PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

MIZART PLUS 40/5 (film-coated tablets)

MIZART PLUS 80/5 (film-coated tablets)

MIZART PLUS 40/10 (film-coated tablets)

MIZART PLUS 80/10 (film-coated tablets)

Telmisartan / Amlodipine

MIZART PLUS 40/5: Each tablet contains 40 mg telmisartan and 5 mg amlodipine (as amlodipine besylate).

Contains sugar: mannitol 176 mg per tablet.

MIZART PLUS 80/5: Each tablet contains 80 mg telmisartan and 5 mg amlodipine (as amlodipine besylate).

Contains sugar: mannitol 352 mg per tablet.

MIZART PLUS 40/10: Each tablet contains 40 mg telmisartan and 10 mg amlodipine (as amlodipine besylate).

Contains sugar: mannitol 176 mg per tablet.

MIZART PLUS 80/10: Each tablet contains 80 mg telmisartan and 10 mg amlodipine (as amlodipine besylate).

Contains sugar: mannitol 352 mg per tablet.

Read all of this leaflet carefully before you start taking MIZART PLUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.
- MIZART PLUS has been prescribed to 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

What MIZART PLUS is and what it is used for

MIZART PLUS tablets contain two active substances called telmisartan and amlodipine.

Both medicines help to control your high blood pressure:

- Telmisartan belongs to a group of substances called “angiotensin-II receptor antagonists”. Angiotensin II is a substance produced in the body which causes blood vessels to narrow, thus increasing blood pressure. Telmisartan works by blocking the effect of angiotensin II.
- Amlodipine belongs to a group of substances called “calcium channel blockers”. Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening.

This means that both active substances work together to help stop your blood vessels tightening. As a result, the blood vessels relax, and blood pressure is lowered.

MIZART PLUS is used to treat high blood pressure (also known as essential hypertension) in patients using the same components as individual components, or when treatment with amlodipine alone did not lower your blood pressure enough.

What you need to know before you take MIZART PLUS

Do not take MIZART PLUS:

- If you are allergic (hypersensitive) to telmisartan, amlodipine or any of the other ingredients of MIZART PLUS (listed in section 6);
- if you are allergic to other medicines of the dihydropyridine type (one type of calcium channel blocker);
- if you have developed swelling and giant wheals on your skin when having previously taken medicines called angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs);
- if you have a narrowing of the aortic blood vessel;
- if both blood vessels to the kidneys are narrowed or if you have a single kidney and the blood vessel to the kidney is narrowed;
- if you suffer from severe liver problems;
- if you suffer from biliary obstruction (a problem with the drainage of the bile from the liver and gall bladder);
- if you suffer from porphyria;
- if you are currently taking potassium sparing water tablets containing spironolactone, triamterene or amiloride;
- if you are currently taking lithium;
- if you suffer from low heart output because of a serious heart problem;
- if you suffer from severe renal impairment;
- if you are currently taking aliskiren-containing medicines;

- If you are currently taking fluoroquinolone antibiotics and you are elderly or have kidney problems;
- if you are pregnant or breastfeeding.

Warnings and precautions

Tell your doctor or healthcare professional before taking MIZART PLUS:

Take special care with MIZART PLUS:

- if you suffer from kidney disease or have ever had a kidney transplant.
- if you suffer from liver problems;
- if you have heart problems;
- if you are taking any of the following medicines used to treat high blood pressure:
  - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
  - aliskiren;
- if you have been told that you have raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals);
- if you have low blood pressure (hypotension), which is likely to 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;
- if you have high potassium levels in your blood or use salt substitutes that contain potassium;
- if you have diabetes;
- In case of surgery or anaesthesia, you should tell your healthcare provider that you are taking MIZART PLUS;
- if you are treated with Angiotensin-converting enzyme (ACE) inhibitors/Angiotensin receptor blockers (ARBs) together with a fluoroquinolone antibiotic.

Children and adolescents

The use of MIZART PLUS in children and adolescents up to the age of 18 years is not recommended.

Other medicines and MIZART PLUS

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

Please consult your healthcare provider for advice. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below when taken together with MIZART PLUS:

- Digoxin which is a heart medicine.
- Lithium-containing medicines used to treat some types of depression.
- Anticonvulsant medicines (e.g. carbamazepine, phenobarbitone, phenytoin, fosphenytoin, primidone).
- Rifampicin used for treatment of tuberculosis.
- St. John’s wort used for treatment of depression.
- Medicines used for HIV/AIDS (e.g. ritonavir) or for treatment of fungal infections (e.g. ketoconazole, itraconazole).
- Simvasatin used to lower your cholesterol levels.
- Ciclosporin or tacrolimus used to suppress your immune system.

The effect of MIZART PLUS may be reduced when you take NSAIDs (non-steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen) or corticosteroids.

MIZART PLUS may increase the blood pressure lowering effect of other medicines used to treat high blood pressure or of medicines with blood pressure lowering potential (e.g. antidepressants, barbiturates, narcotics) or alcohol.

MIZART PLUS can interfere with ACE-inhibitors.

MIZART PLUS with food and drink

You can take MIZART PLUS tablets with water or other non-alcoholic drink and with or without food.

Grapefruit and grapefruit juice:

You should not eat grapefruit or drink grapefruit juice when you take MIZART PLUS because this can increase the blood pressure lowering effect in some people.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking MIZART PLUS.

Do not take MIZART PLUS if you are pregnant, are considering becoming pregnant or are breastfeeding.

If you are a woman of childbearing age, you must use effective contraception.

Driving and using machines

No information is available on the effect of MIZART PLUS on the ability to drive or operate machinery. Some people may experience side effects such as fainting, sleepiness, dizziness, or a feeling of spinning (vertigo) when they are treated for high blood pressure. If you experience these side effects, do not drive, or operate machinery.

Mannitol

MIZART PLUS contains mannitol and may have a laxative effect.

How to take MIZART PLUS

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

Always take MIZART PLUS exactly as your doctor has told you. Check with your doctor if you are not sure.
The usual dose of MIZART PLUS is one tablet per day. Try to take the tablet at the same time each day.
Remove your MIZART PLUS tablet from the blister only immediately prior to intake.
You can take MIZART PLUS with or without food. The tablets should be swallowed with some water or other non-alcoholic drink. It is important that you take MIZART PLUS every day until your healthcare provider tells you otherwise. If you have the impression that the effect of MIZART PLUS is too strong or too weak, talk to your healthcare provider.

If your liver is not working properly, the usual dose should not exceed MIZART PLUS 40/5 mg or MIZART PLUS 40/10 mg once daily.

MIZART PLUS tablets are only for adults and should not be taken by children and adolescents up to 18 years.

If you take more MIZART PLUS than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. You might experience low blood pressure and a rapid heartbeat. Slow heartbeat, dizziness, reduced kidney function including kidney failure, marked and prolonged low blood pressure including shock and death have also been reported.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

If you forget to take MIZART PLUS

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten dose.

Effects when treatment with MIZART PLUS is stopped:

It is important that you take MIZART PLUS every day until your doctor tells you otherwise.

Possible side effects

MIZART PLUS can have side effects.

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

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

Frequency unknown:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to MIZART PLUS. 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:

Less frequent:

- Sepsis (often called "blood poisoning", is a severe infection of the whole-body with high

fever and the feeling of being severely ill), rapid swelling of the skin and mucosa (angioedema). These side effects are extremely serious and you should stop taking MIZART PLUS and see your doctor immediately. If these effects are not treated, they could be fatal. Increased incidence of sepsis has been observed with telmisartan only, however cannot be ruled out for MIZART PLUS.

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

Tell your doctor if you notice any of the following:

Frequent:

- dizziness,
- ankle swelling (oedema).

Less frequent:

- sleepiness, migraines, headaches, tingling or numbness of the hands or feet, feeling of spinning (vertigo), slow heart rate, palpitations (awareness of your heart beat), low blood pressure (hypotension), dizziness on standing up (orthostatic hypotension), flushing, coughing, stomach ache (abdominal pain), diarrhoea, feeling sick (nausea), itching, joint pain, muscle cramps, muscle pain, inability to obtain an erection, weakness, chest pain, tiredness, swelling (oedema), increased levels of hepatic enzymes;
- urinary bladder infection, feeling sad (depression), feeling anxious, sleeplessness, fainting, nerve damage in the hands or feet, reduced sense of touch, taste abnormalities, trembling, vomiting, enlarged gums, discomfort in the abdomen, dry mouth, eczema (a skin disorder), redness of skin, rash, back pain, leg pain, urge to urinate during the night, feeling unwell (malaise), increased levels of uric acid in the blood;
- progressive scarring of lung tissue (interstitial lung disease [mainly pneumonia of the interstitium and pneumonia with excess eosinophils]).

The following side effects have been observed with the components telmisartan or amlodipine and may occur also with MIZART PLUS:

Telmisartan

In patients taking telmisartan alone the following additional side effects have been reported:

Less frequent:

- urinary tract infections, upper respiratory tract infections (e.g. sore throat, inflamed sinuses, common cold), deficiency in red blood cells (anaemia), high potassium levels in the blood, shortness of breath, bloating, increased sweating, kidney damage including sudden inability of the kidneys to work, increased levels of creatinine;
- increase in certain white blood cells (eosinophilia), low platelet count (thrombocytopenia), allergic reaction (e.g. rash, itching, difficulty in breathing, wheezing, swelling of the face or low blood pressure), low blood sugar levels (in diabetic patients), impaired vision, fast heartbeat, upset stomach, abnormal liver function, hives (urticaria), medicine rash, inflammation of the tendons, flu-like illness (for example muscle pain, feeling generally unwell), decreased haemoglobin (a blood protein), increased levels of creatinine phosphokinase in the blood.

Most cases of abnormal liver function and liver disorder from post-marketing experience with telmisartan occurred in Japanese patients. Japanese patients are more likely to experience this side effect.

Amlodipine

In patients taking amlodipine alone the following additional side effects have been reported:

Frequent:

- altered bowel habits, diarrhoea, constipation, visual disturbances, double vision, ankle swelling.

Less frequent:

- mood changes, confusion, impaired vision, ringing in the ears, shortness of breath, sneezing/runny nose, hair loss, unusual bruising and bleeding (red blood cell damage),

skin discolouration, increased sweating, difficulty passing urine, increased need to pass urine especially at night, enlarging of male breasts, pain, weight increased, weight decreased;

- reduced number of white blood cells (leucopenia), low platelet count (thrombocytopenia), allergic reaction (e.g. rash, itching, difficulty breathing, wheezing, swelling of the face or low blood pressure), excess sugar in blood, uncontrollable twitching or jerking movements, heart attack, irregular heartbeat, inflammation of the blood vessels, inflamed pancreas, inflammation of the stomach lining (gastritis), inflammation of the liver, yellowing of the skin (jaundice), increased levels of hepatic enzymes with jaundice, rapid swelling of skin and mucosa (angioedema), severe skin reactions, hives (urticaria), severe allergic reactions with blistering eruptions of the skin and mucous membranes (exfoliative dermatitis, Stevens-Johnson-Syndrome), increased sensitivity of the skin to sun, increased muscle tension.

Frequency unknown:

- severe allergic reactions with blistering eruptions of the skin and mucous membranes (toxic epidermal necrolysis).

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse.

You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/

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

How to store MIZART PLUS

Store all medicines out of reach of children.

- Store at or below 25 ˚C.
- Store in the original package to protect from light and moisture.
- Remove the tablets from the blister only when required for administration.
- Do not use after the expiry date stated on the carton / label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Contents of the pack and other information

What MIZART PLUS contains

The active substances are telmisartan and amlodipine.

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Contains sugar: mannitol 176 mg per tablet.

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The other ingredients are**:**

Tablet core: Hypromellose, magnesium stearate, mannitol, meglumine, povidone (K-30), sodium hydroxide.

Film coating: Hypromellose, titanium dioxide.

Imprinting: Opacode WB Black.

What MIZART PLUS looks like and contents of the pack

MIZART PLUS 40/5: White to off-white, film-coated, round shaped, biconvex, bevelled edge tablet imprinted with TM6 using black ink on one side of the tablet and blank on the other side.

MIZART PLUS 40/10: White to off-white, film-coated, oval shaped, biconvex, bevelled edge tablet imprinted with TM7 using black ink on one side of the tablet and blank on the other side.

MIZART PLUS 80/5: White to off-white, film-coated, round shaped, biconvex, bevelled edge tablet imprinted with TM8 using black ink on one side of the tablet and blank on the other side.

MIZART PLUS 80/10: White to off-white, film-coated, oval shaped, biconvex, bevelled edge tablet imprinted with TM9 using black ink on one side of the tablet and blank on the other side.

Contents of the pack:

Cold Form Blister Pack: comprises of cold form laminate (aluminium foil laminated to oriented polyamide on one side and laminated to PVC on the other side – OPA/Aluminium/PVC) on one side and hard tempered aluminium foil coated with VMCH heat seal lacquer on the other side. A suitable number of blister strips will be placed in an outer cardboard carton. Pack size: 30’s (blister strips of 10’s).

Holder of Certificate of Registration

MYLAN (PTY) LTD

4 Brewery Street

Isando

1600

Republic of South Africa

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MIZART PLUS 80/10: 51/7.1.3/0742

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website.