

What is in this leaflet

1. What Glucoxit Tablet 500mg is used for
2. How Glucoxit Tablet 500mg works
3. Before you use Glucoxit Tablet 500mg
4. How to use Glucoxit Tablet 500mg
5. While you are using it
6. Side effects
7. Storage and Disposal of Glucoxit Tablet 500mg
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What Glucoxit Tablet 500mg is used for

Glucoxit Tablet 500mg contains metformin hydrochloride.

Metformin hydrochloride is used in the treatment of non-insulin-dependent diabetes mellitus (NIDDM) to control high blood sugar that cannot be controlled adequately by diet management, exercise or weight reduction. The medicine can be used alone or in combination with other medications.

How Glucoxit Tablet 500mg works

Metformin hydrochloride increases the sensitivity of target cells to insulin (hormone which regulates the amount of sugar in the blood) to reduce blood sugar level. Since metformin hydrochloride does not stimulate the secretion of insulin, insulin must be present for the medicine to work properly.

Before you use Glucoxit Tablet 500mg

- When you must not use it

Do not take Glucoxit Tablet 500mg:

- 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 very low kidney function (GFR <30 mL/min)
- You have sudden metabolic acidosis (A condition when your body produces too much acid or when the kidneys are not removing enough acid from the body)
- You have allergy to Metformin
- You have any medical condition that requires close blood sugar control, such as severe burns, dehydration, diabetic coma, diabetic ketoacidosis, hyperosmolar non-ketotic coma, severe infection, major surgery and severe trauma.
- You are going to undergo medical examinations using contrast media such as angiography (x-ray imaging to examine blood vessels) and pyelography (x-ray imaging to examine pelvis and urinary tract).

Do not take this medicine after the expiry date printed on the outer package.

If you are unsure whether you should take this medicine, consult your pharmacist or doctor.

- Before you start to use it

Risk of lactic acidosis

Glucoxit Tablet 500mg 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 Tablet 500mg 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 Glucoxit Tablet 500mg 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 Tablet 500mg 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.

Inform your pharmacist or doctor if you have any medical condition (such as thyroid problems and kidney disease)

Inform your pharmacist or doctor if you have allergies to any medicine or food.

Inform your pharmacist or doctor if you are pregnant or breastfeeding.

- Taking other medicines

Inform your pharmacist if you are taking any medicine and supplement, including those from pharmacy, supermarket or health food shop. You should pay extra attention to the following:

- Alcohol
- Cimetidine
- Amiloride, calcium channel blockers (such as amlodipine, nifedipine), digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, vancomycin have potential to increase plasma concentration of metformin or interfere with its excretion.

How to use Glucoxit Tablet 500mg

Follow all directions given to you by your pharmacist or doctor carefully. They may differ from the information listed below.

- How much to use

Adult: 500mg three times daily with meals, gradually increased if necessary to a maximum of 3g daily.

Child: Please consult your doctor.

Elderly: 500mg three times daily with meals, gradually increased if necessary to a maximum of 3g daily. For sensitive individual, lower initial dose may be needed. Maximum dose is not advisable.

Kidney Failure: Kidney function should be assessed before initiation of treatment with Glucosit Tablet 500mg and at least annually thereafter. The dose may be adjusted based on kidney function.

- When to use it

To be taken with/after meals

Use as directed by your doctor or pharmacist.

- How long to use it

The duration of treatment should be determined by your doctor. You are not advised to stop taking Glucosit Tablet 500mg or change its dose without consulting your doctor.

- If you forget to use it

If you are taking Glucosit Tablet 500mg regularly, take the missed dose as soon as you remember and continue taking the medicine at the usual times. If it is almost time for your next dose, skip the missed dose and take the medicine at your next regular schedule. Do not take double dose to make up for your missed dose.

- If you use too much (overdose)

Overdose of metformin hydrochloride put you at risk of:

- Lactic Acidosis (stomach discomfort/pain, muscle pain, breathing problem, feeling weak)
- Low blood sugar (Fast heartbeat, lightheadedness, blurred vision, nervousness or anxiety)

Seek medical attention immediately if you think you have taken too much Glucosit Tablet 500mg.

While you are using it

- Things you must do

Take the medicine as per instruction from your doctor or pharmacist. Discuss with your doctor if you think the medicine is too weak (not effective) or too strong (intolerable side effects). Your doctor will assess your condition and decide further action.

Inform your doctor if you think you might be or are planning to get pregnant. Inform your doctor if you are planning to breast-feed your baby.

- Things you must not do

Do not drink alcohol when you are taking this medicine regularly. Excessive/long-term drinking of alcohol may increase blood lactate concentration or increase the risk of low blood sugar.

Do not take other medications and supplements without consulting your doctor or pharmacist.

Do not take this medicine to treat any other conditions without consulting your doctor. Do not give this medicine to anyone else, even if they have the same condition as you.

- Things to be careful of

Lactic acidosis (buildup of lactate, resulting in low blood pH): A very rare but serious complication, most often occurs at sudden worsening of kidney function or other medical conditions. Some common symptoms are stomach discomfort/pain, muscle pain, breathing problem, feeling weak. In case of suspected symptoms, you should stop taking the medicine and seek immediate medical attention.

Low blood sugar: Low blood sugar does not usually occur with the use of metformin hydrochloride alone, unless other factors are present, such as unusual fasting, use of other diabetes medication, overdose or other medical conditions. Some common symptoms are fast heartbeat, lightheadedness, blurred vision, nervousness or anxiety.

Side effects

Inform your pharmacist or doctor if you do not feel well after taking Glucosit Tablet 500mg. Some common side effects are as follows:

- Loss of appetite
- Indigestion
- Stomach bloating
- Headache
- Metallic taste
- Nausea and vomiting
- Weight loss

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

• 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.

Do not be alarmed by the list of side effects. You may not experience any of them.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Glucosit Tablet 500mg

- Storage

Keep the medicine in a dry place below 30°C. Protect from light. Keep out of reach of children.

- Disposal

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

Product Description

- What it looks like

A 11mm, round, bi-convex, scored on one side, marked 'MET, white tablets.

- Ingredients

Active ingredients

Each tablet contains Metformin Hydrochloride 500mg.

Inactive ingredients

- Pregelatinised starch
- Povidone K90
- Povidone K30
- Crospovidone
- Magnesium stearate
- Purified Water

- MAL number

MAL 19870410AZ

Manufacturer

DUOPHARMA (M) SDN BHD

Lot 2599, Jalan Seruling 59, Kawasan 3,
Taman Klang Jaya, 41200 Klang,
Selangor, Malaysia.

Product Registration Holder

DUOPHARMA (M) SDN BHD

Lot 2599, Jalan Seruling 59, Kawasan 3,
Taman Klang Jaya, 41200 Klang,
Selangor, Malaysia.

Date of Revision

08/02/2024

Serial Number

NPRA(R2/2)240322/1234