

Consumer Medicine Information (CMI) summary

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

1. Why am I taking MIZART?

MIZART contains the active ingredient telmisartan. MIZART is used to treat high blood pressure and prevent cardiovascular complications.

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

2. What should I know before I take MIZART?

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

Do not take MIZART if you have a rare hereditary condition of fructose intolerance. MIZART is not prescribed for children below 18 years of age.

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 take MIZART?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MIZART 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 take MIZART?

The usual dose of MIZART for adults to treat high blood pressure 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.

The usual dose of MIZART for the prevention of cardiovascular complications is one 80 mg tablet once a day. Depending on how you respond to the treatment, your doctor may suggest a higher or a lower dose.

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

5. What should I know while taking MIZART?

Things you should do	- Remind any doctor, dentist or pharmacist you visit that you are taking MIZART. - If you are going to have surgery, tell the surgeon or anaesthetist that you are taking MIZART. - Tell your doctor or pharmacist if you feel that MIZART is not helping your condition.
Things you should not do	- Do not stop taking MIZART or lower the dosage without checking with your doctor. - Do not take MIZART to treat any other complaints unless your doctor tells you to.
Driving or using machines	Be careful driving or operating machinery until you know how MIZART affects you.
Looking after your medicine	- Keep the tablets in the blister strip until it is time to take them. - Keep MIZART in a cool dry place where the temperature stays below 30°C; protect from heat, light and moisture.

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

6. Are there any side effects?

Potential side effects include headaches, upper respiratory tract infections, dizziness, 'flu-like' symptoms, fatigue and back pain.

Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if any of the following happen: swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing or severe and sudden onset of itchy or raised skin rash, hives or nettle rash.

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.

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking MIZART?

MIZART contains the active ingredient telmisartan.

Telmisartan 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.

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

MIZART 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

MIZART 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

MIZART 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 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 MIZART for another reason.

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

MIZART is not addictive.

2. What should I know before I take MIZART?

Warnings

Do not take MIZART if:

- you have an allergy to any medicine containing telmisartan (the active ingredient in MIZART) or any other ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine. Symptoms of an allergic reaction may include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin.
- you suffer from:
 - o severe liver disease
 - o biliary obstructive disorders (problem with the flow of bile from the gall bladder)
 - o diabetes or kidney problems and you are taking aliskiren (a medicine used to treat high blood pressure).

Do not take MIZART if you have a rare hereditary condition of fructose intolerance.

The maximum recommended daily dose of MIZART contains approximately 341 mg of mannitol.

Do not take MIZART 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.

Do not take MIZART if the tablets are discoloured.

If you are not sure whether you should start taking MIZART, talk to your doctor

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have or have had any other medical conditions:
 - o kidney problems
 - o liver problems
 - o heart problems
 - o diabetes
 - o a condition known as primary hyperaldosteronism (raised aldosterone levels, also known as Conn's syndrome)
 - o fructose intolerance
 - o recent severe diarrhoea or vomiting
 - o sodium and/or volume depletion
 - o imbalance of salts in the body
- take any medicines for any other condition
- are following a very low salt diet

If you have not told your doctor about any of the above, tell your doctor before you start taking MIZART.

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 MIZART if you are pregnant.

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

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

Do not breastfeed if you are taking MIZART.

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

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

Use in children

Do not give MIZART 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.

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 may interfere with MIZART and affect how it works. 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 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
- warfarin or 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)
- simvastatin, used to reduce blood cholesterol
- glibenclamide, a medicine used in diabetes.

These medicines may be affected by MIZART 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 MIZART 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 MIZART.

4. How do I take MIZART?

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 MIZART 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 MIZART 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 MIZART exactly as your doctor or pharmacist has told you.

How to take MIZART

- Swallow the tablet whole with a full glass of water.

When to take MIZART

- **Take MIZART 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 MIZART before or after food.

How long to take it

- **Continue taking MIZART for as long as your doctor tells you.**
Follow the instructions provided and take MIZART until your doctor tells you to stop.
MIZART 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 MIZART 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 MIZART

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 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 MIZART

If you think that you or anyone else has taken too much MIZART, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre **(by calling 13 11 26)** for advice, 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 MIZART you may feel dizzy, lightheaded 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.

5. What should I know while taking MIZART?

Things you should do

- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking MIZART.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking MIZART.
MIZART may affect other medicines used during surgery.
- Tell your doctor if you feel that MIZART is not helping your condition.
- Tell your doctor if, for any reason, you have not taken MIZART exactly as prescribed.
Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.
- If you are about to have any blood tests, tell your doctor that you are taking this medicine.
- Keep all of your doctor's appointments so that your progress can be checked.

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

Call your doctor straight away if you:

- become pregnant while taking MIZART.

Remind any doctor, dentist or pharmacist you visit that you are taking MIZART.

Things you should not do

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

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

- Do not take MIZART to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.

Things to be careful of

- You may feel dizzy or light-headed when you begin to take MIZART, especially if you are also taking a diuretic (or fluid tablet) or if you are dehydrated.
- If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

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. Talk to your doctor if this problem continues or gets worse.

- Drink plenty of water if you exercise, or if you sweat, or if the weather is hot.

Driving or using machines

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

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

Looking after your medicine

- **Keep the tablets in the blister strip until it is time to take them.**

The blister pack protects the tablets from light and moisture.

- Store below 30°C.

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.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking MIZART or the expiry date has passed, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MIZART.

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.

Do not be alarmed by the following lists of possible side effects.

You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
Side effects related to an allergic skin reaction: • skin rash (eczema) • itchiness (pruritus) • redness of the skin (erythema) Side effects related to the nervous system: • dizziness or light-headedness when you stand up especially when getting up from a sitting or lying position • dizziness or spinning sensation, fainting • feeling anxious • depression Gastrointestinal related side effects: • diarrhoea • indigestion • stomach pain or discomfort • wind or excessive gas in the stomach or bowel (flatulence) Blood related side effects: • 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 (such changes are usually detected by a blood test). Symptoms of urinary tract infections (including cystitis): • burning sensation when passing urine • pain in the pelvis or mid-back	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
- urine that appears cloudy - straining or pain when passing urine Symptoms that indicate low blood sugar levels in the blood: - sweating - weakness - hunger - dizziness - trembling - headache - numbness (especially in diabetic patients) Symptoms that may indicate worsening kidney function: - passing little or no urine - drowsiness - nausea - vomiting - breathlessness - loss of appetite - weakness Symptoms that may indicate low sodium levels in the blood: - headache - dizziness - confusion - forgetfulness - weakness - unsteadiness or difficulty concentrating Symptoms that may indicate high potassium levels in the blood: - nausea - diarrhoea - muscle weakness - changes in heart rhythm Other side effects - tiredness or weakness 'flu-like' symptoms - pain in the chest - 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 tendonitis-like symptoms	

Less serious side effects	What to do
- trouble sleeping (insomnia) - fast or slow heart beats - abnormal or blurred vision - increased sweating - dry mouth - abnormal liver functions	

Serious side effects

Serious side effects	What to do
- 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.	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

MIZART is the brand name of your medicine.

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

What MIZART contains

Active ingredient (main ingredient)	Telmisartan 40 mg or 80 mg
Other ingredients (inactive ingredients)	- Povidone - Mannitol - Meglumine - Magnesium stearate - Sodium hydroxide - Sodium stearyl fumarate
Potential allergens	Sulfites

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

What MIZART looks like

- **40 mg Tablet:** White to off-white color, oval-shaped, biconvex uncoated tablets debossed with 'L203' on one side and plain on the other side (AUST R 230974).
- **80 mg Tablet:** White to off-white color, oval-shaped, biconvex uncoated tablets debossed with 'L204' on one side and plain on the other side (AUST R 230975).

MIZART tablets are available in blister packs of 28.

Who distributes MIZART

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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