PATIENT INFORMATION LEAFLET

TRYZETOR

SCHEDULING STATUS:

S4

TRYZETOR 10 mg tablets

Ezetimibe

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

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

1. What TRYZETOR is and what it is used for

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

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

TRYZETOR 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 TRYZETOR

Do not take TRYZETOR

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

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

Warnings and precautions

Tell your doctor before taking TRYZETOR:

Take special care with TRYZETOR:

- 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 TRYZETOR 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 TRYZETOR with a statin.

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

Other medicines and TRYZETOR

Always tell your healthcare 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 TRYZETOR 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).

TRYZETOR 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 healthcare provider for advice before taking TRYZETOR.

Do not take TRYZETOR if you are pregnant or breastfeeding.

Driving and using machines

TRYZETOR 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 TRYZETOR affects you.

TRYZETOR contains lactose

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

3. How to take TRYZETOR

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

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

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

Adults and children (10 years of age and older):

The usual dose is one TRYZETOR tablet once a day.

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

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

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

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

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

If you forget to take TRYZETOR

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

4. Possible side effects

TRYZETOR can have side effects.

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

If any of the following happens, stop taking TRYZETOR 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 TRYZETOR. 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-glutamyltransferase 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 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 TRYZETOR.

5. How to store TRYZETOR

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep blisters in carton until required for use.

Keep bottle tightly closed.

Do not use after the expiry date stated on the carton.

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 TRYZETOR contains

Each tablet contains 10 mg ezetimibe.

Contains sugar (lactose monohydrate 78**,**25 mg).

What TRYZETOR looks like and contents of the pack

TRYZETOR is a white to off white, capsule shaped, flat faced, beveled edge tablet, debossed with “E” on one side and “10” on the other side.

TRYZETOR is packed in:

- Clear PVC Aclar film, aluminium foil blister pack of 14 tablets in a pack size of 28 tablets in a carton
- Cold form Alu-Alu, aluminium foil blister pack of 15 tablets in a pack of 30 tablets in a carton
- Cold form dessicant coated aluminium foil blister of 15 tablets in a pack size of 30 tablets in a carton
- White, opaque, round HDPE bottle with child resistant closure, with aluminium foil heat seal liner, containing a dessicant sachet. Pack size of 30 tablets
- White, opaque, round HDPE bottle with child resistant closure, with aluminium foil heat seal liner, containing a molecular sieve sachet. Pack size of 30 tablets.

Not all pack types and sizes are marketed.

Holder of Certificate of Registration

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