

|                           |                                                 |
|---------------------------|-------------------------------------------------|
| Proprietary name:         | METFORMIN XR 500 ALKEM & METFORMIN XR 750 ALKEM |
| Dosage form:              | Extended Release Tablets                        |
| Active Ingredient:        | Metformin hydrochloride                         |
| Strength per dosage unit: | 500 or 750 mg per tablet                        |

---

### 1.3.2 PATIENT INFORMATION LEAFLET

#### SCHEDULING STATUS

S3

#### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

**METFORMIN XR 500 ALKEM** Extended Release Tablets

**METFORMIN XR 750 ALKEM** Extended Release Tablets

Metformin Hydrochloride

**Read all of this leaflet carefully before you start taking METFORMIN XR ALKEM.**

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

|                                  |                                                 |
|----------------------------------|-------------------------------------------------|
| <b>Proprietary name:</b>         | METFORMIN XR 500 ALKEM & METFORMIN XR 750 ALKEM |
| <b>Dosage form:</b>              | Extended Release Tablets                        |
| <b>Active Ingredient:</b>        | Metformin hydrochloride                         |
| <b>Strength per dosage unit:</b> | 500 or 750 mg per tablet                        |

---

## 1. WHAT METFORMIN XR ALKEM IS AND WHAT IT IS USED FOR

METFORMIN XR ALKEM 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. **METFORMIN XR ALKEM** 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.

**METFORMIN XR ALKEM** 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 METFORMIN XR ALKEM

**Do not take METFORMIN XR ALKEM 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.

|                                  |                                                 |
|----------------------------------|-------------------------------------------------|
| <b>Proprietary name:</b>         | METFORMIN XR 500 ALKEM & METFORMIN XR 750 ALKEM |
| <b>Dosage form:</b>              | Extended Release Tablets                        |
| <b>Active Ingredient:</b>        | Metformin hydrochloride                         |
| <b>Strength per dosage unit:</b> | 500 or 750 mg per tablet                        |

---

- 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 **METFORMIN XR ALKEM**

- If you develop the following symptoms while taking **METFORMIN XR ALKEM**:
  - 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.

|                                  |                                                 |
|----------------------------------|-------------------------------------------------|
| <b>Proprietary name:</b>         | METFORMIN XR 500 ALKEM & METFORMIN XR 750 ALKEM |
| <b>Dosage form:</b>              | Extended Release Tablets                        |
| <b>Active Ingredient:</b>        | Metformin hydrochloride                         |
| <b>Strength per dosage unit:</b> | 500 or 750 mg per tablet                        |

---

- If you are taking **METFORMIN XR ALKEM** 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 **METFORMIN XR ALKEM** and need to initiate Vitamin B<sub>12</sub> 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 METFORMIN XR ALKEM** 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 METFORMIN XR ALKEM:**

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 **METFORMIN XR ALKEM** before or at the time of injection. Your doctor will decide when you must stop and when to restart your treatment with **METFORMIN XR ALKEM**.

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

|                                  |                                                 |
|----------------------------------|-------------------------------------------------|
| <b>Proprietary name:</b>         | METFORMIN XR 500 ALKEM & METFORMIN XR 750 ALKEM |
| <b>Dosage form:</b>              | Extended Release Tablets                        |
| <b>Active Ingredient:</b>        | Metformin hydrochloride                         |
| <b>Strength per dosage unit:</b> | 500 or 750 mg per tablet                        |

---

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 **METFORMIN XR ALKEM** 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<sub>12</sub> (Medicines used to increase iron uptake in the intestine).

### **METFORMIN XR ALKEM with alcohol**

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

### **Pregnancy and breast-feeding:**

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

|                                  |                                                 |
|----------------------------------|-------------------------------------------------|
| <b>Proprietary name:</b>         | METFORMIN XR 500 ALKEM & METFORMIN XR 750 ALKEM |
| <b>Dosage form:</b>              | Extended Release Tablets                        |
| <b>Active Ingredient:</b>        | Metformin hydrochloride                         |
| <b>Strength per dosage unit:</b> | 500 or 750 mg per tablet                        |

---

### **Driving and using machines:**

**METFORMIN XR ALKEM** 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 **METFORMIN XR ALKEM** 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 **METFORMIN XR ALKEM** affects you.

### **3. HOW TO TAKE METFORMIN XR ALKEM**

Your doctor may prescribe **METFORMIN XR ALKEM** for you to take on its own, or in combination with other oral antidiabetic medicines or insulin. Always take **METFORMIN XR ALKEM** 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 **METFORMIN XR ALKEM** daily after evening meal. After you have been taking **METFORMIN XR ALKEM** for about 2 weeks, your doctor may measure your blood sugar and adjust the dose. The maximum daily dose is 2000 mg of **METFORMIN XR ALKEM** (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.

|                                  |                                                 |
|----------------------------------|-------------------------------------------------|
| <b>Proprietary name:</b>         | METFORMIN XR 500 ALKEM & METFORMIN XR 750 ALKEM |
| <b>Dosage form:</b>              | Extended Release Tablets                        |
| <b>Active Ingredient:</b>        | Metformin hydrochloride                         |
| <b>Strength per dosage unit:</b> | 500 or 750 mg per tablet                        |

---

**If you take more METFORMIN XR ALKEM 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 **METFORMIN XR ALKEM** immediately and contact a doctor or the nearest hospital straightaway.

**If you forget to take METFORMIN XR ALKEM:**

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 METFORMIN XR ALKEM:**

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

#### **4. POSSIBLE SIDE EFFECTS**

**METFORMIN XR ALKEM** can have side effects.

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

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

|                                  |                                                 |
|----------------------------------|-------------------------------------------------|
| <b>Proprietary name:</b>         | METFORMIN XR 500 ALKEM & METFORMIN XR 750 ALKEM |
| <b>Dosage form:</b>              | Extended Release Tablets                        |
| <b>Active Ingredient:</b>        | Metformin hydrochloride                         |
| <b>Strength per dosage unit:</b> | 500 or 750 mg per tablet                        |

---

- 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 **METFORMIN XR ALKEM**. 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<sub>12</sub> 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

|                                  |                                                 |
|----------------------------------|-------------------------------------------------|
| <b>Proprietary name:</b>         | METFORMIN XR 500 ALKEM & METFORMIN XR 750 ALKEM |
| <b>Dosage form:</b>              | Extended Release Tablets                        |
| <b>Active Ingredient:</b>        | Metformin hydrochloride                         |
| <b>Strength per dosage unit:</b> | 500 or 750 mg per tablet                        |

---

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 **METFORMIN XR ALKEM**.

## 5. HOW TO STORE METFORMIN XR ALKEM

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 METFORMIN XR ALKEM contains:

The active ingredient is metformin hydrochloride.

Each **METFORMIN XR ALKEM** 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 METFORMIN XR ALKEM looks like and contents of the pack:

**METFORMIN XR 500 ALKEM:** White to off white, oval shaped, biconvex, tablets with 'MX500' debossed on one side and plain on other.

**METFORMIN XR 750 ALKEM:** White to off white, capsule shaped tablets with 'MX750' debossed on one side and plain on other side.

|                                  |                                                 |
|----------------------------------|-------------------------------------------------|
| <b>Proprietary name:</b>         | METFORMIN XR 500 ALKEM & METFORMIN XR 750 ALKEM |
| <b>Dosage form:</b>              | Extended Release Tablets                        |
| <b>Active Ingredient:</b>        | Metformin hydrochloride                         |
| <b>Strength per dosage unit:</b> | 500 or 750 mg per tablet                        |

---

### **Contents of the pack:**

**METFORMIN XR 500 ALKEM** 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.

**METFORMIN XR 750 ALKEM** 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**

Alkem Laboratories (Pty) Ltd.

R21 Corporate Park,

121 Sovereign Drive, Block A, Office 202

Irene Ext. 30, Centurion,

0157

### **This leaflet was last revised in**

22 June 2020

### **Application Numbers:**

**METFORMIN XR 500 ALKEM:** 540465

**METFORMIN XR 750 ALKEM:** 540466

### **Access to the corresponding Professional Information**

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