1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

FORTESE XR 500 Extended Release Tablets

FORTESE XR 750 Extended Release Tablets

Metformin Hydrochloride

Read all of this leaflet carefully before you start taking FORTESE XR.

- 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.
- **FORTESE XR** 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 FORTESE XR IS AND WHAT IT IS USED FOR

FORTESE XR Extended release tablets 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. **FORTESE XR** is used together with diet and exercise to lower the risk of developing Type 2 diabetes in overweight adults, where diet and exercise alone have not been enough to control blood glucose (sugar) or when insulin cannot be used.

FORTESE XR Extended release Tablets are specially made to release the medicine slowly in your body and therefore are different to many other types of tablet containing metformin.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FORTESE XR

Do not take FORTESE XR if:

- you are allergic to metformin or to any of the other ingredients of this medicine (listed in section 6). An allergic reaction may cause a rash, itching or shortness of breath.
- you have liver problems.
- you have severely reduced kidney function.
- 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 lost too much water from your body (dehydration). Dehydration may lead to kidney problems, which can put you at risk for lactic acidosis.

- 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.
- you have been treated for acute heart problems or have recently had a heart attack or have severe circulatory problems or breathing difficulties (such as asthma). These conditions may deprive your body of oxygen supply to tissue which can put you at risk for lactic acidosis.
- you have pancreatitis (inflammation of the pancreas).
- you take excessive quantities of alcohol or medicines that contain alcohol, like cough mixtures.
- you are a child under the age of 12.
- you are pregnant, plan to be pregnant or breast-feeding.

Warnings and Precautions:

Take special care with **FORTESE XR**

- If you develop the following symptoms while taking **FORTESE XR:**
    - stomach pain, hyperventilation (fast and deep breathing), exhaustion, rapid heartbeat, nausea and vomiting.

  Contact your doctor immediately if you experience the listed symptoms, as you may have had a life-threatening condition called lactic acidosis.
- If you recently had an X-ray where iodine containing dye was injected.
- If you are taking any medicine used to manage high blood pressure.
- If you are taking **FORTESE XR** 48 hours before going to surgery. Talk to your doctor, as your doctor may temporarily stop the treatment.

- If you are on a low calorie diet.
- If you are on long-term treatment of **FORTESE XR** and need to initiate Vitamin B_{12} and folic treatment, as they may reduce the absorption of nutrients from the intestine, which may lead to anaemia.
- If have a condition that may be associated with dehydration (significant loss of body fluids), diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking FORTESE XR and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma. Symptoms of lactic acidosis include: vomiting, stomach ache (abdominal pain), muscle cramps, a general feeling of not being well with severe tiredness, difficulty in breathing, reduced body temperature and heartbeat.

Other medicines and FORTESE XR:

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

If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, you must stop taking **FORTESE XR** before or at the time of injection. Your doctor will decide when you must stop and when to restart your treatment with **FORTESE XR.**

You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of **FORTESE XR.**

Tell your doctor if you are taking any of the following:

- Medicines which increase urine production (diuretics (water tablets) such as furosemide).
- Medicines used to treat pain and inflammation (NSAID and COX-2 inhibitors, such as ibuprofen and celecoxib).
- Certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists, sulphonylurea).
- Steroids such as prednisolone, mometasone, beclometasone.
- Sympathomimetic medicines including epinephrine and dopamine used to treat heart attacks and low blood pressure. Epinephrine is also included in some dental anaesthetics.
- Medicines that may change the amount of **FORTESE XR** in your blood, especially if you have reduced kidney function (such as cimetidine).
- Anticoagulants such as warfarin (Medicines used in thinning of blood or to prevent your blood from clotting).
- Vitamin B_{12} (Medicines used to increase iron uptake in the intestine).

FORTESE XR with alcohol

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

Pregnancy and breast-feeding:

Do not take **FORTESE XR** if you are pregnant or breast feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:

FORTESE XR given on its own does not cause hypoglycaemia (low blood sugar levels) and therefore does not affect the ability to drive or operate machines. However, you must be aware that when you take **FORTESE XR** together with other medicines used in treating diabetes, there is a risk of developing hypoglycaemia (low blood sugar levels).
Do not drive or operate any dangerous machinery until you know how **FORTESE XR** affects you.

3. HOW TO TAKE FORTESE XR

Your doctor may prescribe **FORTESE XR** for you to take on its own, or in combination with other oral antidiabetic medicines or insulin. Always take **FORTESE XR** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Swallow the tablets whole with a glass of water, do not chew.

Recommended dose: Usually you will start treatment with 500 mg of **FORTESE XR** daily after evening meal. After you have been taking **FORTESE XR** for about 2 weeks, your doctor may measure your blood sugar and adjust the dose. The maximum daily dose is 2000 mg of **FORTESE XR** (4 tablets of 500 mg or 3 tablets of 750 mg).

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

Normally, you should take the tablets once a day, with your evening meal. In some cases, your doctor may recommend that you take the tablets twice a day. Always take the tablets with food.

If you take more FORTESE XR than you should:

If you take extra tablets by mistake you need not worry, but if you have unusual symptoms, contact your doctor. If the overdose is large, lactic acidosis is more likely. Symptoms of lactic acidosis are non-specific, such as vomiting, bellyache with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. Further symptoms are reduced body temperature and heart beat. If you experience some of these symptoms, you should immediately seek medical attention, as lactic acidosis may lead to coma. Stop taking **FORTESE XR** immediately and contact a doctor or the nearest hospital straightaway.

If you forget to take FORTESE XR:

Take it as soon as you remember with some food. Do not take a double dose to make up for a forgotten dose.

If you stop taking FORTESE XR:

Do not stop taking **FORTESE XR** unless your doctor tells you to.

4. POSSIBLE SIDE EFFECTS

FORTESE XR can have side effects.

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

If any of the following happens, stop taking / using **FORTESE XR** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- a very rare but very serious side effect called lactic acidosis (see section 'Warnings and precautions'). Lactic acidosis may lead to coma.

These are all very serious side effects. If you have them, you may have had a serious reaction to **FORTESE XR**. 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:

- abnormal liver function tests and hepatitis (inflammation of the liver) which may result in jaundice.
- If you develop yellowing of the eyes and/or skin contact your doctor immediately.

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:

Diarrhoea, nausea, vomiting, stomach ache or loss of appetite and taste disturbance.

Less frequent side-effects:

Decreased vitamin B_{12} levels, skin rashes including redness, itching and hives.

If you get these, do not stop taking the tablets as these symptoms will normally go away in about 2 weeks. It helps if you take the tablets with or immediately after a meal.

If you notice any side effects not mentioned in this leaflet, tell your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or 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 **FORTESE XR**.

5. HOW TO STORE FORTESE XR

Store at or below 25 °C.

Do not remove blister from carton until required for use. Keep bottle tightly closed. Store in the original package in order to protect from moisture.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the carton, the blister and the bottle.

Do not throw away any medicines in drains or sewage systems.

Return all unused medicine to the pharmacist.

6. CONTENTS OF PACK AND OTHER INFORMATION

What FORTESE XR contains:

The active ingredient is metformin hydrochloride.

Each **FORTESE XR** extended release tablet contains either 500 or 750 mg of metformin hydrochloride.

Other ingredients are carboxymethyl cellulose sodium, copovidone, hydroxy propyl methyl cellulose, microcrystalline cellulose and magnesium stearate.

What FORTESE XR looks like and contents of the pack:

FORTESE XR 500: White to off white, oval shaped, biconvex, tablets with ‘MX500’ debossed on one side and plain on other.

FORTESE XR 750: White to off white, capsule shaped tablets with ‘MX750’ debossed on one side and plain on other side.

Contents of the pack:

FORTESE XR 500 are packed PVC/PVDC/ aluminium blister packs of 10 tablets (inserted in a printed cardboard carton) and in HDPE bottles of 100, 500 and 1000 Tablets.

FORTESE XR 750 is packed in PVC/PVDC/ aluminium blister packs of 10 tablets (inserted in a printed cardboard carton) and in HDPE bottles of 100 and 500 Tablets.

Holder of Certificate of Registration

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0157

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Application Numbers:

FORTESE XR 500: 540465

FORTESE XR 750: 540466

Access to the corresponding Professional Information

The professional information will be included in each unit pack of the product.