

GLUCOXIT XR TABLET

Metformin Hydrochloride (750mg)

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What Glucoxit XR is used for

Glucoxit XR Tablet contain the active ingredient metformin hydrochloride and belong to a group of medicines called biguanides, used in the treatment of diabetes.

Glucoxit XR is used to delay the onset and treat Type 2 (non-insulin dependent) diabetes mellitus when diet and exercise changes alone have not been enough to control blood glucose (sugar).

How Glucoxit XR works

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. Glucoxit XR makes the body more sensitive to insulin and helps return to normal the way your body uses glucose. Glucoxit XR is associated with either a stable body weight or modest weight loss.

Glucoxit XR Tablet are specially made to release the drug slowly in your body and therefore are different to many other types of tablets containing metformin.

Before you take Glucoxit XR

- When you must not take it

Do not take Glucoxit XR if:

- you are allergic to metformin or to any of the other ingredients which are listed later on in the leaflet.
- If you have severely reduced kidney function.
- If you have lactic acidosis [too much lactic acid in the blood (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 of acidosis may include stomach pain, abnormal breathing and drowsiness (if severe).
- you have long-term kidney or liver problems.
- you have had serious complications with your diabetes or other serious conditions which resulted in rapid weight loss, nausea, vomiting or dehydration.
- you have a severe infection or have recently suffered a severe injury.
- you have been treated for heart problems or have recently had a heart attack or have severe circulatory problems or breathing difficulties.
- you are a heavy drinker of alcohol.
- you are under 18 years of age.

- Before you start to take it

Risk of lactic acidosis

Glucoxit XR Tablet 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 Glucoxit XR Tablet for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking Glucoxit XR Tablet 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

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

During treatment with Glucoxit XR Tablet, 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.

- If you have severely reduced kidney function, tell the doctor that you are taking Glucoxit XR Tablet as you may need to stop temporarily.
- If you have serious heart failure, tell the doctor that you are taking Glucoxit XR Tablet as you may need to stop taking it.
- If you are above 75 years old, tell the doctor that you are taking Glucoxit XR Tablet as it may not be helpful for your condition.
- If you are going for a imaging procedure that involves contrast media with iodine, tell the doctor that you are taking

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Glucoxit XR Tablet as you may need to stop temporarily.

- Tell your doctor if you are going to have an operation under anaesthesia, as you may need to stop taking Glucoxit XR Tablet for a couple of days before and after the procedure.
- You should continue to follow any dietary advice that your doctor has given you and you should make sure that you eat regularly throughout the day. Do not stop taking this medicine without speaking to your doctor.

If you are unsure of any situation with respect to you, please talk to a doctor or a pharmacy before you take Glucoxit XR Tablet.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

If you are taking any of the following medicines, your blood sugar levels may need to be checked more often and your dose adjusted:

- Steroids such as prednisolone, mometasone, beclometasone.
- Diuretics (water tablets) such as furosemide.
- Sympathomimetic medicines including epinephrine and dopamine used to treat heart attacks and low blood pressure. Epinephrine is also included in some dental anaesthetics.

How to take Glucoxit XR

Your doctor may prescribe Glucoxit XR for you to take on its own, or in combination with other oral antidiabetic medicines or insulin.

Always take Glucoxit 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.

- How much to take

Usually, you will start treatment with 500mg Metformin Extended-Release daily. After you have been taking Glucoxit XR for about 2 weeks, your doctor may measure your blood sugar and adjust the dose. The maximum daily dose is 2000mg of Glucoxit XR daily.

- When to take it

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.

- How long to take it

The treatment duration is not limited and depends on the severity of the disease. The duration of therapy will be determined by your doctor. Stopping treatment must be discussed with your doctor.

- If you forget to take it

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 take too much (overdose)

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 and this is a medical emergency requiring treatment in hospital.

While you are taking Glucoxit XR

- Things you must do

Pregnancy and breast-feeding

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

- Things you must not do

You should avoid drinking alcohol and using alcohol-containing medicines as this will increase the risk of lactic acidosis.

- Things to be careful of

Glucoxit XR 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 Glucoxit XR taken with other antidiabetic medicines can cause hypos, so in this case you should take extra care when driving or operating machinery.

Side effects

Like all medicines, Glucoxit XR can cause side effects, although not everybody gets them. Possible side effects are listed by frequency as follows:

Very common:

- Nausea, vomiting, diarrhea, stomach ache and loss of appetite. These undesirable effects occur most frequently during the start of treatment and very likely to go away by itself. Your doctor may increase the dose slowly if you feel uncomfortable.

Common side effects (may affect up to 1 in 10 people:

- Taste disturbance
- Decreased or low vitamin B12 levels in the blood (symptoms may include extreme tiredness (fatigue), a sore and red tongue (glossitis), pins and needles (paraesthesia) or pale or yellow skin). 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

Very rare

- The level of vitamin B12 may be decreased if you have been taking metformin for long term.
- Skin discomfort such as itchiness and redness

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug

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Reaction Monitoring by visiting the website nppra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal

- Storage

Keep Glucosit XR Tablet out of the reach and sight of children. Do not use them after the expiry date that is printed on the pack after "Use before:". The expiry date refers to the last day of that month. Protect from moisture, freezing and excessive heat. Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

- Glucosit XR Tablet 750mg: Capsule shape, white to off white, biconvex, with '750' marking on one side and plain on the other side, uncoated tablet.

- Ingredients

- Active Ingredients:
Each tablet contains 750 milligrams of the active ingredient metformin hydrochloride.
- Inactive ingredients:
Sodium
Carboxymethylcellulose,
Hydroxypropyl
Methylcellulose, Colloidal
Silicon Dioxide, Magnesium
Stearate and Purified Water.

MAL number

Glucosit XR Tablet 750mg:
MAL23086013AZ

Product Manufacturer

Duopharma Manufacturing (Bangi)
Sdn. Bhd.
Lot No. 2 & 4, Jalan P/7, Section 13,

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Product Registration Holder

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