SCHEDULING STATUS

S4

TOLEZE 10, 10 mg, tablets.
Ezetimibe.
Contains sugar (lactose monohydrate): 63 mg per tablet

Read all of this leaflet carefully before you start taking **TOLEZE 10**

- 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.
- TOLEZE 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 TOLEZE 10 is and what it is used for
2. What you need to know before you take TOLEZE 10
3. How to take TOLEZE 10
4. Possible side effects
5. How to store TOLEZE 10
6. Contents of the pack and other information

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

TOLEZE 10 is a medicine used to lower increased levels of cholesterol.
TOLEZE 10 lowers levels of total cholesterol, and “bad” cholesterol (LDL cholesterol)
It is used for patients who cannot control their cholesterol levels by cholesterol lowering diet alone. You should stay on your cholesterol lowering diet while taking TOLEZE 10.

TOLEZE 10 is used in addition to your cholesterol lowering diet:

- if you have a raised cholesterol level in your blood (primary hypercholesterolaemia [heterozygous familial and non-familial]).
- together with a statin, when your cholesterol level is not well controlled with a statin alone.
- alone, when statin treatment is inappropriate or is not tolerated.
- if you have a hereditary illness (homozygous familial hypercholesterolaemia) that increases the cholesterol level in your blood. You will also be prescribed a statin and may also receive other treatments.

TOLEZE 10 does not help you lose weight.

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

If you use TOLEZE 10 together with a statin, please read the package leaflet of that particular medicine.

Do not take TOLEZE 10:

- if you are hypersensitive (allergic) to ezetimibe or any of the other ingredients of TOLEZE 10 (listed in **section 6**).
- if you are pregnant or breastfeeding.
- if you are below the age of 10 years.
- if you have moderate to severe liver problems.

Warnings and precautions

Take special care with TOLEZE 10:

- if you have to take TOLEZE 10 together with a statin (medicine that is used to lower cholesterol). Your doctor should do a blood test before you start taking TOLEZE 10 with a statin. This is to check how well your liver is working.
- The safety and efficacy of the combined use of TOLEZE 10 and certain cholesterol lowering medicines, the fibrates have not been established.
- if you experience any muscle pain, tenderness or weakness, dark-coloured urine and/fever as TOLEZE 10 can cause disease of the muscle called myopathy. Let your doctor know immediately if you experience any of these symptoms.
- if you have to take TOLEZE 10 together with ciclosporin. The amount of ciclosporin in your blood should be monitored when taking with TOLEZE 10.
- if you have to take TOLEZE 10 together with warfarin or fluindione, your International Normalised Ratio (INR) should be appropriately monitored.

Children and adolescents

Do not give TOLEZE 10 to children younger than 10 years of age because there is no information in this age group.

The safety and efficacy of TOLEZE 10 when given with doses of simvastatin above 40 mg daily have not been studied in children aged 10 to 17 years of age.

Other medicines and TOLEZE 10

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

It is especially important to tell your doctor if you are using any of the following medicines:

- Ciclosporin (often used in organ transplant patients).
- Medicines with an active ingredient to prevent blood clots, such as warfarin and fluindioine (anticoagulants).
- Cholestyramine (also used to lower cholesterol), because it affects the way TOLEZE 10 works.
- Fibrates (also used to lower cholesterol).

TOLEZE 10 with food and drink
TOLEZE 10 can be taken with or without food.

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 TOLEZE 10.
Do not take TOLEZE 10 if you are pregnant, are trying to get pregnant or think you may be pregnant.
If you get pregnant while taking TOLEZE 10 tell your doctor.

Do not take TOLEZE 10 if you are breastfeeding, because it is not known if the medicine is passed into breast milk.

There is no experience or data available on the effect of TOLEZE 10 on fertility, and should therefore not be used if you are trying to have children.

Driving and using machines
TOLEZE 10 is not expected to interfere with your ability to drive or to use machinery. However, it should be taken into account that some people may get dizzy after taking TOLEZE 10.
It is not always possible to predict to what extent TOLEZE 10 may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which TOLEZE 10 affects you.

TOLEZE 10 contains lactose monohydrate
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking TOLEZE 10.

3. How to take TOLEZE 10
Do not share medicines prescribed for you with any other person.

Always take TOLEZE 10 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You should be on a weight loss programme and diet to lower your cholesterol and you should continue on this diet during your treatment with TOLEZE 10.

The usual dose is one TOLEZE 10 10 mg tablet by mouth once a day, with or without food.

If your doctor has prescribed TOLEZE 10 along with a statin, both medicines can be taken at the same time. In this case, please read the dosage instructions and information in the package leaflet of that particular medicine.

If your doctor has prescribed TOLEZE 10 along with another medicine for lowering cholesterol containing the active ingredient cholestyramine or any other medicine containing bile acid sequestrant, you should take TOLEZE 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 TOLEZE 10 will last. Do not stop treatment early because your cholesterol may rise again. If you have the impression that the effect of TOLEZE 10 is too strong or too weak, tell your doctor or pharmacist.

If you take more TOLEZE 10 than you should:
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take / missed a dose of TOLEZE 10
Do not take a double dose to make up for forgotten individual doses.
Continue to take your normal dose at the same time each day.

If you stop taking/using TOLEZE 10
Talk to your doctor or pharmacist because your cholesterol may rise again.

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

Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness. This is because, muscle problems, including muscle breakdown resulting in kidney damage may occur and, can be serious, and may become a potentially life-threatening condition.

If any of the following happens, stop taking TOLEZE 10 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 all very serious side effects. If you have them, you may have had a serious reaction to TOLEZE 10. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following, when TOLEZE 10 is used alone:
Frequent side effects:

- diarrhoea,
- headache
- passing of excessive amount of gas (flatulence),
- stomach pain,
- tiredness (fatigue).

Less frequent side effects:

- chest pain,
- coughing,
- decreased appetite,
- heartburn or GORD (gastro-oesophageal reflux disease),
- high blood pressure,
- hot flushes,
- indigestion,
- joint pain,
- muscle spasms,
- nausea,
- neck pain,
- pain,
- elevations in some laboratory blood tests,
- abnormal liver function tests.

Tell your doctor if you notice any of the following, when TOLEZE 10 is used with a statin:
Frequent side effects:

- headache,
- muscle pain,
- elevations in some laboratory blood tests.

Less frequent side effects:

- abdominal pain (stomach ache),
- back pain,
- constipation,
- diarrhoea,
- dry mouth,
- hives (red swollen bumps),
- itching (pruritis),
- muscle weakness,
- nausea,
- pain in hands and feet,
- passing of excessive amount of gas (flatulence),

- rash,
- sensation of pins and needles,
- swelling of hands and feet,
- tiredness,
- weakness and lack of energy.

Tell your doctor if you notice any of the following, when TOLEZE 10 is used with or without a statin:
Side effects with an unknown frequency:

- allergic reactions (including rash and swelling of hands and feet),
- anaphylaxis (live threatening allergic reaction),
- bleeding problems,
- breathing difficulty,
- constipation,
- depression,
- dizziness,
- gallstones,
- inflammation of the gallbladder,
- inflammation of the liver (hepatitis),
- inflammation of the pancreases (causing severe stomach pain),
- muscle pains and weakness which can be severe,
- nausea,
- sensation of pins and needles,
- skin reaction,
- weakness and lack of energy,
- elevations in some laboratory blood tests.

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. This includes any possible side effects not listed in this leaflet. 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 TOLEZE 10.

5. How to store TOLEZE 10
Store all medicines out of reach of children.
Store at or below 25 °C.
Blisters: Do not remove the blister from the carton until required for use.
Bottles: Store in the original container until required for use.
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 TOLEZE 10 contains

The active substance is ezetimibe.
The other ingredients are croscarmellose sodium, crospovidone, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate.

What TOLEZE 10 looks like and contents of the pack

White to off white capsule shape tablets (about 8 mm x 4 mm) debossed with '713' on one side and plain on the other side.
Blisters:
28’s or 30’s.
Push through blister: Clear PVC/ Aclar (polychloro-trifluoro-ethylene homopolymer) foil with plain, push through aluminium foil.
Peelable blister: Clear PVC/ Aclar (polychloro-trifluoro-ethylene homopolymer) foil with paper/ PET/ Aluminium peelable foil.
HDPE Bottles:
30’s or 28’s pack size: 40 cc HDPE bottle with a child resistant closure, silica gel dessicant and a 9 g absorbent rayon coil.
100’s pack size: 50 cc HDPE bottle silica gel dessicant and a 9 g absorbent rayon coil.
1000’s pack size: 200 cc HDPE bottle silica gel dessicant and a 9 g absorbent rayon coil.
Not all pack sizes may be marketed.

Holder of Certificate of Registration

Adcock Ingram Limited
1 New Road,
Erand Gardens,
Midrand, 1685
www.adcock.com
Customer Care: 0860 ADCOCK / 232625

This leaflet was last revised in

26 October 2021

Registration number

54/7.5/0617

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