to sleep</li> </ul>	Speak to your doctor if you have any of these side effects and they worry you.  These side effects are usually mild.

### Serious side effects

Derious side effects	
Serious side effects	What to do
<ul> <li>dizziness, spinning sensation or light-headedness when standing up</li> <li>fast or pounding heart beat</li> <li>skin problems such as rash, itching or hives</li> <li>blurred vision or painful or red eyes</li> <li>painful, continual erection</li> <li>tingling or numbness in the hands or feet</li> <li>swelling of the hands, feet or ankles</li> <li>feelings of nervousness or depression</li> <li>severe chest pain, that may also spread to the shoulders, arms and neck</li> <li>sharp pain in the stomach or back</li> <li>fast or slow heart beat</li> <li>chest pain</li> <li>fainting or passing out</li> <li>hallucinations (seeing, hearing or feeling things that aren't there)</li> <li>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</li> </ul>	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

### **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

## 7. Product details

This medicine is only available with a doctor's prescription.

#### What APO-PRAZOSIN contains

Active ingredient (main ingredient)	1 mg, 2 mg or 5 mg of prazosin.
Other ingredients	
(inactive	lactose monohydrate
ingredients)	• polysorbate 80
	microcrystalline cellulose
	croscarmellose sodium
	magnesium stearate.

## Do not take this medicine if you are allergic to any of these ingredients.

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

## 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.

#### Who distributes APO-PRAZOSIN?

Arrotex Pharmaceuticals Pty Ltd 15-17 Chapel Street Cremorne VIC 3121 Australia

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