

APO-Telmisartan Tablets

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

This leaflet answers some common questions about this medicine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking 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

Telmisartan 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

Treatment of high blood pressure (hypertension)

Telmisartan 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 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

Micardis is also used to prevent cardiovascular complications, including death due to cardiovascular causes that may arise in high risk patients older than 55 years of age. Examples include heart attack, stroke, death caused by heart diseases or hospitalisation due to heart failure (a condition which can cause shortness of breath or ankle swelling).

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.

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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

There is no evidence that this medicine is addictive.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Before you take this medicine

When you must not take it

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

- any medicine containing telmisartan
- any of the 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 Micardis if you have a rare hereditary condition of fructose intolerance.

40mg tablet contains approximately 170.54 mg of mannitol per maximum recommended daily dose and 80mg tablet contains approximately 341.08 mg of mannitol per maximum recommended daily dose.

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

- severe liver disease (severe hepatic impairment)
- biliary obstructive disorders (problems with the flow of bile from the gall bladder)
- diabetes or kidney problems and you are taking aliskiren (a medicine used to treat high blood pressure)

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

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

Do not take this medicine if you are breastfeeding or are planning to breastfeed.

Telmisartan may pass into human breast milk.

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 problems
- liver problems
- heart problems
- diabetes
- a condition known as primary hyperaldosteronism (raised aldosterone levels, also known as Conn's syndrome)
- fructose intolerance
- recent severe diarrhoea or vomiting

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

Your doctor can discuss with you the risks and benefits involved.

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

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 may interact with telmisartan. These include:

- other medicines used to treat high blood pressure or heart problems, such as ACE inhibitors (e.g. ramipril).
- 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 (e.g. spironolactone or frusemide)
- nonsteroidal anti-inflammatory agents (NSAIDs) – medicines used to relieve pain, swelling and other symptoms of inflammation (including arthritis), such as aspirin or ibuprofen
- lithium, used to treat certain mental illnesses
- digoxin, used to treat heart failure
- trimethoprim, used to treat bacterial infections
- heparin, used to thin your blood
- corticosteroids, medicines used to treat inflammatory conditions
- immunosuppressants, such as ciclosporin or tacrolimus, used to prevent organ rejection after transplantation

These medicines may be affected by telmisartan or may affect how well it works. Other medicines used to treat high blood pressure or medicines with blood pressure lowering potential may have an additive effect with this medicine in lowering your blood pressure. 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 directions, ask your doctor or pharmacist for help.

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.

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 your 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.

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.

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 symptoms.

If you forget to take it

If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.

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

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

If you take too much (overdose)

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

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

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

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

Tell your doctor if, for any reason, you have not used Micardis exactly as prescribed.

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

Things you must not do

Do not take this medicine to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your 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.

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, 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 but most of the time they are not.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Tell your doctor if you notice any of the following and they worry you:

- headache
- dizziness, spinning sensation or fainting
- dizziness or light-headedness when you stand up, especially when getting up from a sitting or lying position
- tiredness or weakness
- diarrhoea
- indigestion
- stomach pain or discomfort
- wind or excessive gas in the stomach or bowel (flatulence)

Tell your doctor as soon as possible if you notice any of the following:

- chest pain
- 'flu-like' symptoms
- upper respiratory tract infections

- back pain
- aching muscles not caused by exercise (myalgia)
- painful joints (arthralgia)
- tendon pain or tendinitis-like symptoms
- symptoms of urinary tract infections (including cystitis) such as burning sensation when passing urine, pain in the pelvis or mid-back, urine that appears cloudy, straining or pain when passing urine
- trouble sleeping (insomnia)
- feeling anxious
- depression
- shortness of breath
- muscle spasms, leg cramps or leg pain
- fast or slow heart beats
- visual disturbances (abnormal or blurred vision)
- increased sweating
- dry mouth
- allergic skin reactions including skin rash (eczema), itchiness (pruritus) and redness of the skin (erythema)
- signs of anaemia such as tiredness, being short of breath when exercising, dizziness and looking pale
- changes in your red or white blood cell levels – usually only detected through blood tests

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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
- symptoms that may indicate low sodium levels in the blood, such as headache, dizziness, confusion, forgetfulness, weakness, unsteadiness or difficulty concentrating
- 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
- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body which may cause difficulty in swallowing or breathing; severe and sudden onset of rash, itching or hives on the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

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

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

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. The blister pack protects the tablets from light and moisture.

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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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

Sponsor

Arrotex Pharmaceuticals Pty Ltd
15 – 17 Chapel street
Cremorne, 3121 VIC
Australia

This leaflet was last updated in June 2023.

Product description

What APO-Telmisartan looks like

40 mg Tablet

White to off-white colour, oval shape, biconvex, uncoated tablets debossed with L203 on one side and plain on other side. AUST R 209336.

Blister packs of 28 tablets.

80 mg Tablet

White to off-white colour, oval shape, biconvex, uncoated tablets debossed with L204 on one side and plain on other side. AUST R 209334.

Blister packs of 28 tablets.

*Not all strengths 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
- Mannitol
- Meglumine
- Magnesium stearate
- Sodium hydroxide
- Sodium stearyl fumarate