

Teltartan Tablets

Telmisartan

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Teltartan.

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 or doctor 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 Teltartan is used for

Teltartan is used to:

- treat high blood pressure (also called hypertension)
- prevent cardiovascular complications, including death due to cardiovascular causes, in patients older than 55 years of age 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 HYPERTENSION

Teltartan 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.

How Teltartan works

Teltartan contains telmisartan. 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.

Teltartan may be used either alone or in combination with other

medicines used to treat high blood pressure.

PREVENTION OF CARDIOVASCULAR COMPLICATIONS, INCLUDING DEATH DUE TO CARDIOVASCULAR CAUSES

Teltartan 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 hospitalization due to heart failure (a condition which can cause shortness of breath or ankle swelling).

Patients who may be considered at high risk of developing cardiovascular complications or at 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 high risk of developing cardiovascular complications or if you are at high risk of death due to cardiovascular causes.

Your doctor may have prescribed Teltartan for another reason. Ask your doctor if you have any

questions about why Teltartan has been prescribed for you.

Teltartan is not addictive.

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

Use in children

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

Before you take Teltartan

When you must not take it

Do not take Teltartan if you have ever had an allergic reaction after taking:

- telmisartan (the active ingredient in Teltartan)
- any other ingredients listed at the end of this leaflet

Symptoms of an allergic reaction to Teltartan 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 teltartan if you have a rare hereditary condition of fructose intolerance.

Do not take Teltartan if you are pregnant.

Like other similar medicines, it may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking Teltartan

It is not known if telmisartan, the active ingredient in teltartan, passes into breast milk and there is a possibility that your baby may be affected.

Do not give Teltartan to a child under the age of 18 years.

Safety and effectiveness in children and teenagers up to 18 years of age have not been established.

Do not take Teltartan if you suffer from:

- severe liver disease
- biliary obstructive disorders (problem 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 Teltartan after the expiry date printed on the pack.

Do not take Teltartan if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not take Teltartan if the tablets are discolored.

If you are not sure whether you should start taking Teltartan 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
- diabetes
- a condition known as primary hyperaldosteronism (raised aldosterone levels, also known as Conn's syndrome)
- fructose intolerance
- recent severe diarrhea or vomiting

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.

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

If you have not told your doctor about any of the above, tell your doctor before you take Teltartan.

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 Teltartan may interfere with each other. 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
- aspirin
- nonsteroidal anti-inflammatory agents such as aspirin or ibuprofen (medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis)
- lithium, a medicine used to treat certain mental illnesses
- digoxin, a medicine used to treat heart failure
- trimethoprim, a medicine used to treat bacterial infections.
- Heparin, a medicine used to thin your blood
- Corticosteroids, medicines used to treat inflammatory conditions
- Immunosuppressants, such as ciclosporin or tacrolimus (medicines used to prevent

organ rejection after transplantation).

These medicines may be affected by Teltartan or may affect the way it works. Also, other medicines used to treat high blood pressure or medicines with blood pressure lowering potential may have an additive effect with Teltartan 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 may have more information on medicines to be careful with or avoid while taking Teltartan.

How to take Teltartan

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

FOR THE TREATMENT OF HYPERTENSION

The usual dose of Teltartan 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 of Teltartan 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.

It is important to take Teltartan exactly as your doctor or pharmacist has told you.

When to take it

Take Teltartan 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 Teltartan before or after food.

How to take it

Swallow the tablet whole with a full glass of water.

You can take Teltartan with or without food.

How long to take it

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

Teltartan 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 Teltartan 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 Teltartan.

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

You may need urgent medical attention.

If you take too much Teltartan you may feel dizzy, light-headed or faint. Your heartbeat may be faster or lower than usual. You may experience rapid, shallow breathing or cold, clammy skin. This is because your blood pressure is too low.

While you are taking Teltartan

Things you must do

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

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

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

Teltartan may affect other medicines used during surgery.

If you become pregnant while taking Teltartan, tell your doctor immediately.

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

Tell your doctor if, for any reason, you have not used Teltartan 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 use Teltartan 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 yours.

Do not stop taking Teltartan or lower the dosage without checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery while you are taking Teltartan until you know how it affects you.

Like other medicines used to treat high blood pressure, Teltartan may cause sleepiness, dizziness or lightheadedness 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 Teltartan, 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 Teltartan 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:

- dizziness or lightheadedness when you stand up especially when getting up from a sitting or lying position
- dizziness or spinning sensation, fainting
- 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 in the blood, such as sweating, weakness, hunger, dizziness, trembling, headache or numbness (especially in diabetic patients)
- abnormal liver functions
- 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)

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 itchy or raised skin rash, hives or nettle rash

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

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

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

After taking Teltartan

Storage

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

The blister pack protects the tablets from light and moisture.

Keep Teltartan in a cool dry place where the temperature stays below 30C.

Do not store Teltartan or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Teltartan where young children cannot reach it.

Disposal

If your doctor tells you to stop using Teltartan 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

Teltartan is the brand name of your medicine.

Teltartan tablets are available in two strengths: 40 mg and 80 mg tablets.

Teltartan 40 mg tablets are white to off-white color, oval shape, biconvex, uncoated tablets debossed with 'L203' on one side and plain on other side.

Teltartan 80 mg tablets are white to off-white color, oval shape, biconvex, uncoated tablets debossed with 'L204' on one side and plain on other side.

Teltartan tablets are available in blister packs of 28 tablets.

Ingredients

Each Teltartan 40 mg tablet contains 40 mg telmisartan.

Each Teltartan 80 mg tablet contains 80 mg telmisartan.

The other ingredients found in both strengths are:

- povidone K25
- meglumine
- sodium hydroxide
- mannitol
- Sodium stearoyl fumarate
- magnesium stearate

Sponsor

Arrow Pharma Pty Ltd
15 – 17 Chapel Street
Cremorne VIC 3121

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Australian Registration Numbers

AUST R 209341 for Teltartan 40 mg tablets

AUST R 209343 for Teltartan 80 mg tablets