

MIZART Tablets

contains the active ingredient *Telmisartan*

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MIZART. 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, doctor, or from www.medicines.org.au and may contain important information about the medicine and its use of which you should be aware.

Keep this information with your MIZART tablets.

You may need to read it again later.

To find out more about MIZART

Ask your doctor or pharmacist if you have any questions about your medicine or if you have any trouble before, during or after using MIZART.

What MIZART is used for

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 (also called 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 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. You may feel fine and have no symptoms, but if high blood pressure is not treated, it can lead to serious health problems (such as stroke, heart disease and kidney failure).

How MIZART works

Mizart 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.

MIZART 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

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.

MIZART may have been prescribed for you for another reason.

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

MIZART is not addictive

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

Before you take MIZART

When you must not take it

Only take MIZART if it has been prescribed for you by a doctor.

Never give it to someone else even if their symptoms seem to be the same as yours.

Do not take MIZART if you are allergic to telmisartan or to any of the other ingredients in MIZART.

These ingredients are listed in full at the end of this leaflet.

Symptoms of an allergic reaction to MIZART may include: skin rash, itchiness, or hives on the skin, shortness of breath, wheezing or difficulty breathing, swelling of the face, lips or tongue or other parts of the body, muscle pain or tenderness or joint pain.

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

The maximum recommended daily dose of MIZART contains approximately 340 mg of mannitol.

If you are uncertain as to whether you have these allergies or conditions you should raise those concerns with your doctor.

Do not take MIZART if you suffer from:

- severe liver disease
- biliary obstructive disorders (problem with the flow of bile from the gall bladder)
- low potassium levels in the blood
- high calcium levels in the blood.
- diabetes or kidney problems and you are taking aliskiren (a medicine used to treat high blood pressure).

Do not take MIZART if you are pregnant.

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

Do not take MIZART if you are breastfeeding.

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.

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.

Do not take MIZART after the EXPIRY DATE on the carton or blister strips has passed.

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

Do not take MIZART if the tablets are discoloured.

If you are not sure whether you should start taking Mizart talk to your doctor.

Before you start to take it

It is essential that your doctor knows your medical history before prescribing MIZART.

Before taking MIZART, tell your doctor if you have, or have had, any of the following conditions:

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

Tell your doctor if you have or have had any medical conditions, especially the following:

- a kidney transplant
- heart, kidney or liver problems
- diabetes
- primary aldosteronism, also known as Conn's syndrome
- fructose intolerance
- recent severe diarrhoea or vomiting

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

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

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 Mizart.

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 Mizart may interfere with each other. These include:

- ramipril or any other medicines used to treat high blood pressure or heart problems
- potassium tablets (potassium supplements)
- 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 (medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis) such as aspirin or ibuprofen
- 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 MIZART, or may affect the way it works. Also, other medicines used to treat high blood pressure may have an additive effect with MIZART in lowering your blood pressure. Therefore, you may need different amounts of your medicines.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking MIZART

Pregnancy

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication.

MIZART should not be taken if you are pregnant.

Breastfeeding

Ask for your doctor's advice if you are breastfeeding or likely to breastfeed during the course of your medication.

MIZART should not be taken if you are breastfeeding.

Children

MIZART is not recommended for use in children and teenagers up to 18 years of age.

How to 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.

When to take it

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 to take it

Swallow the tablet whole with a full glass of water

You can take MIZART with or without food.

How long to take it

Take MIZART every day 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 a dose

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 of MIZART to make up for a dose that 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 have taken 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 MIZART.

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

You may need urgent medical attention.

If you take too much MIZART 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 taking MIZART

Things you must do

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

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

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

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

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

Tell your doctor immediately if you become pregnant while taking MIZART.

You should not take this medicine while you are pregnant.

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

MIZART may affect some medicines you receive during surgery.

Things you must not do

Do not use MIZART 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 MIZART 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 MIZART until you know how it affects you.

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

Lifestyle measures that help reduce heart disease risk

By following these simple measures, you can further reduce the risk from heart disease.

- Quit smoking and avoid second-hand smoke.
- Limit alcohol intake.
- Enjoy healthy eating by:
 - eating plenty of vegetables and fruit;
 - reducing your saturated fat intake (eat less fatty meats, full fat dairy products, butter, coconut and palm oils, most take-away foods, commercially-baked products).
- Be active. Progress, over time, to at least 30 minutes of moderate-intensity physical activity on 5 or more days each week. Can be accumulated in shorter bouts of 10 minutes duration. If you have been prescribed anti-angina medicine, carry it with you when being physically active.
- Maintain a healthy weight.
- Discuss your lifestyle and lifestyle plans with your doctor.
- For more information and tools to improve your heart health, call Heartline, the Heart Foundation's national telephone information service, on 1300 36 27 87 (local call cost).

Know warning signs of heart attack and what to do:

- Tightness, fullness, pressure, squeezing, heaviness or pain in your chest, neck, jaw, throat, shoulders, arms or back.
- You may also have difficulty breathing, or have a cold sweat or feel dizzy or light headed or feel like vomiting (or actually vomit).

- If you have heart attack warning signs that are severe, get worse or last for 10 minutes even if they are mild, call triple zero (000). Every minute counts.

Side effects

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

Storage

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

The blister pack protects the tablets from light and moisture.

MIZART should be kept in a cool, dry place where the temperature stays below 25°C.

Do not store MIZART 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 MIZART 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.

Disposal

If your doctor tells you to stop using MIZART 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

MIZART is the brand name of your medicine.

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

MIZART 40 mg tablets are white to off white, oblong, biconvex tablets debossed with 'TN40' on one side and 'M' on the other side

MIZART 80 mg tablets are white to off white, oblong, biconvex tablets debossed with 'TN80' on one side and 'M' on the other side

MIZART tablets are available in blister packs of 28 tablets.

Ingredients

Each MIZART 40 mg tablet contains 40 mg telmisartan.

Each MIZART 80 mg tablet contains 80 mg telmisartan.

The other ingredients found in the tablets are:

- magnesium stearate
- meglumine
- povidone
- sodium hydroxide
- mannitol

Sponsor

MIZART is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.mylan.com.au

Australian registration number:

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Aust R 180992

MIZART 80 mg (blister)-

Aust R 180995

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