Approved Patient Information Leaflet for Medicines for Human Use:

MIBEZIT

SCHEDULING STATUS: S4

MIBEZIT 10 mg tablet

Ezetimibe

Contains Sugar

Read all of this leaflet carefully before you start taking MIBEZIT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- MIBEZIT 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 MIBEZIT is and what it is used for

MIBEZIT is a tablet that contains 10 mg of ezetimibe as the active ingredient.

- MIBEZIT is a cholesterol-lowering medicine.
- MIBEZIT is for patients whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.
- MIBEZIT reduces elevated total-cholesterol and low-density lipoproteins (LDL) (bad) cholesterol.
- MIBEZIT may be taken with other cholesterol-lowering medicines known as statins or alone, in addition to diet.

2. What you need to know before you take MIBEZIT

Do not take MIBEZIT:

- if you are hypersensitive (allergic) to Ezetimibe or any of the other ingredients of MIBEZIT (listed in section 6)
- if you are pregnant or plan to become pregnant, you should not use MIBEZIT
- if you are breastfeeding, MIBEZIT may be passed in your milk to your baby. You should not breastfeed while using MIBEZIT
- if you have moderate to severe problems with your liver
- MIBEZIT is not for use in children below the age of 10 years.

Warnings and precautions

Take special care with MIBEZIT**:**

- if myopathy is suspected based on muscle symptoms or is confirmed by a creatine phosphokinase
- if you are taking fibrates such as fenofibrate or gemfibrozil
- if you are taking warfarin or any other anticoagulant

Children and adolescents

MIBEZIT has not been studied in patients younger than 10 years of age.

Other medicines and MIBEZIT

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

MIBEZIT can be affected by other medicines you are using, tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This is particularly important if you are taking:

- antacids (medicine for heartburn and indigestion) or cholestyramine (medicine for lowering cholesterol), as these may decrease the action of MIBEZIT
- fibrates such as fenofibrate or gemfibrozil (medicines for lowering cholesterol)
- ciclosporin (a medicine used for transplants)
- anticoagulants such as warfarin (medicine used for treating or preventing blot clots).

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking MIBEZIT.
Do not take MIBEZIT if you are pregnant or you are breastfeeding your baby.

Driving and using machines

It is not always possible to predict to what extent MIBEZIT may interfere with your daily activities. There have been side effects such as dizziness reported that may affect your ability to drive or operate machinery. Ensure that you do not engage in the above activities until you are aware of the measure to which MIBEZIT affects you.

MIBEZIT contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking MIBEZIT.

3. How to take MIBEZIT

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

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

The usual dose unless otherwise recommended by your doctor is one 10 mg tablet taken by mouth each day, at any time of day.

Take MIBEZIT with or without food.

Your may have to take MIBEZIT along with other medicines, known as statins, to help you better control your cholesterol.

- If you are taking a statin, MIBEZIT can be taken at the same time as the statin.
- If your doctor has prescribed MIBEZIT along with cholestyramine (a bile acid sequestrant) or any other bile acid sequestrant, MIBEZIT should be taken at least 2 hours before or 4 hours after taking the bile acid sequestrant.
- MIBEZIT should be taken as directed by your health care provider. Continue taking your other cholesterol-lowering medicines unless your doctor tells you to stop.

Duration of administration

Your doctor will tell you how long your treatment with MIBEZIT will last. Do not stop treatment early because your cholesterol levels may increase again. If you have the impression that the effect of MIBEZIT is too strong or too weak, tell your doctor or pharmacist.

If you take more MIBEZIT than you should

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

If you forget to takeMIBEZIT

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

MIBEZIT can have side effects.

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

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

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

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

- dark reddish urine, a decreased amount of urine, unexplained muscle pain, tenderness, or weakness
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems
- severe pain in the upper-right belly and bloating which may be signs of inflammation of the gallbladder or stones in the tube leading from the gallbladder to the small intestine.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- myalgia (pain in the muscles)
- abdominal (stomach) pain; diarrhoea; flatulence
- headache
- fatigue
- ALT and/or AST increased (these are liver enzymes; increases will be noticed on a blood test).

Less frequent side effects:

- decreased appetite
- paraesthesia (tingling feeling in the hands and feet “pins and needles”)
- hot flush; hypertension
- cough
- dyspepsia (indigestion); gastro oesophageal reflux disease; nausea; dry mouth; gastritis (inflammation of the stomach lining)
- pruritus (itchy rash); rash; urticaria (hives)
- arthralgia (pain in the joints); muscle spasms; neck pain; back pain

- muscular weakness; pain in extremity
- chest pain; pain; asthenia (extreme tiredness or weakness)
- noticed on a blood test: increased peripheral oedema blood CPK; increased gamma-glutamyl transferase; abnormal liver function test.

Side effects with frequency unknown:

- thrombocytopaenia (low number of platelets which are cells important for clotting, you may notice that it takes longer for your blood to clot)
- depression
- dizziness
- dyspnoea (difficulty breathing)
- pancreatitis (inflammation of the pancreas); constipation
- erythema multiforme (skin rash).

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 or 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/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of MIBEZIT

5. How to store MIBEZIT

- Store all medicines out of reach of children
- this medicine does not require any special temperature storage conditions".
- Do not refrigerate
- Store in the original package / container
- Protect from light / moisture

- Do not store in a bathroom
- Do not use after the expiry date stated on the label

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 MIBEZIT contains

- The active substance is ezetimibe
- The other ingredients are

  Croscarmellose sodium

  Lactose monohydrate

  Povidone k-30

  Polysorbate 80

  Sodium lauryl sulfate

What MIBEZIT looks like and contents of the pack

MIBEZIT is supplied in Alu-Alu blister/Alu-PVC/HDPE bottle pack.

The blisters and HDPE bottle are further packed in approved pack size of carton along with package leaflet.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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