Applicant: Teva Pharmaceuticals (Pty) Ltd	**Product name: EZETIMIBE 10 TEVA** **Dosage form & strength:** Each tablet contains 10 mg ezetimibe

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: S4

EZETIMIBE 10 TEVA, tablets

Ezetimibe.

Contains sugar: 35 mg lactose monohydrate

Read all of this leaflet carefully before you start taking EZETIMIBE 10 TEVA:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- EZETIMIBE 10 TEVA 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 EZETIMIBE 10 TEVA IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE EZETIMIBE 10 TEVA

3. HOW TO TAKE EZETIMIBE 10 TEVA

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE EZETIMIBE 10 TEVA

6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT EZETIMIBE 10 TEVA IS AND WHAT IT IS USED FOR:

EZETIMIBE 10 TEVA is a medicine used to lower levels of total cholesterol, ‘bad’ cholesterol (LDL cholesterol) and fatty substances called triglycerides in the blood. Additionally,

EZETIMIBE 10 TEVA raises levels of 'good' cholesterol (HDL cholesterol). EZETIMIBE 10 TEVA works by reducing the cholesterol absorbed in your digestive tract.

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

EZETIMIBE 10 TEVA 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 EZETIMIBE 10 TEVA:

Do not take EZETIMIBE 10 TEVA:

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

Warnings and precautions:

Take special care with EZETIMIBE 10 TEVA:

- If you experience any unexplained muscle pain, tenderness or 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 EZETIMIBE 10 TEVA 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 EZETIMIBE 10 TEVA with a statin.

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

Other medicines with EZETIMIBE 10 TEVA:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any medicines with the following active ingredients:

- Cholestyramine (medicine taken to reduce cholesterol levels), because it affects the way EZETIMIBE 10 TEVA works.
- Fibrates (medicine to lower cholesterol).
- Ciclosporin (used to prevent organ rejection after a transplant).
- Medicines to prevent blood clots, such as warfarin (anticoagulants).

EZETIMIBE 10 TEVA 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 EZETIMIBE 10 TEVA.

Do not take EZETIMIBE 10 TEVA if you are pregnant or breastfeeding.

Driving and using machines:

EZETIMIBE 10 TEVA 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 EZETIMIBE 10 TEVA affects you.

EZETIMIBE 10 TEVA contains lactose:

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

3. HOW TO TAKE EZETIMIBE 10 TEVA:

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

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

Before starting EZETIMIBE 10 TEVA, you should be on a diet to lower your cholesterol. You should stay on this diet while taking EZETIMIBE 10 TEVA.

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

The recommended dose is one EZETIMIBE 10 TEVA tablet by mouth once a day.

The tablets can be taken at any time of the day, with or without food.

If your doctor has prescribed EZETIMIBE 10 TEVA along with any other medicine containing a bile acid sequestrant, you should take EZETIMIBE 10 TEVA at least 2 hours before or 4 hours after taking the bile acid sequestrant.

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

If you take more EZETIMIBE 10 TEVA than you should:

In the event of 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 EZETIMIBE 10 TEVA with you so the doctor will know what you have taken.

If you forget to take EZETIMIBE 10 TEVA:

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

4. POSSIBLE SIDE EFFECTS:

EZETIMIBE 10 TEVA can have side effects.

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

If any of the following happens, stop taking EZETIMIBE 10 TEVA 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 EZETIMIBE 10 TEVA. 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 side effects:

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 flushes
- high blood pressure
- indigestion
- dry mouth
- heart burn
- nausea
- pain in the joints
- muscle spasms
- neck pain
- hand or foot pain
- chest 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, 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 EZETIMIBE 10 TEVA.

5. HOW TO STORE EZETIMIBE 10 TEVA:

Store all medicine out of reach of children.

Store at or below 25 °C.

Do not remove blisters from carton until required for use.

Do not use the tablets after the expiry date shown on the container.

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 EZETIMIBE 10 TEVA contains:

The active substance is ezetimibe. Each tablet contains 10 mg ezetimibe.

The other ingredients are:

croscarmellose sodium (type A),

lactose monohydrate,

microcrystalline cellulose,

poloxamer 407,

povidone,

silica colloidal anhydrous,

sodium lauryl sulphate,

starch pregelatinised,

stearic acid.

What EZETIMIBE 10 TEVA looks like and contents of the pack:

Each EZETIMIBE 10 TEVA tablet is a white, biconvex, capsule-shaped tablet, debossed with '10' on one side.

EZETIMIBE 10 TEVA tablets are packed in:

- PVC/ACLAR/PVC/Aluminium (clear, transparent/silver, opaque) blister strips.
- PVC/AquaBA SW/PVC blisters.

  Pack sizes: 7, 10, 14, 20, 28, 30, 50, 84, 90, 98, 100 or 300 tablets per outer cardboard carton.
- HDPE bottles (white, opaque) with a desiccant canister (white, opaque) containing silica gel and activated charcoal, closed with polypropylene closures (green, opaque).

  Pack sizes: 100 tablets per bottle placed in an outer cardboard carton.

HOLDER OF THE CERTIFICATE OF REGISTRATION:

Teva Pharmaceuticals (Pty) Ltd

Maxwell Office Park,

Magwa Cresent West,

Waterfall City,

Midrand,

Applicant: Teva Pharmaceuticals (Pty) Ltd	Product name: EZETIMIBE 10 TEVA **Dosage form & strength:** Each tablet contains 10 mg ezetimibe

Gauteng,

South Africa,

2090

Tel: 011 055 0200

This leaflet was last revised in:

21 January 2021

REGISTRATION NUMBER:

EZETIMIBE 10 TEVA: 50/7.5/0760