1.3.2 Patient Information Leaflet

SCHEDULING STATUS

S3

MIZART 40 mg (tablets)

Telmisartan, 40 mg

Contains sugar: Mannitol 170,20 mg

MIZART 80 mg (tablets)

Telmisartan, 80 mg

Contains sugar: Mannitol 340,40 mg

Read all of this leaflet carefully before you start taking MIZART

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

MIZART has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MIZART is and what it is used for

What MIZART is:

MIZART belongs to a class of medicines known as angiotensin II receptor antagonists. Angiotensin II is a substance produced in your body which causes your blood vessels to narrow, thus increasing your blood pressure. MIZART blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

What it is used for:

MIZART is used to treat mild to moderate high blood pressure and can be used alone or in combination with hydrochlorothiazide (a diuretic – water tablets).

2. What you need to know before you take MIZART

Do not take MIZART:

- if you are allergic (hypersensitive) to telmisartan or any of the other ingredients of this medicine (*listed in section 6)*;
- if you are pregnant or breastfeeding. You must tell your healthcare professional if you think you are (or might become) pregnant. MIZART is not recommended in pregnancy and must not be taken if you are pregnant, as it may cause serious harm to your baby if used at that stage (*see 'Pregnancy and breastfeeding and fertility'*);
- if you have severe liver problems such as cholestasis or biliary obstruction (problems with the drainage of the bile from the liver and gall bladder) or any other severe liver disease;
- if you ever had a serious allergic reaction called "angioedema" when you have previously been treated with medicines called ACE inhibitors or angiotensin receptor blockers (ARBs). The signs include itching, hives (urticaria), red marks on the hands,

feet and throat, swelling of the throat and tongue, swelling around the eyes and lips, difficulty in breathing and swallowing. You must never again take these medicines;

- if you have been told you have *cardiomyopathy* (heart muscle disease), or *aortic stenosis* (narrowing of the main blood vessel from your heart), or any other heart problems;
- if you have various kidney diseases including disorders where the blood supply to your kidneys is reduced (renal artery stenosis) and kidney transplant;
- if you are receiving treatment with certain diuretics (water tablets) such as spironolactone, triamterene, amiloride (*see Taking MIZART with other medicines)*.
- if you have porphyria;
- if you receive treatment with lithium (for mental health problems). MIZART may increase the amount of lithium in your blood;
- if you have severe liver problems such as cholestasis or biliary obstruction (problems with drainage of the bile from the liver and gall bladder) or any other severe liver disease;
- if you have impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren;
- Concomitant use of fluoroquinolones with ACE inhibitors/Renin-Angiotensin blockers is contraindicated in patients with moderate to severe renal impairment.

Warnings and precautions

WARNING: If you become pregnant while taking MIZART, the treatment should be stopped, and an alternate medicine used. If you plan to become pregnant, your doctor should consider giving you alternative medicine.

Take special care with MIZART if you are suffering or have ever suffered from:

- Kidney disease or a kidney transplant.

- Low blood pressure (hypotension), as it may occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy (water tablets), low-salt diet, diarrhoea or vomiting.
- Raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals).
- Heart failure.
- Liver disorders.
- Stomach ulcers.
- If your blood pressure decreases too much and you have certain heart conditions, this could result in a heart attack or stroke.
- MIZART may be less effective in lowering the blood pressure in black patients.
- Concomitant use of fluoroquinolones and ACE inhibitors/renin-angiotensin receptor blockers may precipitate acute kidney injury in patients, especially those with moderate to severe renal impairment and elderly patients *(see Do not take MIZART*). Renal function should be assessed before initiating treatment, and monitor during treatment, with fluoroquinolones of ACE inhibitors/renin-angiotensin receptor blockers.
- *If you are taking any of the following medicines used to treat high blood pressure:*
  - an ACE (angiotensin-converting-enzyme) inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems;
  - aliskiren (medicine used to treat high blood pressure (hypertension);
- Diabetes;
- Renal artery stenosis (narrowing of the blood vessels to one or both kidneys).
- Elevated potassium levels in your blood.

Children/ and adolescents:

There is no information available on the safety and efficacy of MIZART in children and adolescents up to 18 years old.

Other medicines and MIZART

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- MIZART may increase the blood pressure lowering effect of other medicines used to treat high blood pressure. Furthermore, low blood pressure may be aggravated by alcohol, barbiturates (medicines that have calming effects on the body), narcotics (medicines used for pain relief or narcosis (state of stupor or sleep) or antidepressants.
- Digoxin - used to treat certain heart problems, such as: heart failure and certain types of irregular heartbeats.
- Lithium-containing medicines to treat some types of depression (*see "Do not take MIZART"*).
- Certain painkillers called non-steroidal anti-inflammatory medicines (NSAIDs), including aspirin.
- *Medicines that may increase blood potassium levels such as:*
  - salt substitutes containing potassium,
  - potassium-sparing diuretics (certain 'water tablets'),
  - ACE (angiotensin-converting-enzyme) inhibitors, angiotensin II receptor antagonists (medicines used to treat high blood pressure and heart failure);
  - heparin (medicine used to treat and prevent the symptoms of blood clots);
  - immunosuppressives (medicines used to prevent organ rejection after transplantation e.g. cyclosporin or tacrolimus);

- trimethoprim (an antibiotic).
- If you are taking an ACE (angiotensin-converting-enzyme) inhibitor or aliskiren (*see 'Do not take MIZART' and 'Warnings and precautions'*).
- Concomitant use of fluoroquinolones and ACE inhibitors/renin-angiotensin receptor blockers may precipitate acute kidney injury (*see 'Do not take MIZART)*.

Pregnancy and breastfeeding and fertility

- Safety in pregnancy and breastfeeding has not been established.
- Do not take MIZART when you are planning to become pregnant or breastfeeding your infant.
- MIZART can cause embryonal toxicity, foetal and neonatal morbidity and mortality when administered to pregnant women.
- Women of childbearing age should ensure effective contraception.
- MIZART is excreted in breast milk and you should not breastfeed your baby while receiving treatment.
- If you become pregnant while you are taking MIZART, tell your doctor immediately so that he/she can give you a different medicine.
- If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking MIZART.

Driving and using machinery

It is not always possible to predict to what extent MIZART may interfere with the daily activities of a patient. MIZART may cause dizziness or drowsiness and patients should ensure that they do not engage in the above activities until they are aware of the measure to which MIZART affects them.

MIZART contains mannitol

MIZART contains mannitol which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told that you have an intolerance to some sugars, you should not take MIZART.

3. How to take MIZART

Do not share medicines prescribed for you with any other person.

Always take MIZART exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

- The tablets must be swallowed whole with some liquid.
- The usual starting dose is 40 mg once a day. If the full benefit has not been achieved your doctor could increase the dose to 80 mg a day.
- The maximum antihypertensive effect (benefit) will be reached within 4-8 weeks of starting your treatment.
- If you have kidney or liver problems, make sure you inform your doctor so that he can adjust your dosage, if necessary.
- If you are elderly with normal kidney and liver function, no dosage change is necessary.
- There is no information available on the safety and efficacy of MIZART in children and adolescents up to 18 years old.
- If you want to stop taking MIZART, talk to your doctor first so that he can advise you on how to stop.
- If you have the impression that the effect of MIZART is too strong or too weak, tell your doctor or pharmacist.

If you take more MIZART than you should

In the event of over dosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

If you forget to take MIZART

- If you missed a dose, take it as soon as possible.
- However, if you do not remember the missed dose until the next day, skip the missed dose and go back to your regular dosing schedule.
- Do not take a double dose to make up for forgotten individual doses.

If you stop taking [MIZART

Do not stop treatment early. Your doctor will tell you how long your treatment with MIZARTwill last.

4. Possible side effects

MIZART can have side effects.

Not all side effects reported for MIZART are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MIZART, please consult your healthcare professional for advice.

If any of the following happens, stop taking MIZART and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting;

- sepsis (often called “blood poisoning”, is a severe infection with whole-body inflammatory response), rapid swelling of the skin and mucosa (angioedema); these side-effects are extremely serious, and you should stop taking MIZART and contact your doctor immediately. If these side effects are not treated they could be fatal;
- rapid swelling of the skin and mucosa which can also lead to death (angioedema also with fatal outcome).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MIZART. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Blood disorders (e.g. weakness, tiredness, drowsiness; you may also experience fainting, seeing spots or have bruising/bleeding into the skin and bleeding of your nose);
- pain in the chest, feeling of weakness, flu-like-illness.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported less frequently:

- Urinary tract infections, upper respiratory tract infections (e.g. sore throat, inflamed sinuses, common cold);
- low blood sugar levels (in diabetic patients);
- difficulty falling asleep, feeling sad (depression), anxiety;
- fainting, sleepiness;
- impaired vision;
- feeling of spinning (dizziness);
- slow heart rate;

- fast heartbeat;
- low blood pressure;
- dizziness on standing up;
- shortness of breath, cough;
- lung disorders;
- abdominal (stomach) pain, diarrhoea, heartburn, bloating, vomiting, dry mouth, stomach discomfort;
- abnormal liver function/liver disorder;
- itching, increased sweating, severe rash, eczema (a skin disorder), hives, redness of the skin;
- back pain, muscle spasms, muscle pain, joint pain, pain in extremity, tendon pain;
- kidney impairment including acute kidney failure;
- blood tests will determine: increased level of creatinine in the blood, decreased haemoglobin (a blood protein), increased levels of uric acid, increased liver enzymes or creatine phosphokinase in the blood.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

You can also report side effects to to SAHPRA on the SAHPRA website at: https://medsafety.sahpra.org.za/#download, via email at: adr@sahpra.org.za or via telephone at: 0125010311

By reporting side effects, you can help provide more information on the safety of MIZART.

5. How to store MIZART

- Store all medicines out of reach of children.
- Store at or below 25 °C.

- MIZART Tablets should not be removed from their foil pack until required for use.
- Keep the container well closed.
- Keep in the original container until required for use.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MIZART contains:

- The active substance is telmisartan.
- The other ingredients are magnesium stearate, mannitol, meglumine and povidone (K-30), sodium hydroxide.

What MIZART looks like and contents of the pack:

What MIZART looks like:

MIZART 40 mg Tablets: White to off white, oblong, biconvex tablets debossed with “TN 40” on one side and “M” on the other side.

MIZART 80 mg Tablets: White to off white, oblong, biconvex tablets debossed with “TN 80” on one side and “M” on the other side.

Contents of the pack:

Cold form blister pack comprising of cold form laminate (aluminium foil laminated to oriented polyamide on one side and laminated to PVC on the other side i.e. OPA/Al/PVC) on one side and hard tempered aluminium foil coated with heat seal lacquer on the other side in a carton. Each carton consists of 3 blister strips (10 tablets/blister).

or

High density polyethylene (HDPE) bottle pack comprising of round wide mouth white HDPE bottle with white opaque polypropylene (PP) screw closure with aluminium induction sealing wad. A desiccant (silica gel) and absorbent cotton is placed in the bottle. Bottle pack is packaged in a carton.

Pack sizes of 30's.

Not all pack sizes may be marketed.

Holder of Certificate of Registration and Manufacturer

Mylan (Pty) Ltd

4 Brewery Street

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1600

Republic of South Africa

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MIZART 40 mg: 45/7.1.3/0606

MIZART 80 mg: 45/7.1.3/0607

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website