SCHEDULING STATUS

S3

GLUCONORM 500 (500 mg film-coated tablets)

GLUCONORM 850 (850 mg film-coated tablets)

Metformin hydrochloride

Sugar Free

Read all of this leaflet carefully before you start taking GLUCONORM

- 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.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. (See section 4)
- GLUCONORM 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 GLUCONORM is and what it is used for
2. What you need to know before you take GLUCONORM
3. How to take GLUCONORM
4. Possible side effects
5. How to store GLUCONORM
6. Contents of the pack and other information

1. What GLUCONORM is and what it is used for

GLUCONORM contains metformin, a medicine used to treat diabetes. It belongs to a group of medicines called biguanides.

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 use properly the insulin it produces. This leads to a high level of glucose in your blood. Glucophage helps to lower your blood glucose to as normal a level as possible.

If you are an overweight adult, taking Glucophage over a long period of time also helps to lower the risk of complications associated with diabetes. Glucophage is associated with either a stable body weight or modest weight loss.

GLUCONORM is used to treat type 2 diabetes mellitus, particularly in overweight patients, when dietary management and exercise alone have not been enough to control your blood glucose levels.

- In adults, GLUCONORM may be used on its own or together with other medicines to treat diabetes (medicines taken by mouth or insulin).
- In children over 12 years of age and adolescents with type 2 diabetes, GLUCONORM may be used on its own or together with insulin.

2. What you need to know before you take GLUCONORM

Do not take GLUCONORM

- if you are hypersensitive (allergic) to metformin or any of the other ingredients of GLUCONORM (listed in section 6).
- if you suffer from any type of metabolic acidosis (too much acid is in your body) such as lactic acidosis (see Warnings and Precautions).
- if you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic or if you suffer from diabetic ketoacidosis (a condition in which substances called ‘ketone bodies’ accumulate in the blood, 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 suffer from diabetic pre-coma (dangerously high blood sugar or dangerously low blood sugar).
- if you have kidney failure or kidney dysfunction.

- if you suffer from conditions which may alter kidney function such as:
  - dehydration (if you lost too much water from your body, due to long-lasting or severe diarrhoea, or if you have vomited several times in a row).
  - severe infection.
  - shock (severe problems with your blood circulation).
  - if you need to have an examination such as X-ray or scan involving the injection of contrast agents that contain iodine into your bloodstream.
- if you suffer from acute or chronic disease which may cause low levels of oxygen in your body tissues (hypoxia) such as:
  - heart failure or recent heart disease.
  - respiratory failure (difficulty in breathing – if your lungs cannot supply enough oxygen to your organs).
  - shock (severe problems with your blood circulation that causes reduced oxygen delivery or increased oxygen consumption).
  - inflammation of the pancreas.
- if you have liver problems.
- if you drink a lot of alcohol.
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with GLUCONORM

• Risk of lactic acidosis

GLUCONORM may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or 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 any of the above apply to you, talk to your doctor for further instructions.

Stop taking GLUCONORM for a short time 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. Talk to your doctor for further instructions.

Stop taking GLUCONORM 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

Lactic acidosis is a medical emergency and must be treated in a hospital.

• GLUCONORM on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take GLUCONORM together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, insulin, meglitinides), there is a risk of hypoglycaemia. If you experience symptoms of hypoglycaemia such as weakness, dizziness, increased sweating, fast heart beating, visions disorders or difficulty in concentration, it usually helps to eat or drink something containing sugar.

During treatment with GLUCONORM, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if you have worsening kidney function.

• You should continue your diet with a regular distribution of carbohydrate intake during the day. Overweight patients should continue their energy-restricted diet.

• Make sure you ask your doctor for advice if you:

- need to have an examination such as X-ray or scan involving the injection of contrast medicines that contain iodine into your bloodstream
- need to have major surgery

You must stop taking GLUCONORM for a certain period of time before and after the examination or the surgery. Your doctor will decide when you must stop and when to restart your treatment with GLUCONORM and whether you need any other treatment for this time. It is important that you follow

your doctor's instructions precisely.

• If you are on long-term GLUCONORM treatment, your Vitamin B_{12} levels should be checked at least once a year since GLUCONORM may cause mal absorption of Vitamin B_{12}, which may result in a disease called megaloblastic anaemia (lack of enough red blood cells to carry adequate oxygen to your body's tissue which can make you feel weak and tired) (see Possible side-effects).

Children and adolescents

GLUCONORM can be used in children from 12 years of age and adolescents. The diagnosis of type 2 diabetes mellitus must be confirmed before treatment with GLUCONORM is initiated.

Other medicines and GLUCONORM

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

Tell your doctor if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of GLUCONORM. It is especially important to mention if you are taking or have been given any the following:

- an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan.
- medicines which increase urine production (diuretics).
- 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).
- beta-2 agonists such as salbutamol or terbutaline (used to treat asthma).
- glucocorticoids (systemic and local routes) used to treat a variety of conditions, such as severe inflammation of the skin or in asthma.
- tetracosactide, which is a diagnostic test to find out if the adrenal glands, small glands next to the kidneys, are working as well as they should.
- danazol, a medicine used to treat endometriosis and the symptoms of fibrocystic breast disease in

women.

- high doses of chlorpromazine, a medication used to manage and treat schizophrenia, bipolar disorder, and acute psychosis.
- medicines used to treat clotting (anticoagulants).
- other medicines used to treat diabetes (such as sulphonylureas)
- medicines that may change the amount of GLUCONORM in your blood (such as verapamil, rifampicin; cimetidine, dolutegravir, ranolazine, trimethoprime, vandetanib, isavuconazole, crizotinib, olaparib).

GLUCONORM with alcohol

Avoid consumption of alcohol and alcohol-containing medicine while taking GLUCONORM since this may increase the risk of lactic acidosis (see 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 this medicine. GLUCONORM is not recommended in pregnancy and lactation.

Driving and using machines

It is not always possible to predict to what extent GLUCONORM may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which GLUCONORM affects you.

GLUCONORM 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 GLUCONORM together with other medicines 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 GLUCONORM

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

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

GLUCONORM cannot replace the benefits of a healthy lifestyle. Continue to follow any advice about diet that your doctor has given you and get some regular exercise.

The usual dose in adults:

Initially, one 500 mg tablet three times a day, or 850 mg or 1 000 mg twice a day, with or after food.

After 10 to 15 days the dose may be changed according to blood glucose measurements. You will feel better within a few days, but it is not unusual for the full effect to be delayed for up to two weeks. The maximum daily dose is 3000 mg taken as 3 divided doses.

The usual dose in children and adolescents:

GLUCONORM can be used in children from 12 years of age and adolescents. The usual starting dose is 500 mg or 850 mg once daily, given during meals or after meals. After 10 to 15 days the dose may be adjusted on the basis of blood glucose measurements. The maximum recommended dose is 2000 mg daily, taken as 2 or 3 divided doses.

The usual dose in the elderly:

GLUCONORM dose in the elderly should be adjusted based on renal function.

If you take insulin too, your doctor will tell you how to start GLUCONORM.

Monitoring

• Your doctor will perform regular blood glucose tests and will adapt your dose of GLUCONORM to your blood glucose levels. Make sure that you talk to your doctor regularly. This is particularly important for children and adolescents or if you are an older person.

• Your doctor will also check at least once a year how well your kidneys work. You may need more frequent checks if you are an older person or if your kidneys are not working normally.

How to take GLUCONORM

• Swallow the tablet whole with a drink of water.

• Take GLUCONORM with or after a meal. This will avoid you having side effects affecting your digestion.

• If you take one dose a day, take it in the morning (breakfast).

• If you take two divided doses a day, take them in the morning (breakfast) and evening (dinner).

• If you take three divided doses a day, take them in the morning (breakfast), at noon (lunch) and in the evening (dinner).

• Try to take your tablet at the same time each day.

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

If you take more GLUCONORM than you should

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

If you have taken more GLUCONORM that 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.

If you forget to take GLUCONORM

Do not take a double dose to make up for individual forgotten doses. Take the next dose at the usual time.

4. Possible side effects

GLUCONORM can have side effects.

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

healthcare provider for advice.

If any of the following happens, stop taking GLUCONORM 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.

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

- lactic acidosis. This is a very rare but serious complication particularly if your kidneys are not working properly. Symptoms of lactic acidosis are non-specific (see Warning and precautions).

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:

- digestive problems, such as feeling sick (nausea), being sick (vomiting), diarrhoea, bellyache (abdominal pain) and loss of appetite. These side effects most often happen at the beginning of the treatment with GLUCONORM and resolve spontaneously in most cases. It helps if you spread the doses over the day and if you take GLUCONORM with or straight after a meal. A slow increase of the dose may also improve gastrointestinal tolerability,
- anorexia
- changes in taste, metallic taste,
- decreased or low vitamin B_{12} levels in the blood (symptoms may include extreme tiredness, nausea, weight loss, irritability, pins and needles, swollen and inflamed tongue, mouth ulcers or visual disturbances). Your doctor may arrange some tests to find out the cause of your symptoms because some of these may also be caused by diabetes or due to other unrelated health problems.

Less frequent side effects:

- abnormalities in liver function tests or hepatitis (inflammation of the liver; this may cause tiredness, loss of appetite, weight loss, with or without yellowing of the skin or whites of the eyes). If this happens to you, stop taking GLUCONORM and talk to your doctor,
- skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives),
- lack of enough red blood cells to carry adequate oxygen to your body's tissue which can make you feel weak and tired (megaloblastic anaemia),
- low blood sugar (hypoglycaemia).

Side effects with an unknown frequency:

- constipation,
- body produces high levels of blood acids called ketone (ketoacidosis),
- high levels of ketones (which occur when cells are broken down for energy) are present in the urine (ketonuria).

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. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. Side effects must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to vigilance@unicornpharma.co.za. By reporting side effects, you can help provide more information on the safety Gluconorm.

5. How to store GLUCONORM

Store all medicines out of reach of children.

Store in a cool (at or below 25 °C), dry place.

Protect from light and moisture.

The blister should not be removed from the carton until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 GLUCONORM contains

- The active substance in each **GLUCONORM 500** film-coated tablet is 500 mg of metformin hydrochloride equivalent to 390 mg metformin.
- The active substance in each GLUCONORM 850 film-coated tablet is 850 mg of metformin hydrochloride equivalent to 663 mg metformin.
- The other ingredients are:

  Povidone (Kollidon 90 F)

  Magnesium Stearate

  Hypromellose

  Macrogol

  Sugar free

What GLUCONORM looks like and contents of the pack

GLUCONORM 500 Tablets

White, biconvex, circular shaped film-coated tablets, with “A” debossed on one side and “60” debossed on the other side.

100’s: Printed unit cartons containing 10 blister packs (composed of transparent PVC and silver coloured aluminium foil backing) of 10 tablets each.

GLUCONORM 850 Tablets

White, biconvex, circular shaped film-coated tablets, with “A” debossed on one side and “61” debossed on the other side.

30’s: Printed unit cartons containing 3 blister packs (composed of transparent PVC and silver coloured aluminium foil backing) of 10 tablets each.
60’s: Printed unit cartons containing 6 blister packs (composed of transparent PVC and silver coloured

aluminium foil backing) of 10 tablets each.

Holder of Certificate of Registration

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