

TELMISARTAN-DRLA

Contains the active ingredient telmisartan

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some of the common questions about telmisartan. It does not contain all the information that is known about rosuvastatin.

It does not take the place of talking to your doctor and pharmacist.

All medicines have risks and benefits. Your doctor will have 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

The name of your medicine is Telmisartan-DRLA. It contains the active ingredient telmisartan.

Telmisartan 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

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 this medicine works

Telmisartan belongs to a group of medicines known as angiotensin II receptor antagonists. Angiotensin II is 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.

Telmisartan 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

Telmisartan 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 high risk of developing cardiovascular complications or at high risk of death due to cardiovascular causes are these 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 will have explained why you are being treated with this medicine and told you what dose to take.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

Telmisartan is not addictive.

Use in children

Telmisartan is not recommended for use in children and teenagers up to 18 years of age as its effects in children have not been established.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- 1. you have had an allergy to**
 - **telmisartan or 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 in breathing
- swelling of the face, lips, tongue or other parts of the body rash, itching, hives on the skin

- 2. you are pregnant or intend to become pregnant.**

Telmisartan is not recommended for use in pregnancy. Like similar medicines, it could affect your unborn baby if you take it during pregnancy.

- 3. if you are breastfeeding**

It is not known if this medicine passes into breast milk and there is a possibility that your baby may be affected.

- 4. you suffer from**
 - **severe liver disease**
 - **biliary obstructive disorders (problems with the flow of bile from the gall bladder)**
- 5. the package is torn or shows signs of tampering**
- 6. the expiry date (EXP) printed on the pack has passed**

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if:

- 1. you have or have ever had any medical conditions, especially the following:**

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

- 2. you are following a very low salt diet**

- 3. you plan to become pregnant or breastfeed.**

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Some medicines and telmisartan 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 (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

These medicines may be affected by telmisartan, or may affect how well it works. Also, other medicines used to treat high blood pressure may have an additive effect with telmisartan.

You may need to use different amounts of your medicine, or take different medicines.

Your doctor or pharmacist will advise you. Your doctor or pharmacist has more information on medicines to be careful with or avoid while using this medicine.

How to take it

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 telmisartan 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 telmisartan 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 this medicine exactly as your doctor or pharmacist has told you.

How to take it

Swallow each tablet whole with a full glass of water.

You can take telmisartan with or without food.

When to take it

Take this medicine once a day, at about the same time each day, either morning or evening.

Keeping a regular time for taking your medicine will help to remind you to take it.

It does not matter whether you take it with food or on an empty stomach.

If you are not sure when to take this medicine, ask your doctor.

How long to take it

You must continue to take it as directed, 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 this medicine 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 double the dose to make up for the one you missed.

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

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

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 slower 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 this medicine

Things you must do

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

Tell all the doctors, dentists and pharmacists who are treating you that you are using this medicine.

If you become pregnant while you are using this medicine, stop

using it and tell your doctor immediately.

You should not take this medicine while you are pregnant.

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 taken this medicine exactly as prescribed.

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

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

Telmisartan may affect some medicines you receive during surgery.

Things you must not do

Do not:

- Stop taking your medicine, or change the dosage, without first discussing it with your doctor.
- 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 or pharmacist tells you to
- Let yourself run out of medicine over the weekend or on holidays

Things to be careful of

Be careful driving a car 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.

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 have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor or pharmacist 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 Accident and Emergency at

your nearest hospital if you notice any of the following:

- swelling of the face, lips, mouth 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.

These serious side effects are rare.

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

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

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.

After taking this medicine

Storage

Keep your medicine in its original packaging until it is time to take it

The medicine will not keep as well if taken out of the packaging.

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

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 or pharmacist 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 Telmisartan-DRLA looks like

Telmisartan-DRLA 40 mg tablets are white to off-white, uncoated, modified capsule shaped tablet with 'T' & 'L' debossed on either side of the breakline on one side and '40' debossed on other side

Telmisartan-DRLA 80 mg tablets are white to off-white, uncoated, modified capsule shaped tablet with 'T' & 'L' debossed on either side of the breakline on one side and '80' debossed on other side

Available in blister packs of 7, 10, 28, 56 and 96 tablets.

Not all strengths and pack sizes may be available.

Ingredients

Each Telmisartan-DRLA tablet contains 40 or 80 mg of telmisartan as the active ingredient.

It also contains the following inactive ingredients:

- meglumine
- povidone
- mannitol
- polysorbate 80
- magnesium stearate
- Sodium Hydroxide

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

Australian Registration Numbers

Telmisartan-DRLA 40 mg:
AUST R 197307

Telmisartan-DRLA 80 mg:
AUST R 197309

Sponsor

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