

APO-Telmisartan

Contains the active ingredient telmisartan

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 telmisartan. 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-Telmisartan. It contains the active ingredient telmisartan.

It is used to:

- treat high blood pressure (also called hypertension).
- prevent cardiovascular complications, including death due to cardiovascular causes, in patients aged 55 years of age or older with coronary artery disease, peripheral vascular disease, previous stroke, previous transient ischaemic attack (TIA) or high risk diabetes with evidence of end organ damage.

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 normal, 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.

Prevention of cardiovascular complications, including death due to cardiovascular causes

Patients who may be considered at a high risk of developing cardiovascular complications, or at a high risk of death due to cardiovascular causes, are those aged 55 or more who have problems such as coronary artery disease (a heart disease caused by poor blood flow in the blood vessels of the heart), peripheral vascular disease (poor circulation in the hands or feet), previous stroke, previous transient ischaemic attack (TIA) or diabetes with additional high risk factors and evidence of end organ damage (e.g. damage occurring in the kidneys, heart, brain or eyes).

Your doctor can tell you if you are at a high risk of developing cardiovascular complications or if you are at a high risk of death due to cardiovascular causes.

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

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, the blood vessels relax and your blood pressure goes down.

Telmisartan may be used either alone or in combination with other medicines used to treat high blood pressure.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children. The safety and effectiveness in children below 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 or have had any of the following:**
- **Severe liver disease (severe hepatic impairment)**
- **Biliary obstructive disorders (problems with the flow of bile from the gall bladder).**
- **You are pregnant or are planning to become pregnant.** Telmisartan may affect your developing baby if you take it during pregnancy.
- **You are breast-feeding or are planning to breast-feed.** Telmisartan may pass into human breast milk.
- 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, telmisartan 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:
 - kidney problems
 - liver problems
 - heart problems
 - a condition known as primary hyperaldosteronism (raised aldersterone levels, also known as Conn's syndrome)
 - recent severe diarrhoea or vomiting
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 following a very low salt diet.
6. You are planning to have surgery or an anaesthetic.
7. You are currently receiving or are planning to receive dental treatment.
8. 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 telmisartan. These include:

- ramipril or any other medicines used to treat high blood pressure or heart problems
- potassium supplements or potassium-containing salt substitutes
- medicines or salt-substitutes which may increase your potassium levels
- diuretics or fluid tablets, medicines used to help the kidneys get rid of salt and water by increasing the amount of urine produced
- nonsteroidal anti-inflammatory agents (NSAIDs - medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis) such as aspirin
- lithium, a medicine used to treat certain mental illnesses
- digoxin, a medicine used to treat heart failure

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

Other medicines not listed above may also interact with telmisartan. Your doctor may have more information on medicines to be careful with or avoid while taking telmisartan.

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.

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

For the treatment of high blood pressure (hypertension):

The usual dose for adults is one 40 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 80 mg.

For the prevention of cardiovascular complications, including death due to cardiovascular causes:

The usual dose is one 80 mg tablet, once a day.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

How to take it

Swallow the tablet whole 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.

It does not matter if you take it before, with or after food.

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.

Take telmisartan every day until your doctor tells you to stop.

Telmisartan helps to control your high blood pressure, and/or prevents you from developing cardiovascular complications, but does not cure it. It is important to keep taking telmisartan 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 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.

If you take too much telmisartan you may feel dizzy, light-headed or faint. Your heartbeat may be faster or lower than usual and you may experience rapid, shallow breathing or cold, clammy skin. 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 plan to have any vaccinations or immunisations
- you are pregnant or are planning to become 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 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.

Like other medicines used to treat high blood pressure, telmisartan 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 telmisartan, 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.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking telmisartan 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:

- headache
- dizziness or spinning sensation, fainting
- dizziness or lightheadedness when you stand up, especially when getting up from a sitting or lying position
- tiredness or weakness
- 'flu-like' symptoms
- pain in the chest
- diarrhoea
- indigestion
- stomach pain or discomfort
- wind or excessive gas in the stomach or bowel (flatulence)
- upper respiratory tract infections
- shortness of breath
- back pain
- aching muscles not caused by exercise (myalgia)
- muscle spasms or leg cramps or leg pain
- painful joints (arthralgia)

- tendon pain or tendinitis-like symptoms
- urinary tract infections (including cystitis)
- trouble sleeping (insomnia)
- feeling anxious
- depression
- fast or slow heart beats
- visual disturbance
- increased sweating
- dry mouth
- allergic skin reactions including: skin rash (eczema); itchiness (pruritus); redness of the skin (erythema)
- symptoms that may indicate low blood sugar levels, such as sweating, weakness, hunger, dizziness, trembling, headache or numbness (especially in diabetic patients)
- abnormal liver function
- symptoms that may indicate a worsening of the kidney function, such as passing little or no urine, drowsiness, nausea, vomiting, breathlessness, loss of appetite and weakness
- symptoms that may indicate high potassium levels in the blood, such as nausea, diarrhoea, muscle weakness and changes in heart rhythm
- signs of anaemia such as tiredness, being short of breath when exercising, dizziness and looking pale
- bleeding or bruising more easily than normal (thrombocytopenia)
- symptoms that may indicate an infection of the blood, such as high fever, chills, headache, confusion and rapid breathing
- changes in your red or white blood cell levels may occur (such changes are usually detected by a blood test).

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

Allergic reactions

If you think you are having an allergic reaction to telmisartan, 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 30°C. Protect from light and 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 tells you to stop taking this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Telmisartan looks like

40 mg Tablet

White to off-white, biconvex, oval-shaped tablets, one face marked with L203 and plain on the other side.

80 mg Tablet

White to off-white, biconvex, oval-shaped tablets, one face marked with L204 and plain on the other side.

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

Ingredients

Each tablet contains (40 mg or 80 mg) of telmisartan as the active ingredient.

It also contains the following inactive ingredients:

- Povidone K25
- Mannitol
- Meglumine
- Magnesium stearate
- Sodium hydroxide
- Sodium stearyl fumarate

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

Australian Registration Numbers

APO-Telmisartan 40 mg tablets
(blister pack: Alu silver/Alu HSL) of
28 tablets: AUST R 209336

APO-Telmisartan 80 mg tablets
(blister pack: Alu silver/Alu HSL) of
28 tablets: AUST R 209334

Name and Address of the Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park, NSW 2113
Australia

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