

APO-TELMISARTAN HCTZ Tablets

Telmisartan and Hydrochlorothiazide

Consumer Medicine Information

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

What is in this leaflet

This leaflet answers some common questions about APO-TELMISARTAN HCTZ .

It does not contain all available information. It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available.

The latest Consumer Medicine Information is available from your pharmacist, doctor, or from www.medicines.org.au and may contain important information about the medicine and its use of which you should be aware.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking this medicine against the benefits it is expected to have for you.

If you have any concerns about this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine.

You may need to read it again.

What APO-TELMISARTAN HCTZ is used for

APO-TELMISARTAN HCTZ is used to lower high blood pressure (hypertension).

Everyone has blood pressure. This pressure helps your blood move 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 (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm or relaxed. There are usually no signs of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis.

If high blood pressure is not treated, it can lead to serious health problems, including stroke, heart disease and kidney failure.

How APO-TELMISARTAN HCTZ works

APO-TELMISARTAN HCTZ contains telmisartan and hydrochlorothiazide in one single tablet. These two active ingredients help to reduce blood pressure in different ways:

- Telmisartan belongs to a group of medicines called angiotensin II receptor antagonists. Angiotensin II is a substance in the body which causes blood vessels to narrow, thus increasing blood

pressure. Telmisartan works by blocking the effect of angiotensin II. When the effect of angiotensin II is blocked, your blood vessels relax and your blood pressure goes down.

- Hydrochlorothiazide belongs to the group of medicines called diuretics. Diuretics help to reduce the amount of excess fluid in the body by increasing the amount of urine produced. They help with lowering blood pressure particularly when used with other blood pressure lowering medicines. Your doctor may have prescribed APO-TELMISARTAN HCTZ for another reason.

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

APO-TELMISARTAN HCTZ is not addictive. This medicine is available only with a doctor's prescription.

Use in children

The safety and effectiveness of APO-TELMISARTAN HCTZ in children and teenagers up to 18 years of age have not been established.

Before you take APO-TELMISARTAN HCTZ

When you must not take it

Do not take APO-TELMISARTAN HCTZ if you have ever had an allergic reaction after taking:

- Telmisartan or hydrochlorothiazide (the two active ingredients in APO-TELMISARTAN HCTZ),
- Other sulfonamide-derived medicines
- any of the other ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to APO-TELMISARTAN HCTZ 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.

Do not take APO-TELMISARTAN HCTZ if you have a rare hereditary condition of fructose intolerance.

The maximum recommended daily dose of APO-TELMISARTAN HCTZ contains 170 mg of mannitol (in the 40/12.5 mg tablets) and approximately 340 mg of mannitol (in the 80/12.5 mg and 80/25 mg tablets).

Do not take APO-TELMISARTAN HCTZ if you have a rare hereditary condition of galactose intolerance.

The maximum recommended daily dose of APO-TELMISARTAN HCTZ contains 84 mg of lactose monohydrate (in the 40/12.5 mg) and 180.5mg of lactose monohydrate (in the 80/12.5 mg tablets) and 169.4 mg of lactose monohydrate (in the 80/25 mg tablets).

Do not take APO-TELMISARTAN HCTZ if you are pregnant or intend to become pregnant.

APO-TELMISARTAN HCTZ is not recommended for use in pregnancy. Like other similar medicines, it may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking APO-TELMISARTAN HCTZ.

It is not known if telmisartan or hydrochlorothiazide, the active ingredients in APO-TELMISARTAN HCTZ, pass into breast milk and there is a possibility that your baby may be affected.

Do not take APO-TELMISARTAN HCTZ if you have any of the following medical conditions:

- severe liver disease
- severe kidney disease
- cholestasis or biliary obstructive disorders (problem with the flow of bile from the gall bladder)
- low potassium levels in the blood
- high calcium levels in the blood.
- diabetes or kidney problems and you are taking aliskiren (a medicine used to treat high blood pressure).

Do not take APO-TELMISARTAN HCTZ after the expiry date printed on the pack.

Do not take APO-TELMISARTAN HCTZ 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 APO-TELMISARTAN HCTZ, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- kidney problems
- liver problems
- heart problems
- a condition known as primary hyperaldosteronism (raised aldosterone levels, also known as Conn's syndrome)
- diabetes
- gout

- fructose intolerance
- galactose intolerance
- recent severe diarrhoea or vomiting
- asthma
- systemic lupus erythematosus (a disease affecting the skin, joints and kidney)
- eye problems

Tell your doctor if you are following a very low salt diet.

Tell your doctor if you are pregnant or plan to become pregnant or breastfeed.

If you have not told your doctor about any of the above, tell your doctor before you take APO-TELMISARTAN HCTZ.

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 APO-TELMISARTAN HCTZ may interfere with each other. These include:

- any other medicines used to treat high blood pressure such as beta-blockers
- heart medicines such as digoxin, a medicine used to treat heart failure or antiarrhythmic medicines
- lithium, a medicine used to treat certain mental illnesses
- other diuretics or fluid tablets medicines used to help the kidneys get rid of salt and water by increasing the amount of urine produced
- laxatives
- potassium supplements or potassium-containing salt substitutes
- medicines or salt substitutes which may increase your potassium levels
- amphotericin B, a medicine used to treat fungal infections

- penicillin antibiotics used to treat bacterial infections
- alcohol
- sleeping tablets
- strong pain killing medicines
- medicines for diabetes (oral tablets or capsules or insulin)
- powder or granules used to help reduce cholesterol
- corticosteroid medicines such as prednisolone, cortisone or ACTH
- aspirin
- nonsteroidal anti-inflammatory agents (medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis)
- medicines used to treat gout
- calcium supplements or medicines containing calcium
- anticholinergic medicines, which can be used to treat Parkinson's disease, relieve stomach cramps or prevent travel sickness
- amantadine, a medicine used to treat Parkinson's disease or to prevent influenza
- medicines used to treat cancer (cytotoxic medicines)

These medicines may be affected by APO-TELMISARTAN HCTZ, or may affect the way it works. Also, other medicines used to treat high blood pressure may have an additive effect with APO-TELMISARTAN HCTZ in lowering your blood pressure. Therefore, you may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist may have more information on medicines to be careful with or avoid while taking APO-TELMISARTAN HCTZ.

How to take APO-TELMISARTAN HCTZ

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

They may differ from the information contained in this leaflet. Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

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

How much to take

The usual dose for adults is one APO-TELMISARTAN HCTZ 40/12.5 mg tablet once a day. If your blood pressure is still too high after 4-8 weeks of starting treatment, your doctor may increase your dose to one APO-TELMISARTAN HCTZ 80/12.5 mg tablet once a day.

If your blood pressure is still not satisfactorily controlled with APO-TELMISARTAN HCTZ 80/12.5 mg, your doctor may increase your dose to one APO-TELMISARTAN HCTZ 80/25 mg tablet once a day.

It is important to take APO-TELMISARTAN HCTZ exactly as your doctor or pharmacist has told you.

When to take it

Take APO-TELMISARTAN HCTZ at about the same time each day, either morning or evening.

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 APO-TELMISARTAN HCTZ before or after food.

How to take it

Swallow the tablet whole with a full glass of water.

You can take APO-TELMISARTAN HCTZ with or without food.

How long to take it

Take APO-TELMISARTAN HCTZ every day until your doctor tells you to stop.

APO-TELMISARTAN HCTZ helps control your high blood pressure but does not cure it. It is important to keep taking APO-TELMISARTAN HCTZ every day even if you feel well.

People who have high blood pressure often feel well and do not notice any signs of this problem.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take the dose as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting unwanted side effects.

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

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much APO-TELMISARTAN HCTZ.

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

You may need urgent medical attention. If you take too much APO-TELMISARTAN HCTZ you may feel dizzy, light-headed or faint. Your heartbeat may be faster or lower than usual. You may experience dehydration, nausea, drowsiness and muscle spasm.

While you are taking APO-TELMISARTAN HCTZ

Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you are taking APO-TELMISARTAN HCTZ.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking APO-TELMISARTAN HCTZ.

If you feel that APO-TELMISARTAN HCTZ is not helping your condition, tell your doctor or pharmacist.

Tell your doctor if, for any reason, you have not used APO-TELMISARTAN HCTZ exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor immediately if you become pregnant while taking APO-TELMISARTAN HCTZ.

You should not take this medicine while you are pregnant.

If you are going to have surgery, tell your doctor and anaesthetist that you are taking APO-TELMISARTAN HCTZ.

APO-TELMISARTAN HCTZ may affect some medicines you receive during surgery.

Things you must not do

Do not use APO-TELMISARTAN HCTZ to treat other complaints unless your doctor or pharmacist tells you to.

Do not give this medicine to anyone else, even if they have the same symptoms as you.

Do not stop taking APO-TELMISARTAN HCTZ or lower the dosage without checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how APO-TELMISARTAN HCTZ affects you.

Like other medicines used to treat high blood pressure, APO-TELMISARTAN HCTZ may cause sleepiness, dizziness or light-headedness in some people.

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

You may feel dizzy or light-headed when you begin to take APO-TELMISARTAN HCTZ, especially if you are also taking a diuretic (or fluid tablet) or if you are dehydrated.

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

Standing up slowly, especially when you get up from a bed or chair, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

If you exercise, or if you sweat, or if the weather is hot, you should drink plenty of water.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking APO-TELMISARTAN HCTZ even if you do not think it is connected with the medicine.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have. Tell your doctor if you notice any of the following and they worry you:

- 'flu-like' symptoms
- fainting, dizziness or spinning sensation
- a feeling of tension or fullness in the nose, cheeks and behind the eyes, sometimes with a throbbing ache (sinusitis)
- infections of the air passages
- shortness of breath or difficulty breathing
- abnormal or blurred vision
- eye pain
- back pain
- changes in heart rhythm or increased heart rate
- rash or redness or itchiness of skin
- increased sweating
- dizziness or light-headedness when you stand up (postural hypotension)
- stomach pain or discomfort (abdominal pain, dyspepsia, gastritis)
- wind or excessive gas in the stomach or bowel
- vomiting
- diarrhoea or constipation
- dry mouth
- pins and needles
- sleep disturbances or trouble sleeping
- feeling anxious
- depression
- impotence
- leg pain or cramps in legs
- aching muscles or aching joints not caused by exercise or muscle spasms
- chest pain
- pain
- liver problems
- changes in the levels of potassium or sodium or uric acid in your blood (such changes are usually detected by a blood test)

Tell your doctor as soon as possible if you experience any side effects during or after taking APO-TELMISARTAN HCTZ, so that these may be properly treated.

Symptoms such as feeling very thirsty, sleepy, sick or vomiting, a dry mouth, general weakness, muscle pain or cramps, a very fast heart rate, may mean that the hydrochlorothiazide part of APO-TELMISARTAN HCTZ is having an excessive effect.

You should tell your doctor if you experience any of these symptoms. Tell your doctor immediately or go to casualty at your nearest hospital if you notice any of the following:

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash
- developing or worsening of a disease called systemic lupus erythematosus which affects the skin, joints and kidney

These are serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor or pharmacist if you notice anything else that is making you unwell.

Other side effects not listed above may also occur in some people.

After taking APO-TELMISARTAN HCTZ

Storage

Leave the tablets in the blister strip until it is time to take a dose.

The blister pack protects the tablets from light and moisture.

Keep APO-TELMISARTAN HCTZ in a cool, dry place where the temperature stays below 25°C.

Do not store APO-TELMISARTAN HCTZ or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sill.

Heat and dampness can destroy some medicines.

Keep APO-TELMISARTAN HCTZ where children cannot reach it.

Disposal

If your doctor tells you to stop using APO-TELMISARTAN HCTZ or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

APO-TELMISARTAN HCTZ is the brand name of your medicine. APO-TELMISARTAN HCTZ tablets are available in three strengths: 40/12.5 mg, 80/12.5 mg and 80/25 mg tablets.

APO-TELMISARTAN HCTZ 40/12.5 mg and 80/12.5 mg tablets are pink mottled and white to off-white biconvex, oval shaped, two layer tablets. The white to off-white layer may contain pink specks. Each tablet contains either 40 mg or 80 mg of telmisartan and 12.5 mg of hydrochlorothiazide. The pink mottled face of APO-TELMISARTAN HCTZ 40/12.5 mg tablets are marked with L199. The pink mottled face of APO-TELMISARTAN HCTZ 80/12.5 mg tablets are marked with L200.

APO-TELMISARTAN HCTZ 80/25 mg tablets are yellow mottled and white to off-white biconvex, oval shaped, two layer tablets. The white to off-white layer may contain yellow specks. Each tablet contains 80 mg of telmisartan and 25 mg of hydrochlorothiazide. The white face of APO-TELMISARTAN HCTZ 80/25 mg tablets are marked with L201.

APO-TELMISARTAN HCTZ tablets are available in blister packs of 28 tablets.

The following Australian Registration Numbers appear on the carton:

AUST R 208064 for APO-TELMISARTAN HCTZ 40/12.5 mg tablets

AUST R 208069 for APO-TELMISARTAN HCTZ 80/12.5 mg tablets

AUST R 208063 for APO-TELMISARTAN HCTZ 80/25 mg tablets

Ingredients

Each APO-TELMISARTAN HCTZ 40/12.5 mg tablet contains 40 mg telmisartan and 12.5 mg hydrochlorothiazide.

Each APO-TELMISARTAN HCTZ 80/12.5 mg tablet contains 80 mg telmisartan and 12.5 mg hydrochlorothiazide.

Each APO-TELMISARTAN HCTZ 80/25 mg tablet contains 80 mg telmisartan and 25 mg hydrochlorothiazide.

The other ingredients found in the tablets are:

- povidone (K25)
- lactose monohydrate
- magnesium stearate
- meglumine
- sodium hydroxide
- sodium stearyl fumarate
- mannitol

APO-TELMISARTAN HCTZ 40/12.5 mg and 80/12.5 mg tablets also contain Pigment Blend PB-24880 Pink and APO-TELMISARTAN HCTZ 80/25 mg tablets also contain Pigment Blend PB-52290 Yellow, as colouring agent.

Sponsor

ALEMBIC PHARMACEUTICALS AUSTRALIA PTY LIMITED
Level 2, 108 Power Street
Hawthorn VIC 3122

Distributor

Apotex Pty Ltd
Level 3,
16 Giffnock Avenue
Macquarie Park

NSW 2113

Australia

This leaflet was last updated in

June 2017