What is this leaflet

This leaflet answers some common questions about Apo-Doxazosin tablet. 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 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

Apo-Doxazosin tablet is used to treat:
- Hypertension
- Benign Prostatic Hyperplasia

It belongs to a group of medicines called antihypertensive.
Antihypertensive medicines are a class of drug that help for the treatment of hypertension.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.
Your doctor may have prescribed it for another reason.
This medicine is available only with a doctor's prescription.

Use in children

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

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:
- any medicine containing Doxazosin mesylate or 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

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.

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 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 have recently been vaccinated or plan to get a vaccination.

Tell your doctor if you are planning to have surgery or an anaesthetic.

Tell your doctor if you are currently receiving or are planning to receive dental treatment.

If you have not told your doctor about any of the above, tell him/her 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 and Doxazosin mesylate may interfere with each other. This includes:

- Phosphodiesterase-5-inhibitors (e.g. sildenafil, tadalafil, vardenafil)

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

Other medicines not listed above may also interact with Doxazosin mesylate. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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**How to take this medicine**

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

**How much to take**

**High blood pressure**

The recommended initial dose is 1mg given once daily. This initial dose is intended to minimise the effects of postural hypotension. After 1 to 2 weeks, the dose may then be gradually increased to 2mg given once daily. This dose is also retained for 2 weeks. If necessary the daily dosage can be increased to 4mg, 8mg, and 16mg per day until the desired reduction in blood pressure is achieved.

The maximum daily dose is 16mg.

**Prostate Enlargement**

The recommended initial dose is 1mg given once daily. After this the usual dose is 2mg or 4mg and 8mg once daily. The maximum recommended daily dose is 8mg.

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

Your doctor or pharmacist 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 or pharmacist.

**How to take it**

Swallow the tablet whole with a full glass of water. Apo-Doxazosin may be taken with or without food.

**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.

It does not matter if you take this medicine before or after food.

**How long to take it**

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 to take your next dose, 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.

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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 have trouble remembering to take your medicine, ask your pharmacist for some hints.

**If you take too much (overdose)**

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital.

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

You may need urgent medical attention.

No data is available regarding overdosage with doxazosin in humans.

Should over-dosage lead to hypotension, support of the cardiovascular system is of first importance. Restoration of blood pressure and normalization of heart rate may be accomplished by keeping the patient in a supine, head down position. If this is inadequate shock should first be treated with volume expanders and if necessary vasopressors used. As doxazosin is highly protein bound, dialysis may not be of benefit.

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

If you are going to have 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 plan to breastfeed while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of 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 or pharmacist 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 or pharmacist.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

**Things to be careful of**

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

This medicine may likely to produce minor or moderate adverse effects on the ability to drive or use machinery. Especially when therapy is being initiated, the patient’s ability to drive or operate machinery may be impaired.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

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.

**Possible side effects**

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

Doxazosin mesylate helps most people but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

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

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

- Feeling tired and weak
- Feeling of dizziness or spinning (vertigo)
- Headache
- Feeling of discomfort
- Swelling of ankles, feet or fingers due to fluid build up
- Hay fever like symptoms
- Sleepiness
- Bladder control problems
- Sexual dysfunction in males
- Blurred vision
- Symptoms of liver problems (skin and white eye turning yellow) or liver diseases (hepatitis)
- Heart problems
- Bleeding from nose
- Presence of blood in urine
- Purple coloured spots on your skin
- Skin rash
- Blood disorders and diseases

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.

**Storage and disposal**

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 stays below 25°C.

Do not store any 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, your pharmacist can dispose of the remaining medicine safely.

**Product description**

**What it looks like**

1mg Tablet:
White, round, biconvex tablets, 4.8mm in diameter, engraved APO on one side and D1 on the other side.
2mg Tablet:
White, capsule-shaped, biconvex tablets, 4.5mm x 9mm, engraved APO on one side and D2 and a partial bisect on the other side.

4mg Tablet:
White, diamond-shaped, biconvex tablets, 9mm x 12mm, engraved APO on one side and D4 and scored on the other side.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients
Each tablet contains 1mg, 2mg & 4mg of Doxazosin mesylate as the active ingredient.
It also contains the following inactive ingredients:
- Microcrystalline cellulose
- Croscarmellose sodium
- Lactose
- Magnesium Stearate
This medicine does not contain gluten.

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This leaflet was last updated in:
February 2018.