SCHEDULING STATUS: S3

METFORMIN 500 XR ADCO, 500 mg prolonged release tablet
Metformin hydrochloride
Sugar free

METFORMIN 1000 XR ADCO, 1 000 mg prolonged release tablet
Metformin hydrochloride
Sugar free

Read all of this leaflet carefully before you start taking METFORMIN XR ADCO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- METFORMIN XR ADCO 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 ADCO is and what it is used for
2. What you need to know before you take METFORMIN XR ADCO
3. How to take METFORMIN XR ADCO
4. Possible side effects
5. How to store METFORMIN XR ADCO
6. Contents of the pack and other information

1. What METFORMIN XR ADCO is and what it is used for

METFORMIN XR ADCO contains the active ingredient metformin, a medicine to treat diabetes. It belongs to a group of medicines called biguanides which helps reduce high blood sugar levels.
METFORMIN XR ADCO does not stimulate insulin secretion and therefore the unwanted effects of an over reduction of blood sugar will not be produced.

Insulin is a hormone produced by the pancreas that makes your body take in glucose (sugar) from the blood. Your body uses glucose to produce energy or stores it for future use.

If you have diabetes, your pancreas does not make enough insulin or your body is not able to properly use the insulin it produces. This leads to a high level of glucose in your blood. METFORMIN XR ADCO tablets helps to lower your blood glucose to as normal a level as possible.

METFORMIN XR ADCO is used for the treatment of type 2 diabetes mellitus in adults, when diet and exercise alone have not been enough to control blood glucose (sugar). METFORMIN XR ADCO can be given alone or can be taken with other oral antidiabetic medicines or with insulin.

2. What you need to know before you take METFORMIN XR ADCO

Do not take METFORMIN XR ADCO:

- if you are hypersensitive (allergic) to (metformin hydrochloride) or any of the other ingredients of METFORMIN XR ADCO (listed in section 6),
- if you have severe complications of your diabetes such as diabetic ketoacidosis (a metabolic state resulting from a serious lack of insulin) or diabetic pre-coma (when complications are left untreated). 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,
- if you have severely weakened kidney function or kidney failure,
- if you have a short term conditions that may affect your kidney function e.g., dehydration, severe infection, shock, or if you have had injections of contrast mediums that contains iodine through the veins,
- if you have short or long term conditions that may cause a lack of oxygen to your tissues such as heart or breathing/lung failure, a recent heart attack, shock,
- if you have had a recent heart attack,
- if you have previously had inflammation of your pancreas,
- if you suffer from a liver condition, or use excessive amounts of alcohol,
- if you are pregnant.

Warnings and precautions

Take special care with METFORMIN XR ADCO:

- If you have serious kidney problems, cardiorespiratory illness (range of conditions that affect the heart and lungs) or sepsis (body's extreme response to an infection), the risk for developing a complication such as lactic acidosis is higher. 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.
- 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 and talk to your doctor for further instructions.
- If you show symptoms of lactic acidosis such as acidotic dyspnoea (hyperventilation), abdominal / stomach pain, muscle cramps, asthenia (a general feeling of not being well with severe tiredness and hypothermia), reduced body temperature and heartbeat followed by a state of coma (unconsciousness), the use of METFORMIN XR ADCO should be stopped and should urgently be treated in a hospital environment.

- If you take other medicines which can lower the kidney's capacity to function properly for a short period of time (such as blood pressure reducing medicines, diuretics (water pills) and NSAIDs (non-steroidal anti-inflammatory drugs). During the treatment with METFORMIN XR ADCO, your doctor should monitor your kidney functioning more frequently.
- If you have risk factors for the development of lactic acidosis such as uncontrolled diabetes, serious infections, prolonged fasting or high amounts of alcohol intake, dehydration, 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).
- If you are using METFORMIN XR ADCO as long-term treatment, your vitamin B_{12} levels should be monitored yearly to assess for the development of megaloblastic anaemia (abnormal, immature red blood cells).
- If you have heart failure or kidney disease, continuous monitoring is needed.
- You must not use METFORMIN XR ADCO if you have unstable heart failure.
- If you are older than 75 years, treatment with METFORMIN XR ADCO should not be started to lower the risk or slow down the development of type 2 diabetes.
- If you are to be injected with a contrast medium that contains iodine, the use of metformin should be stopped for a period before and after the procedure. Only when your kidney function is stable may metformin be restarted again.
- If you need to have major surgery, METFORMIN XR ADCO should be discontinued 48 hours before and some time after the procedure. Your doctor will decide when you should stop and when to restart treatment with METFORMIN XR ADCO.
- If you are taking other blood sugar lowering tablets (e.g., sulphonylurea or meglitinides), or insulin.
- If you are starting treatment with METFORMIN XR ADCO and insulin, you might have to be admitted to hospital as you might be at risk for developing low blood glucose levels (until the correct ratio of the two medicines have been determined),
- If you are overweight: you should continue with your energy-restricted diet and be regularly monitored. You should continue your diet with a regular distribution of carbohydrate intake throughout the day.
- If you see the tablet shells in your stools. This is normal and will not cause you harm.

Other medicines and METFORMIN XR ADCO

Always tell your health care provider if you are taking any other medicine.
(This includes all complementary or traditional medicines.)
You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of METFORMIN XR ADCO. It is especially important to mention the following:

- When you drink large amounts of alcohol and /or use alcohol-containing medications (e.g., elixirs or cough syrups).
- If you need to have an injection of contrast mediums that contains
- iodine into a vein, when you need an X-ray or a scan. Your doctor will decide when you must stop and when to restart your treatment with METFORMIN XR ADCO.

- Medicines used to treat pain and inflammation such as NSAID (e.g., ibuprofen) and COX-2-inhibitors (e.g., celecoxib)
- Certain medicines for the treatment of high blood pressure such as ACE inhibitors and angiotensin II receptor antagonists (e.g., enalapril or valsartan) or diuretics (water pills) especially loop diuretics (e.g., furosemide).
- Medicines to treat asthma such as beta-2 agonists (e.g., salbutamol or terbutaline).
- Corticosteroids to treat a variety of conditions, including severe inflammation of the skin or in asthma.
- Anticoagulants (medicines used to prevent clotting of the blood).
- Sulphonylurea (medicines that are used to help control your blood glucose levels).
- METFORMIN XR ADCO may reduce the uptake of vitamin B_{12} from your gastro-intestinal tract. The dose of METFORMIN XR ADCO may need to be adjusted.
- If you are taking verapamil (for the treatment of high blood pressure), rifampicin (an antibiotic used to treat tuberculosis), cimetidine (medicines used to treat heartburn or stomach ulcers), dolutegravir (an anti-viral), ranolazine (treats heart related chest pain), trimethoprime (antibiotic), isavuconazole (antifungal), rizotinib, olaparib and vandetanib (chemotherapy medicines used for certain types of cancer). These medicines may increase the amount of METFORMIN XR ADCO in your blood, especially if you have reduced kidney function.

METFORMIN XR ADCO with food and drink
Avoid excessive alcohol intake while taking METFORMIN XR ADCO since this may increase the risk of lactic acidosis (see section 2, Warnings and precautions).

Pregnancy and 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 this medicine.
You should not take METFORMIN XR ADCO during pregnancy and breastfeeding.

No data on the influence of fertility is available.

Driving and using machines:
It is not always possible to predict to what extent METFORMIN XR ADCO may interfere with your daily actitivies. You should ensure that you do not engage in activites requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware ofthe measure to which METFORMIN XR ADCO affects you.

METFORMIN XR ADCO on its own does not cause hypoglycaemia (a blood glucose level which is too low). This means that it will not affect your ability to drive or use machines. However, take special care if you take METFORMIN XR ADCO together with other medicines used to treat diabetes that can cause hypoglycaemia (such as

sulphonylureas, insulin, meglitinides). Symptoms of hypoglycaemia include weakness, dizziness, increased sweating, fast heartbeat, vision disorders or difficulty in concentration. Do not drive or use machines if you start to feel these symptoms.

3. How to take METFORMIN XR ADCO

Do not share medicines prescribed for you with any other person:
Always take METFORMIN XR ADCO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

METFORMIN XR ADCO is for oral use only.
METFORMIN 500 XR ADCO:
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 maximum recommended dosage is usually not more than four tablets daily.

METFORMIN 1000 XR ADCO:
The usual starting dose is one tablet daily taken with the evening meal at a maximum recommended dose of 2 tablets per day.
METFORMIN XR 1000 ADCO is intended as maintenance therapy for patients currently treated with either 1 000 mg or 2 000 mg of metformin hydrochloride.

If you take more METFORMIN XR ADCO 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 you have taken more METFORMIN XR ADCO than you should have, you may experience lactic acidosis. Symptoms of lactic acidosis are non-specific such as vomiting, bellyache (abdominal pain) 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 seek immediately medical attention, as lactic acidosis may lead to coma. Stop taking METFORMIN XR ADCO immediately and contact a doctor or the nearest hospital straight away.

If you forget to take METFORMIN XR ADCO

Do not take a double dose to make up for forgotten individual dose. Take the dose as soon as you remember.

4. Possible side effects

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

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

- severe skin reactions such as erythema, a type of hypersensitivity reaction with fever, itching and skin lesions, pruritus (itching) and urticaria (hives or rash of the skin).

These are all very serious side effects. If you have them, you may have had a serious reaction to METFORMIN XR ADCO. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:
Frequent side effects:

- taste disturbance,
- nausea, vomiting, diarrhoea, abdominal pain and loss of appetite. These side-effects occur most frequently during start of therapy and resolve spontaneously in most cases. A slow increase of the dose may also reduce unwanted effects affecting the bowels.

Less frequent side effects:

- decrease of the absorption of a nutrient namely vitamin B_{12} with decrease of blood levels during long-term use of METFORMIN XR ADCO. This decrease in absorption should be considered if you present with megaloblastic anaemia (a deficiency of folic acid or Vitamin B_{12}),
- lactic acidosis (a condition where lactic acid build up in the bloodstream faster than it can be removed) (see section 2, Warnings and precautions).

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 METFORMIN XR ADCO.

5. How to store METFORMIN XR ADCO

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What METFORMIN XR ADCO contains

The active substance is metformin hydrochloride.

The other ingredients for METFORMIN 500 XR ADCO are carboxymethylcellulose (sodium CMC) 9M31F PH, hypromellose K 100M, magnesium stearate.

The other ingredients for METFORMIN 1000 XR ADCO are carmellose sodium, hypromellose K 100M, magnesium stearate, povidone K 90.

What METFORMIN XR ADCO looks like and contents of the pack

METFORMIN 500 XR ADCO:
Prolonged release tablets.
White to off white capsule shaped, biconvex, bevelled edge tablet, with occasionally mottled appearance, debossed with "1001" on one side and plain on other side.

Contents of the pack:

- 10 X 10 prolonged release tablets are packed in clear, transparent, non-toxic PVC/PVDC film on a printed aluminium foil blister pack with a heat seal lacquer.

The blisters are further packed into a carton with a leaflet.

METFORMIN 1000 XR ADCO:
Prolonged release tablets.
White to off white oval, biconvex, bevelled edge, uncoated tablet with occasionally mottled appearance, debossed '1089' on one side and plain on other side.

Contents of the pack:

- 6 x 10 prolonged release tablets are packed in blister strips composed of plain aluminium foil and clear, transparent, non-toxic PVC/PVDC film with text matter printed on dull surface of aluminium (with NC coating) and heat seal lacquer coating on other side (silver coloured).

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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