Patient Information Leaflet

SCHEDULING STATUS

S4

MEZIBE 10 Tablets

Ezetimibe

Contains Sugar: Lactose monohydrate 63 mg/ tablet

Read all of this leaflet carefully before you start taking MEZIBE 10

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- **MEZIBE 10** 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 **MEZIBE 10** is and what it is used for
2. What you need to know before you take **MEZIBE 10**
3. How to take **MEZIBE 10**
4. Possible side effects
5. How to store **MEZIBE 10**
6. Contents of the pack and other information

1. What MEZIBE 10 is and what it is used for

MEZIBE 10 is a medicine used to lower levels of total cholesterol, "bad" cholesterol (LDL cholesterol) and fatty substances called triglycerides in the blood. Additionally, **MEZIBE 10** raises levels of "good" cholesterol (HDL cholesterol). **MEZIBE 10** works by reducing the cholesterol absorbed in your digestive tract.

MEZIBE 10 is used for patients who cannot control their cholesterol levels by diet alone. You should however stay on a cholesterol-lowering diet while taking **MEZIBE 10.**

MEZIBE 10 adds to the cholesterol-lowering effect of statins, a group of medicines that reduce the cholesterol your body makes by itself.

2. What you need to know before you take MEZIBE 10

Do not take **MEZIBE 10**

- If you are hypersensitive (allergic) to ezetimibe or any of the other ingredients of **MEZIBE 10** (see What **MEZIBE 10** contains).
- If you are pregnant or breastfeeding (see Pregnancy, breastfeeding and fertility).
- If you have moderate or severe liver problems.
- **MEZIBE 10** co-administered with a statin is contraindicated in patients with active liver disease or unexplained persistent elevations in serum transaminases.
- **MEZIBE 10** is not recommended in children under the age of 10 years.

Warnings and precautions

Tell your doctor before taking **MEZIBE 10**:

Take special care with **MEZIBE 10**:

- If you experience any unexplained muscle pain, tenderness or muscle weakness. Contact your doctor immediately.
- If you are already taking other medicines to lower your cholesterol levels in the blood.
- If you are taking warfarin tablets used to prevent blood clots or any other anti-clotting medicine.

Your doctor should do a blood test before you start taking **MEZIBE 10** with a statin. This is to check how well your liver is working.

Your doctor may also want you to do blood tests to check how well your liver is working after you start taking **MEZIBE 10** with a statin.

Do not give **MEZIBE 10** to children below 10 years, as safety and efficacy have not been established.

Other medicines and MEZIBE 10

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

Tell your doctor or pharmacist if you are currently using:

- cholestyramine (used to lower cholesterol), because it affects the way **MEZIBE 10** works;
- fibrates (medicines used to lower cholesterol);
- ciclosporin (used to prevent organ rejection after a transplant);
- medicines to prevent blood clots, such as warfarin (anticoagulants).

MEZIBE 10 with food, drink and alcohol

See section 3.

Pregnancy, breast-feeding 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 **MEZIBE 10**.

Do not take **MEZIBE 10** if you are pregnant or breastfeeding.

Driving and using machines

MEZIBE 10 can cause side effects, such as dizziness. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how **MEZIBE 10** affects you.

MEZIBE 10 contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking **MEZIBE 10.**

3. How to take MEZIBE 10

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

Always take **MEZIBE 10** exactly as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Before starting **MEZIBE 10,** you should be on a diet to lower your cholesterol. You should stay on this diet whilst taking **MEZIBE 10**.

Adults and children (10 years of age and older):
The usual dose is one **MEZIBE 10** tablet once a day.

Take **MEZIBE 10** at any time of the day. You can take **MEZIBE 10** with or without food.
If your doctor has prescribed **MEZIBE 10** along with any other medicine containing bile acid sequestrant, you should take **MEZIBE 10** at least 2 hours before or 4 hours after taking the bile acid sequestrant.

Your doctor will tell you how long your treatment with **MEZIBE 10** will last. Do not stop treatment early.
If you have the impression that the effect of **MEZIBE 10** is too strong or too weak, tell your doctor or pharmacist.

If you take more MEZIBE 10 than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.
Take this leaflet and the rest of the remaining **MEZIBE 10** with you so the doctor will know what you have taken.

If you forget to take MEZIBE 10

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

4. Possible side effects

MEZIBE 10 can have side effects.
Not all side effects reported for **MEZIBE 10** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **MEZIBE 10**, please consult your health care provider for advice.

If any of the following happens, stop taking **MEZIBE 10** and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **MEZIBE 10**. 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:

- chest pain;
- bleeding or bruising more easily than normal;
- myopathy (unexplained muscle pain, tenderness or weakness, stiffness or cramping);
- inflammation of pancreas (nausea, vomiting, fever, pain of your stomach area that radiates to your back, increased heart rate);
- rhabdomyolysis (temporary paralysis or weakness of muscles);
- yellowing of your skin and eyes, dark urine, and tiredness which may be symptoms of liver problems;
- inflammation of your gallbladder or gallstones (persistent pain in the abdominal area, fever, nausea and vomiting, sweating, loss of appetite).

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

- viral infections, infections of the sinuses (runny nose, nasal congestion);
- upper respiratory tract infection (sneezing, runny nose, scratchy or sore throat, fever);
- cough;
- abdominal pain, diarrhoea, flatulence (wind), constipation, nausea (feeling sick);
- joint pain, back pain, muscle pain;

- headache, dizziness;
- feeling tired;
- elevations in liver function when blood tests are done (increased alanine transaminases (ALT) and/or aspartate transaminase (AST)).

Less frequent side effects

- decreased appetite;
- hot flush;
- high blood pressure;
- indigestion, dry mouth, heartburn;
- muscle spasms, neck pain, hand or foot pain;
- increased blood creatinine phosphokinase or gamma-glutamyl transferase levels when blood tests are done;
- tingling or numbness of your hands and feet (pins and needles)
- weakness or lack of energy.

Frequency unknown side effects

- feeling depressed;
- shortness of breath (dyspnoea);
- raised red rash, sometimes with target-shaped lesions (erythema multiforme).

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. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of **MEZIBE 10**.

5. How to store MEZIBE 10

Store all medicines out of reach of children.

Store at or below 25 °C in the original pack.

Do not remove the blisters from the carton until required for use.

Do not take **MEZIBE 10** after the expiry date stated on the strip pack and carton.

Return all unused or expired medicines to your pharmacist for safe disposal.

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

6. Contents of the pack and other information

What MEZIBE 10 contains

Each tablet contains 10 mg ezetimibe

The other ingredients are: Croscarmellose sodium, lactose monohydrate, magnesium stearate, povidone, pregelatinised starch, sodium lauryl sulphate.

What MEZIBE 10 looks like and contents of the pack

White to off white capsule shaped uncoated tablets with ‘E 10’ debossed on one side and plain on other side.

Each carton contains 28 or 30 tablets packed in cold form blister or aclar blister packs. Each blister strip contains 10 or 14 tablets.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road,

Stormill, Ext.1, Roodepoort, 1724

South Africa

This leaflet was last revised in

February 2021

Registration number

48/7.5/0637