ZYTEZO

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ZYTEZO 10 mg tablets

Ezetimibe

Contains sugar (76,75 mg lactose monohydrate per tablet).

Read all of this leaflet carefully before you start taking ZYTEZO.

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

1. What ZYTEZO is and what it is used for

ZYTEZO is a medicine used to lower levels of total cholesterol, "bad" cholesterol (LDL cholesterol) and fatty substances called triglycerides in the blood. Additionally, ZYTEZO raises

levels of "good" cholesterol (HDL cholesterol). ZYTEZO works by reducing the cholesterol absorbed in your digestive tract.

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

ZYTEZO 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 ZYTEZO

Do not take ZYTEZO

- If you are hypersensitive (allergic) to ezetimibe or any of the other ingredients of ZYTEZO (see **What ZYTEZO contains**).
- If you are pregnant or breastfeeding (see **Pregnancy, breastfeeding and fertility**).
- If you have moderate or severe liver problems.
- ZYTEZO co-administered with a statin is contraindicated in patients with active liver disease or unexplained persistent elevations in serum transaminases.

ZYTEZO is not recommended in children under the age of 10 years.

Warnings and precautions

Tell your doctor before taking ZYTEZO:

Take special care with ZYTEZO:

- 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 ZYTEZO 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 ZYTEZO with a statin.

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

Other medicines and ZYTEZO

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

Tell your doctor or pharmacist if you are currently using:

- cholestyramine (used to lower cholesterol), because it affects the way ZYTEZO 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).

ZYTEZO with food, drink and alcohol

See section 3.

Pregnancy, 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 ZYTEZO.

Do not take ZYTEZO if you are pregnant or breastfeeding.

Driving and using machines

ZYTEZO 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 ZYTEZO affects you.

ZYTEZO contains lactose

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

3. How to take ZYTEZO

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

Always take ZYTEZO exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Before starting ZYTEZO, you should be on a diet to lower your cholesterol.

You should stay on this diet whilst taking ZYTEZO.

Adults and adolescents (10 to 17 years of age):

The usual dose is one ZYTEZO tablet once a day.

Take ZYTEZO at any time of the day. You can take ZYTEZO with or without food.

If your doctor has prescribed ZYTEZO along with any other medicine containing bile acid sequestrant, you should take ZYTEZO at least 2 hours before or 4 hours after taking the bile acid sequestrant.

If you have the impression that the effect of ZYTEZO is too strong or too weak, tell your doctor or pharmacist.

If you take more ZYTEZO 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 ZYTEZO with you so the doctor will know what you have taken.

If you forget to take ZYTEZO

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

4. Possible side effects

ZYTEZO can have side effects.

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

If any of the following happens, stop taking ZYTEZO 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 ZYTEZO. 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 ZYTEZO.

5. How to store ZYTEZO

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the blister or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ZYTEZO contains

Each tablet contains 10 mg ezetimibe.

The other ingredients are crospovidone, lactose monohydrate, magnesium stearate (E572), microcrystalline cellulose (E460(i)), povidone, pregelatinised starch, sodium lauryl sulfate, sodium stearyl fumarate.

What ZYTEZO looks like and contents of the pack

White to off-white, capsule shape, flat face bevelled edge uncoated tablets plain on both the sides.

PVC/Aclar/aluminium blister strips containing 30 tablets in a cardboard carton.

Holder of certificate of registration

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