

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

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 this medicine 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 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.

Untreated hypertension can lead to serious health problems, including stroke, heart disease and kidney failure.

APO-Telmisartan HCTZ contains both telmisartan and hydrochlorothiazide (HCTZ) 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

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 not addictive.

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

The safety and effectiveness of this medicine in children and teenagers up to 18 years of age have not been established.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- telmisartan
- hydrochlorothiazide

- sulfonamide-derived medicines
- any of the other 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.

Do not take this medicine 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 this medicine 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 this medicine if you are pregnant or intend to become pregnant.

Telmisartan/HCTZ is not recommended for use in pregnancy. It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.

It is not known if telmisartan or hydrochlorothiazide pass into breast milk and there is a possibility that your baby may be affected.

Do not take this medicine if you have any of the following medical conditions:

- severe liver or kidney disease, including the inability to produce urine
- cholestasis or biliary obstructive disorders (problem with the flow of bile from the gall bladder)
- low potassium levels or high calcium levels in the blood
- low sodium levels that is treatment resistant
- low blood volume causing very low blood pressure
- gout
- diabetes or kidney problems and you are taking aliskiren (a medicine used to treat high blood pressure)

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 have or have had any of the following medical conditions:

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

- diabetes
- fructose or galactose intolerance
- recent severe diarrhoea or vomiting
- asthma
- systemic lupus erythematosus
- eye problems
- high cholesterol levels
- skin cancer

Tell your doctor if you have experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past.

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

If you have not told your doctor about any of the above, tell your doctor before you take 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 this one may interfere with each other. These include:

- other medicines used to treat high blood pressure (e.g. beta-blockers)
- heart medicines such as digoxin, a medicine used to treat heart failure or antiarrhythmic medicines
- lithium, used to treat certain mental illness
- medicines used to treat depression
- antipsychotics, medicines used to treat certain mental and emotional conditions.
- Antiepileptic's, medicines used to treat epilepsy or fits
- diuretics or fluid tablets, used to help the kidneys get rid of salt and water by increasing the amount of urine produced.
- laxatives
- medicines or salt substitutes which may increase your potassium levels (e.g. potassium supplements or potassium-containing salt substitutes)
- medicines used to treat infections (e.g. amphotericin B or penicillin antibiotics)
- alcohol
- sleeping tablets
- strong pain killing medicines
- medicines for diabetes (oral tablets or insulin)
- powder or granules used to help reduce cholesterol
- corticosteroid medicines such as prednisolone, cortisone or ACTH (a hormone) medicines used to treat a weakened immune system (e.g. prednisolone, cancer medicines)
- nonsteroidal anti-inflammatory agents used to relieve pain (medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis) (e.g. aspirin)
- medicines used to treat gout
- medicines used to increase blood pressure, such as noradrenaline

- ciclosporin, a medicine used to help prevent organ transplant rejection or to treat certain problems with the immune system
- calcium supplements or medicines containing calcium
- vitamin D supplements
- some medicines used to treat Parkinson's disease (e.g. anticholinergic medicines, amantadine)
- medicines used to treat cancer (e.g. cytotoxic medicines such as methotrexate)
- 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

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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 label, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your condition and whether you are taking any other medicines.

The usual dose for this medicine is one tablet taken once a day.

If your blood pressure is still too high after 4-8 weeks of starting treatment, your doctor may increase your dose.

If your blood pressure is still not satisfactorily controlled, your doctor may increase your dose.

When to take it

Take this 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.

How to take it

Swallow the tablet whole with a full glass of water.

You can take it with or without food.

How long to take it for

Take this medicine every day until your doctor tells you to stop.

This medicine helps control your high blood pressure but does not cure it. It is important to keep taking it 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 the Emergency department at your nearest hospital, if you think that you or anyone else may have taken too much medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. If you take too much, 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 this medicine

Things you must do

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

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

If you feel that this medicine is not helping your condition, tell your doctor or pharmacist.

Tell your doctor if, for any reason, you have not used this medicine 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 this medicine.

If you are going to have surgery, tell your doctor and anaesthetist that you are taking this medicine.

It may affect some medicines you receive during surgery.

Tell your doctor if you develop an unexpected abnormal lump, bump, ulcer, sore or coloured area on the skin (skin lesion) during the treatment.

Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (nonmelanoma skin cancer).

Protect your skin from sun exposure and UV rays while telmisartan/HCTZ.

If you develop any severe shortness of breath or difficulty breathing after taking APO-Telmisartan/HCTZ, seek medical attention immediately

Things you must not do

Do not use this medicine 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 condition as you.

Do not stop taking this medicine 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 this medicine affects you.

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 this medicine, especially if you are also taking a diuretic 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 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 this 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 complaints, including pain, discomfort, dyspepsia, gastritis, wind, or excessive gas in stomach or bowel, nausea, vomiting, diarrhoea or constipation
- dry mouth
- pins and needles
- sleep disturbances or trouble sleeping
- feeling anxious or depression
- impotence
- leg pain or cramps in legs
- aching muscles or aching joints not caused by exercise or muscle spasms
- chest pain
- headache
- pain
- liver problems
- changes in the levels of potassium, magnesium, calcium or sodium or uric acid

in your blood (such changes are usually detected by a blood test)

- symptoms that may indicate low sodium levels in the blood, such as headache, dizziness, confusion, forgetfulness, weakness, unsteadiness or difficulty concentrating.
- decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye or acute angle-closure glaucoma).

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

Symptoms such as feeling very thirsty, sleepy, sick or vomiting, a dry mouth, general weakness, restlessness, seizures (fits), confusion, muscle pain or cramps, passing less urine than normal, a very fast heart rate, may mean that the HCTZ part of telmisartan/HCTZ is having an excessive effect.

Tell your doctor as soon as possible if you notice any unexpected changes to your skin, including your lips. This could be a type of skin or lip cancer (non-melanoma skin cancer)

If you notice any of the following, tell your doctor immediately or go to the Emergency department at your nearest hospital:

- 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
- acute respiratory distress which is very rare but possible side effect (signs include severe shortness of breath, fever, weakness and confusion).
- Increased sensitivity of the skin to the sun with symptoms of sunburn (such as redness, itching swelling, blistering) which may occur more quickly than normal.

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 this medicine

Storage

Keep your tablets in the pack until it is time to take them.

The blister pack protects the tablets from light and moisture.

Keep this medicine in a cool, dry place where the temperature stays below 25°C.

Do not store this medicine 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 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 tells you to stop using this medicine or it has passed its expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

40/12.5 mg:

Pink mottled and white to off-white biconvex, oval shaped, two-layer tablets. The white to off-white layer may contain pink specks. The pink mottled face of 40/12.5 mg tablets are marked with L199. AUST R 208064.

80/12.5 mg tablets:

Pink mottled and white to off-white biconvex, oval shaped, two-layer tablets. The white to off-white layer may contain pink specks. The pink mottled face of 80/12.5 mg tablets are marked with L200. AUST R 208069.

80/25 mg tablets:

Yellow mottled and white to off-white biconvex, oval shaped, two-layer tablet. The white to off-white layer may contain yellow specks. The white face of 80/25 mg tablets are marked with L201. AUST R 208063.

Available in blister packs of 28 tablets.

Ingredients

Each tablet contains either 40 mg or 80 mg of telmisartan and contains either 12.5 mg or 25 mg of hydrochlorothiazide.

Other ingredients in the tablets include:

- povidone
- lactose monohydrate
- magnesium stearate
- meglumine
- sodium hydroxide
- sodium stearyl fumarate
- mannitol
- Pigment Blend PB-24880 Pink colouring (40/12.5 mg and 80/12.5 mg strength only)
- Pigment Blend PB-52290 Yellow colouring (80/25 mg strength only)

This medicine contains sugars as lactose.

Sponsor

Arrotex Pharmaceuticals Pty Ltd
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Australia

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