

APO-Valsartan

Contains the active ingredient valsartan

Consumer Medicine Information

For a copy of a large print leaflet,
Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about valsartan. 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-Valsartan. It contains the active ingredient valsartan.

This medicine belongs to a group of medicines called angiotensin II receptor antagonists (AIIRAs).

It is used to treat:

Hypertension

This medicine is used to control high blood pressure, also called hypertension. Everyone has blood pressure. This pressure helps get your blood around your body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have hypertension when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have it is to have your blood pressure checked regularly.

High blood pressure increases the workload of the heart and blood vessels. If it continues for a long time, it can damage the blood vessels in the brain, heart and kidneys. This can lead to stroke, heart failure or kidney failure. High blood pressure increases the risk of heart attacks. Lowering your blood pressure reduces the chance of these disorders happening.

Heart Failure

This medicine is used to treat heart failure. Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as heart attack and does not mean that the heart stops. This medicine helps the heart to function better and relieves some of the symptoms of heart failure.

Heart Attack

This medicine is also used to treat people after they have had a heart attack (myocardial infarction), to reduce the risk of further heart damage and reduce further heart problems.

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 medicine that this medicine is addictive.

Use in children

There is not enough information to recommend the use of this medicine in children (below 18 years of age).

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are also taking other blood pressure lowering medicines containing aliskiren and have type 2 diabetes.**
- **You have or have had liver disease caused by blockage in the bile duct or any other severe liver disease.**

- **You are pregnant or intend to become pregnant.**

Valsartan may affect your developing baby if you take it during pregnancy.

- 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.
- **You are hypersensitive to or have had an allergic reaction to valsartan 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 hayfever-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.

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 disease, heart failure or high blood pressure that is being treated with large doses of diuretics (also called water or fluid tablets), or are being treated with beta-blockers, aliskiren and/or ACE-inhibitors
- high blood pressure due to narrowing of the arteries in the kidney
- any other kidney problems or are having dialysis
- milder forms of liver disease
- a hormonal disorder called primary hyperaldosteronism, which can increase blood pressure
- swelling, mainly of the face and throat, while taking other medicines (including an ACE inhibitor or aliskiren)
- you have recently had severe vomiting or diarrhoea
- you are severely limiting your salt intake.

3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant.

4. You are currently breast-feeding or you plan to breast-feed. It is not known if valsartan, the active ingredient can pass into the breast milk. Do not take this medicine whilst breast-feeding.

5. You are planning to have surgery or an anaesthetic.

6. You are currently receiving or are planning to receive dental treatment.

7. 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.

Some medicines may interact with valsartan. These include:

- ACE-inhibitors or aliskiren, which are also medicines used to treat hypertension or other heart conditions

- some diuretics (water or fluid pills) e.g. spironolactone, triamterene, amiloride
- a class of anti-inflammatory medicines called NSAIDs and COX-2 inhibitors
- potassium supplements
- salt substitutes containing potassium
- some antibiotics (rifampicin), anti-rejection drugs (cyclosporin), antiretrovirals (ritonavir)
- lithium salts used to treat conditions such as bipolar or schizophrenia.

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

Other medicines not listed above may also interact with valsartan.

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 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.

For hypertension, the usual dose is one 80 mg tablet once a day. If your blood pressure is still too high after 4 weeks, your doctor may increase the dose to 160 mg once a day, or from 160 mg to 320 mg once a day. If your blood pressure is still too high, your doctor may add a different type of blood pressure lowering medicine.

For heart failure, the usual starting dose is 40 mg twice daily. Your doctor may increase the dose gradually up to one 160 mg tablet twice daily.

Following a heart attack, treatment is generally started at a dose of 20 mg (half a 40 mg tablet) twice daily. Your doctor may increase the dose gradually up to 160 mg twice daily.

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

How to take it

Swallow the tablet with a full glass of water.

Always take it in the same way in relation to food. It does not matter if you take it after food or on an empty stomach, as long as you take it the same way each day.

If your stomach is upset after taking this medicine, always take it after a meal (e.g. breakfast).

When to take it

This medicine comes in a calendar pack with the days of the week marked on it to help you remember to take your tablet each day.

When you take the first tablet from the pack of this medicine, take the one marked with the correct day of the week (e.g. if it is Wednesday, take the tablet marked 'Wednesday').

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

How long to take it for

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

It will take at least 4 weeks for this medicine to have its full effect. After that, it will be continued for as long as your doctor thinks is needed.

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

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 missed dose and take your next dose at the usual time. 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 experiencing side effects.

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)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Too much of this medicine may make you feel dizzy, lightheaded or faint. You may experience rapid, shallow breathing or cold, clammy skin. Your heartbeat may be faster than usual. This is because your blood pressure is too low.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- for any reason, you have not taken your medicine exactly as prescribed, otherwise your doctor may think that it was not effective and change your treatment unnecessarily
- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant. You should not take this medicine while you are pregnant.
- you are breast-feeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Be sure to keep all of your doctor's appointments so that your progress can be checked. Do this even if you feel well.

It is important to keep track of your progress. Your doctor will want to check your blood pressure and your kidney and liver function from time to time.

Tell any other doctors, dentists and pharmacists who are treating you that you take 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 or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery or doing jobs that require you to be alert while you are taking this medicine until you know how this medicine affects you.

This medicine can cause tiredness, sleepiness or dizziness in some people. If you have these symptoms, do not drive or do anything else that could be dangerous.

If this medicine makes you feel dizzy or lightheaded, be careful when getting up from a sitting or lying position.

Dizziness can usually be prevented by getting up slowly and flexing leg muscles and toes to get the blood flowing. When getting out of bed, dangle your legs over the side for a minute or two before standing up.

Possible side effects

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

Do not be alarmed by the following lists 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.

Tell your doctor or pharmacist if you notice any of the following side effects.

Mostly, these are mild:

- headache
- dizziness, spinning sensation (vertigo)
- tiredness or weakness
- diarrhoea, constipation or wind
- nausea (feeling sick), vomiting
- loss of appetite, stomach pains or indigestion
- dry cough, sore throat or hoarse voice
- runny nose or congested sinuses

- more infections than usual
- pain in the back or joints
- muscle pain or cramps
- difficulty sleeping
- feeling anxious
- tingling or numbness in the hands or feet
- problems with sexual function.

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 may be serious side effects. You may need medical attention:

- feeling of fast or irregular heart beat (pounding, racing, skipping beats)
- chest pain
- shortness of breath not caused by exercise, with swelling of legs or feet
- tiredness or lack of energy, being short of breath when exercising, dizziness and looking pale
- constant "flu-like" symptoms such as chills, fever, sore throat, aching joints, sores in mouth, swollen glands
- severe dizziness or fainting
- liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine.

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

Allergic reactions

If you think you are having an allergic reaction to valsartan, 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, or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms.

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.

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 this medicine 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 or pharmacist 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-Valsartan looks like

- **Valsartan 40 mg tablets**
Yellow, modified, capsule shaped, film-coated tablets, engraved 'APO' on one side and 'VA' scored '40' on the other side.

- **Valsartan 80 mg tablets**
Pale red, round, biconvex, film-coated tablets, engraved 'APO' on one side and 'VA' over '80' on the other side.
- **Valsartan 160 mg tablets**
Yellow, modified, capsule shaped, film-coated tablets, engraved 'APO' on one side and 'VA160' on the other side.
- **Valsartan 320 mg tablets**
Dark grey-violet, oval shaped, film-coated tablets, engraved 'APO' on one side and 'VA320' on the other side.
- APO-Valsartan 80 mg tablet:
(blister pack of 7, 14, 28, 30, 56):
AUST R 185814.
(bottles of 28, 100, 500): AUST R 185854
- APO-Valsartan 160 mg tablet:
(blister pack of 7, 14, 28, 30, 56):
AUST R 185821.
(bottles of 28, 100, 500): AUST R 185855.
- APO-Valsartan 320 mg tablet:
(blister pack of 7, 14, 28, 30, 56):
AUST R 185826.
(bottles of 28, 100, 500): AUST R 185856.

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

Ingredients

Each tablet contains 40, 80, 160 or 320 mg of valsartan as the active ingredient.

It also contains the following inactive ingredients:

- cellulose powdered
- calcium hydrogen phosphate dihydrate
- croscarmellose sodium
- silica colloidal anhydrous
- magnesium stearate
- hypromellose
- hydroxypropyl cellulose
- macrogol 8000
- titanium dioxide
- yellow iron oxide
- red iron oxide
- purified water
- The 160 and 320 mg tablets also contain: black iron oxide.

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

Australian Registration Numbers

- APO-Valsartan 40 mg tablet:
(blister pack of 7, 14, 28, 30, 56):
AUST R 185806.
(bottles of 28, 100, 500): AUST R 185853.

Sponsor

Apotex Pty Ltd

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This leaflet was last updated in:
July 2014.