

TELTARTAN

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using TELTARTAN?

TELTARTAN contains the active ingredient telmisartan. TELTARTAN is used to treat high blood pressure (also called hypertension). It is also used to 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.

For more information, see Section [1. Why am I using TELTARTAN?](#) in the full CMI.

2. What should I know before I use TELTARTAN?

Do not use if you have ever had an allergic reaction to telmisartan or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use TELTARTAN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TELTARTAN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use TELTARTAN?

- For the treatment of hypertension: the usual dose of TELTARTAN for adults is one 40 mg tablet once a day.
- For the treatment of cardiovascular complications: 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.

More instructions can be found in Section [4. How do I use TELTARTAN?](#) in the full CMI.

5. What should I know while using TELTARTAN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using telmisartan.• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking TELTARTAN.• If you become pregnant while taking TELTARTAN, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking TELTARTAN or lower the dosage without checking with your doctor• Do not use TELTARTAN to treat other complaints unless your doctor or pharmacist tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful when driving or operating machinery while you are taking TELTARTAN until you know how it affects you.
Looking after your medicine	<ul style="list-style-type: none">• Leave the tablets in the blister strip until it is time to take them.• Keep TELTARTAN in a cool dry place where the temperature stays below 30C.

For more information, see Section [5. What should I know while using TELTARTAN?](#) in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking RALOVISTA, even if you do not think it is connected with this medicine.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

TELTARTAN

Active ingredient(s): *telmisartan*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TELTARTAN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TELTARTAN.**

Where to find information in this leaflet:

- [1. Why am I using TELTARTAN?](#)
- [2. What should I know before I use TELTARTAN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use TELTARTAN?](#)
- [5. What should I know while using TELTARTAN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using TELTARTAN?

TELTARTAN contains the active ingredient telmisartan. TELTARTAN belongs to a group of medicines called angiotensin II receptor blockers. 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.

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.

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.

2. What should I know before I use TELTARTAN?

Warnings

Do not use TELTARTAN if:

- You are allergic to telmisartan, or any of the ingredients listed at the end of this leaflet
- Always check the ingredients to make sure you can use this medicine
- You have a rare hereditary condition of fructose intolerance
TELTARTAN 40mg contains approximately 170.54 mg of mannitol per maximum recommended daily dose and TELTARTAN 80mg contains approximately 341.08 mg of mannitol per maximum recommended daily dose
- You are pregnant
- You are breastfeeding
- You have the following medical conditions:
 - 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).

Check with your doctor if you:

- have any other medical conditions, especially the following:
 - 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).
 - a condition known as primary hyperaldosteronism (raised aldosterone levels, also known as Conn's syndrome)
 - fructose intolerance
 - recent severe diarrhea or vomiting
 - take any medicines for any other condition
 - are following a very low salt diet
 - you are pregnant, plan to become pregnant or breastfeed
- Your doctor can discuss with you the risks and benefits involved.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take TELTARTAN if you are pregnant.

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

Check with your doctor if you are pregnant or intend to become pregnant.

Do not breastfeed if you are taking TELTARTAN

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Children under 18 years

- Do not give TELTARTAN to a child under the age of 18 years.
- This refers to any medical condition-specific, medicine-specific, and/or age-specific subheading(s) relevant for inclusion for certain categories/groups of users, as applicable to the medicine.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TELTARTAN.

4. How do I use 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.

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 TELTARTAN

- **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 TELTARTAN

- 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 use TELTARTAN

TELTARTAN should be used regularly at the same time each day. If you miss your dose at the usual time, skip the dose you missed and take your next dose when you are meant. 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 you missed.

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

If you use too much TELTARTAN

If you think that you have used too much TELTARTAN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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.

5. What should I know while using TELTARTAN?

Things you should 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 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.

Call your doctor straight away if you:

- Become pregnant while taking TELTARTAN.

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TELTARTAN 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.

Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• 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• Symptoms of urinary tract	Speak to your doctor if you have any of these less serious side effects and they worry you.

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
- Fast or slow heart beats
- Visual disturbance (abnormal or blurred vision)
- 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
- Symptoms that may indicate low sodium levels in the blood, such as headache, dizziness, confusion, forgetfulness, weakness, unsteadiness or difficulty concentrating
- 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)

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathingSevere and sudden onset of itchy or raised skin rash, hives or nettle rash	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What TELTARTAN contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">Each TELTARTAN 40 mg tablet contains 40 mg telmisartan.Each TELTARTAN 80 mg tablet contains 80 mg telmisartan.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">PovidoneMeglumineSodium hydroxideMannitolSodium stearyl fumarateMagnesium stearate

Do not take this medicine if you are allergic to any of these ingredients.

What TELTARTAN looks like

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. (AUST R 209341)

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. (AUST R 209343)

Who distributes TELTARTAN

Arrotex Pharmaceuticals Pty Ltd

15 – 17 Chapel Street

Cremorne VIC 3121

This leaflet was prepared in August 2024.