Applicant: Teva Pharmaceuticals (Pty) Ltd	Product: METFORMIN TEVA ER 500 METFORMIN TEVA ER 750 METFORMIN TEVA ER 1000
Registration Nos.: 53/21.2/0227-9	**Dosage Form:** Extended release tablet **Strength:** 500 mg, 750 mg & 1000 mg, respectively.

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: S3

METFORMIN TEVA ER 500; METFORMIN TEVA ER 750; METFORMIN TEVA ER 1000

Extended Release Tablets

Metformin hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking METFORMIN TEVA ER.

- 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.
- METFORMIN TEVA ER 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 METFORMIN TEVA ER is and what it is used for

2. What you need to know before you take METFORMIN TEVA ER

3. How to take METFORMIN TEVA ER

4. Possible side effects

5. How to store METFORMIN TEVA ER

6. Contents of the pack and other information

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1. WHAT METFORMIN TEVA ER IS AND WHAT IT IS USED FOR:

METFORMIN TEVA ER contain the active ingredient metformin hydrochloride and belong to a group of medicines called biguanides, used in the treatment of Type 2 (non-insulin dependent) diabetes mellitus.

METFORMIN TEVA ER is used for the treatment of Type 2 diabetes when diet and exercise changes alone have not been enough to control blood glucose (sugar). Insulin is a hormone that enables body tissues to take glucose from the blood and to use it for energy or for storage for future use. People with Type 2 diabetes do not make enough insulin in their pancreas or their body does not respond properly to the insulin it does make. This causes a build-up of glucose in the blood which can cause a number of serious long term problems so it is important that you continue to take your medicine, even though you may not have any obvious symptoms. METFORMIN TEVA ER makes the body more sensitive to insulin and helps return to normal the way your body uses glucose.

METFORMIN TEVA ER Extended Release Tablets are specially made to release the medicine slowly in your body. METFORMIN TEVA ER can be given alone as initial therapy or can be administered in combination with other oral antidiabetic medicines or with insulin.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE METFORMIN TEVA ER:

Do not take METFORMIN TEVA ER if:

- you are hypersensitive to metformin hydrochloride or any of the other ingredients of METFORMIN TEVA ER (listed in **section 6**).
- you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see Risk of lactic acidosis below) or ketoacidosis. Ketoacidosis is a condition in which substances called ketone bodies accumulate in

the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual, fruity smell.

- you have reduced kidney function or kidney failure
- you have lost too much water from your body (dehydration). Dehydration may lead to kidney problems, which can put you at risk for lactic acidosis (see Warnings and precautions)
- you have a severe infection, such as an infection affecting your lung or bronchial system or your kidney. Severe infections may lead to kidney problems, which can put you at risk for lactic acidosis (see Warnings and precautions)
- you have been treated for acute heart problems or have recently had a heart attack or have severe circulatory problems or breathing difficulties. This may lead to a lack in oxygen supply to tissue which can put you at risk for lactic acidosis (see Warnings and precautions)
- you have pancreatitis
- you have liver problems
- you are a heavy drinker of alcohol
- you are receiving intravascular iodinated contrast media
- you are pregnant.

Warnings and precautions:

Take special care with METFORMIN TEVA ER:

- if you are at risk of developing lactic acidosis - lactic acidosis is a rare, but serious and life threatening complication that can occur when lactic acid builds up in the blood stream faster than it can be removed. The risk of developing lactic acidosis is also increased with if your kidneys are not working properly, uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration (see further information below), liver problems and any medical conditions in which a

part of the body has a reduced supply of oxygen (such as acute severe heart disease). Talk to your doctor if you think you may be at risk of developing lactic acidosis

- if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal, you should stop taking METFORMIN TEVA ER for a short time and talk to your doctor for further instructions
- if you are elderly and/or if you have worsening kidney function, your doctor will check your kidney function at least once a year or more frequently during treatment with METFORMIN TEVA ER and your dosage will be adjusted based on your kidney function
- if you are elderly, your serum creatinine levels will be determined before initiating treatment and two to four times in a year thereafter. Decreased kidney function in elderly patients happen frequently and may not present with any symptoms. Special precaution should thus be exercised if you are at risk of your kidney function becoming impaired, for example if you are being started on medication for high blood pressure, a diuretic or a NSAID
- if you need to have major surgery you must stop taking METFORMIN TEVA ER during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with METFORMIN TEVA ER
- if you see some remains of the tablets in your stools, you should not worry as this is normal for this type of tablet.

You should continue to follow any dietary advice that your doctor has given you and you should make sure that you eat carbohydrates regularly throughout the day.

Children and adolescents:

METFORMIN TEVA ER is not for use in children.

Other medicines and METFORMIN TEVA ER:

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Tell your doctor is you are taking or receiving any of the following medicines:

- Contrast medium injection that contains iodine, for example in the context of an X-ray or scan, you must stop taking METFORMIN TEVA ER before or at the time of injection. Your doctor will decide when you must stop and when to restart your treatment with METFORMIN TEVA ER.
- Medicines used to treat pain and inflammation (NSAID and COX-2 inhibitors, such as ibuprofen and celecoxib)
- Medicines which increase urine production (diuretics (water tablets) such as furosemide)
- Certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists)
- Steroids such as prednisolone, mometasone, beclometasone
- Sympathomimetic medicines including adrenaline (epinephrine) and dopamine used to treat heart attacks and low blood pressure. Adrenaline (epinephrine) is also included in some dental anaesthetics
- Medicines that may change the amount of METFORMIN TEVA ER in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib).

METFORMIN TEVA ER with food and alcohol:

METFORMIN TEVA ER should be taken with food.

Avoid excessive alcohol intake while taking METFORMIN TEVA ER since this may increase the risk of lactic acidosis (see section **Warnings and precautions**).

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 METFORMIN TEVA ER.

You should not take METFORMIN TEVA ER if you are pregnant or breastfeeding your baby.

Driving and using machines:

METFORMIN TEVA ER taken on its own does not cause 'hypos' (symptoms of low blood sugar or hypoglycaemia, such as faintness, confusion and increased sweating) and therefore should not affect your ability to drive or use machinery.

You should be aware, however, that METFORMIN TEVA ER taken with other antidiabetic medicines can cause hypos, so in this case you should take extra care when driving or operating machinery.

It is not always possible to predict to what extent METFORMIN TEVA ER may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which METFORMIN TEVA ER affects you.

3. HOW TO TAKE METFORMIN TEVA ER:

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

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

METFORMIN TEVA ER 500: Usually you will start treatment with 500 milligrams METFORMIN TEVA ER daily. After you have been taking METFORMIN TEVA ER for about 2 weeks, your doctor may measure your blood sugar and adjust the dose. The maximum daily dose is 2000 milligrams (4 tablets of 500 mg) of METFORMIN TEVA ER.

METFORMIN TEVA ER 750: The usual starting dose is one tablet daily taken with the evening meal. Your doctor may adjust your dose after 10 to 15 days. The recommended dosage is 2 tablets daily.

METFORMIN TEVA ER 1000: The usual starting dose is one tablet daily taken with the evening meal at a maximum, recommended dose of 2 tablets per day.
METFORMIN TEVA ER 1000 is intended as maintenance therapy for patients currently treated with either 1000 mg or 2 000 mg metformin hydrochloride.

Switching you to prolonged release tablets: the starting dose of the prolonged release tablets should be the same as the daily dose of the immediate release tablets. If your dose is above 2000 mg daily, you should not take METFORMIN TEVA ER tablets.

Combination therapy with Insulin:
The usual starting dose is METFORMIN TEVA ER 500 once daily with the evening meal, while insulin dosage is adjusted on the basis of blood glucose measurements. Switching to METFORMIN TEVA ER 1000 may be considered after titration.

If you have reduced kidney function, your doctor may prescribe a lower dose.

Swallow the tablets whole with a glass of water, do not chew.

If you take more METFORMIN TEVA ER than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If the overdose is large, lactic acidosis is more likely. Symptoms of lactic acidosis are non-specific, such as vomiting, belly ache with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. Further symptoms are reduced body temperature and heartbeat. If you experience some of these symptoms, you should immediately seek medical attention, as lactic acidosis may lead to coma.

If you forget to take METFORMIN TEVA ER:

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

If you stop taking METFORMIN TEVA ER:

Do not stop taking METFORMIN TEVA ER without speaking to your doctor.

4. POSSIBLE SIDE EFFECTS:

METFORMIN TEVA ER can have side effects.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking METFORMIN TEVA ER, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking METFORMIN TEVA ER 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
- lactic acidosis with symptoms such as vomiting, stomach pain, muscle cramps, not feeling well with severe tiredness, reduced body temperature and heartbeat
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to METFORMIN TEVA ER. 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:

- yellowing of the eyes and/or skin.

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- taste disturbance
- diarrhoea
- nausea
- vomiting
- stomach pain
- loss of appetite
- decreased vitamin B12 levels.

Less frequent side effects:

- blood tests that show abnormal liver function tests
- superficial reddening of the skin, usually in patches

- hives.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of METFORMIN TEVA ER.

5. HOW TO STORE METFORMIN TEVA ER:

Store all medicine out of reach of children.

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

Do not remove blister from carton until required for use.

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

Return the expired medicine to your pharmacist for safe disposal.

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What METFORMIN TEVA ER contains:

The active ingredient is metformin hydrochloride.

The other ingredients are carmellose sodium, hypromellose, magnesium stearate, silica colloidal anhydrous.

What METFORMIN TEVA ER looks like and contents of the pack:

METFORMIN TEVA ER 500: White to off-white, capsule shaped tablet debossed with ‘SR 500’ on one side and plain on other side.

METFORMIN TEVA ER 750: White to off-white, capsule shaped tablet debossed with 'SR 750' on one side and plain on other side.

METFORMIN TEVA ER 1000: White to off-white, oval tablet debossed with 'SR 1000' on one side and plain on other side.

METFORMIN TEVA ER 500, 750 & 1000 Extended Release Tablets is packed in Blister of 10 tablets (packed in foil blister aluminium 0,02 mm x 198 mm plain & PVC film 0,35 mm x 202 mm transparent) and 6 blisters per carton.

The blisters are packed in secondary packaging material: outer cardboard carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

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REGISTRATION NUMBER(S):

Applicant: Teva Pharmaceuticals (Pty) Ltd	**Product: METFORMIN TEVA ER 500** **METFORMIN TEVA ER 750** **METFORMIN TEVA ER 1000**
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METFORMIN TEVA ER 500: 53/21.2/0227

METFORMIN TEVA ER 750: 53/21.2/0228

METFORMIN TEVA ER 1000: 53/21.2/0229