

APO-Valsartan HCTZ Tablets

Contains the active ingredients valsartan and hydrochlorothiazide

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 HCTZ. 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 HCTZ. It contains the active ingredients valsartan and hydrochlorothiazide.

It is used to treat hypertension (high blood pressure).

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.

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

Valsartan HCTZ reduces blood pressure in two different ways.

1. Valsartan blocks the effect of angiotensin II, which is a substance in the body that tightens blood vessels and makes your blood pressure rise. When the effect of angiotensin II is blocked, your blood vessels relax

and your blood pressure goes down.

2. Hydrochlorothiazide helps reduce the amount of excess fluid in the body by increasing the amount of urine produced. This helps lower your blood pressure.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children. Safety and effectiveness in children have not been established.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have or have had any of the following:**
- severe kidney or liver disease, including biliary cirrhosis
- cholestasis, a condition where the flow of bile is blocked or reduced
- anuria, a condition where you are unable to urinate
- symptomatic hyperuricaemia, a condition where you have a high level of uric acid in your blood, which can be present as gout, stones or kidney disease
- refractory hypokalaemia, a condition where you have a low level of potassium in your blood

- hyponatraemia, a condition where you have a low level of sodium in your blood
- hypercalcaemia, a condition where you have a high level of calcium in your blood.
- diabetes and taking a medication containing aliskiren,
- **You are pregnant.**
Valsartan HCTZ may affect your developing baby if you take it during pregnancy.

- **You have had a severe allergic reaction to sulphonamide-derived medicines, such as some antibiotics, e.g., trimethoprim and sulfamethoxazole.**
- **You are hypersensitive to, or have had an allergic reaction to, valsartan, hydrochlorothiazide or sulphonamide-derived medicines 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.

- 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:
 - sulphonamide or penicillin
 - any other medicines

- any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - kidney problems
 - liver problems
 - heart problems
 - systemic lupus erythematosus, a disease affecting the skin, joints and kidneys
 - high cholesterol levels
 - diabetes swelling, mainly of the face and throat, while taking other medicines (including an ACE - inhibitor or aliskiren)
 - primary hyperaldosteronism (Conn's syndrome), a hormone disorder causing fluid retention
 - obstructed blood flow through the heart from narrowing of valves (stenosis) or enlarged septum of the heart (HOCM)
 - recent excessive vomiting or diarrhoea
 - salt restricted diet
 - asthma.
 - acute angle closure glaucoma, a condition where you have reduced vision
 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. 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.

Taking other medicines

Some medicines may interact with valsartan HCTZ. These include:

- medicines used to treat high blood pressure, including ACE inhibitors, any other angiotensin receptor agonists, beta-blockers, calcium channel blockers, methyl dopa and renin inhibitors (e.g. aliskiren)
- medicines used to treat other heart conditions, including digitalis glycosides (e.g., digoxin), antiarrhythmics (used to treat irregular heart rhythms) and pressor amines (e.g., noradrenaline)
- anti-inflammatory medicines, including NSAIDs and COX-2 inhibitors, medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- diuretic medicines, also known as water / fluid tablets.
- medicines or supplements which contain potassium
- some antibiotics, such as penicillin, tetracyclines and rifamycin.
- anti-rejection drugs (cyclosporin),
- medicines or supplements containing calcium
- vitamin D
- other medicines that raise blood pressure
- medicines used to relax muscles before or during surgery
- steroid medicines such as cortisone, prednisone and adrenocorticotrophic hormone (ACTH)
- antidepressant and antipsychotic medicines, including lithium, medicines used to treat mood swings and some types of depression cytotoxic medicines, such as cyclophosphamide or methotrexate
- products containing salicylic acid
- amphotericin, a medicine used to treat fungal infections

- medicines used to treat diabetes, such as oral tablets or insulin
- medicines used to treat gout including allopurinol and uricosuric agents (e.g., probenecid and sulfapyrazone)
- antiepileptic medicines, including carbamazepine medicines used to lower cholesterol, such as cholestyramine and colestipol
- amantadine, a medicine used to treat Parkinson's disease or to prevent influenza
- anticholinergic medicines (e.g. atropine), used to treat Parkinson's disease, relieve stomach cramps, spasms and prevent travel sickness
- carbenoxolone, a medicine used to treat stomach ulcers
- alcohol, anaesthetics and sedatives
- high doses of iodine,

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 HCTZ.

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.

The usual dose is one tablet of either 80/12.5mg, 160/12.5mg or 320/12.5mg per day.

If your blood pressure is still too high after 4 weeks, your doctor may increase the dose to one tablet of

either 160/25mg or 320/25mg per day.

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.

When to take it

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.

Always take this medicine in the same way in relation to food. It does not matter if you take it before, with or after food, as long as you take it the same way each day.

How long to take it for

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 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 valsartan HCTZ may make you feel dizzy, light headed 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:

- 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 whilst 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.

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 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 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 light-headed, be careful when getting up from a sitting or lying position.

When you are outdoors, wear protective clothing and use at least a 15+ sunscreen. Do not use a sunlamp.

This medicine may cause your skin to be much more sensitive to sunlight than it normally is.

Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn. If your skin does appear to be burning, tell your doctor.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking valsartan HCTZ 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 if you notice any of the following.

This list includes the more common side effects. Mostly, they are mild:

- headache
- dizziness, spinning sensation, blurred vision
- dizziness on standing up, especially when getting up from a sitting or lying position

- sleepiness, tiredness or weakness
- pain in the back or joints
- runny nose or congested sinuses
- dry cough, sore throat or hoarse voice
- dry mouth
- diarrhoea, constipation or wind
- nausea (feeling sick), vomiting, loss of appetite, stomach upset or indigestion
- muscle pain, muscle tenderness or weakness, cramps or joint pain
- tingling or numbness in hands or feet
- symptoms of sunburn which happen more quickly than normal
- difficulty sleeping
- feeling anxious or sad
- problems with sexual function
- pain when passing urine, frequent urge to urinate
- hair loss
- facial pain.
- anaemia

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 are usually rare. You may need urgent medical attention or hospitalisation.

- feeling of fast or irregular heart beat (pounding, racing, skipping beats)
- chest pain
- 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
- pain in the stomach, often accompanied by nausea and vomiting

- signs of a serious skin reaction such as painful red areas, large blisters, peeling of layers of skin, bleeding in the lips, eyes, mouth, nose or genitals. These signs may be accompanied by fever and chills, aching muscles and feeling generally unwell
- unusual bleeding or bruising under the skin
- severe dizziness or fainting
- passing less urine than normal
- signs of liver disease such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine
- decrease in vision or pain in your eyes.

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

Allergic reactions

If you think you are having an allergic reaction to valsartan HCTZ, 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
- 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. Protect from moisture.

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 HCTZ looks like

160/12.5 mg

Dark red, modified, capsule shaped, film-coated tablets, engraved "APO" on one side and "160/12.5" on the other side.

320/12.5 mg

Pink, oval shaped, film-coated tablets, engraved "APO" on one side and "320/12.5" on the other side.

320/25 mg

Yellow, oval shaped, film-coated tablets, engraved "APO" on one side and "320/25" on the other side

80/12.5 mg

Orange, modified, capsule shaped, film-coated tablets, engraved "APO" on one side and "80/12.5" on the other side.

160/25 mg

Brown, modified capsule shaped, film-coated tablets, engraved "APO" on one side and "160/25" on the other side.

Available in blisters packs of 28 tablets.

* Not all strengths may be available.

Ingredients

Each tablet contains the following amount of valsartan and hydrochlorothiazide respectively: 160/12.5mg, 320/12.5mg, 320/25mg, 80/12.5mg and 160/25mg.

Each tablet also contains the following inactive ingredients:

- powdered cellulose
- calcium hydrogen phosphate
- colloidal anhydrous silica
- croscarmellose sodium
- magnesium stearate
- hypromellose
- hydroxypropyl cellulose
- titanium dioxide
- iron oxide red (80/12.5mg, 160/12.5mg, 320/12.5mg & 160/25mg tablets)
- iron oxide yellow (80/12.5mg, 320/25mg & 160/25mg tablets)
- iron oxide black (160/25mg & 320/12.5mg tablets).

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

Australian Registration Numbers

APO-Valsartan HCTZ 160/12.5 tablets (blisters): AUST R 202354.

APO-Valsartan HCTZ 320/12.5 tablets (blisters): AUST R 202344.

APO-Valsartan HCTZ 320/25 tablets (blisters): AUST R 202345

APO-Valsartan HCTZ 80/12.5 mg tablets (blisters): AUST R 222296.

APO-Valsartan HCTZ 160/25 mg tablets (blisters): AUST R 222295.

Sponsor

Apotex Pty Ltd
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