

GLUCOMIN-G 500MG/2.5MG TABLET

GLUCOMIN-G 500MG/5MG TABLET

Metformin Hydrochloride 500mg/Glibenclamide 2.5mg

Metformin Hydrochloride 500mg/Glibenclamide 5mg

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What is GLUCOMIN-G use for

Metformin and Glibenclamide is a combination of two oral diabetes medicines that help control blood sugar levels. GLUCOMIN-G is indicated as second-line therapy when diet, exercise and initial treatment with a sulfonylurea (Glibenclamide) or metformin do not result in controlling the patients' glucose level in the blood of patients with type 2 diabetes patients. This medication is not for treating the type 1 diabetes.

How GLUCOMIN-G works

Metformin may act via 3 mechanisms;

- By reducing hepatic glucose production (net release of glucose from the liver).
 - By inhibiting synthesizing of glucose and breakdown of glycogen in muscle,
 - By increasing insulin sensitivity, improving peripheral glucose uptake and utilization and by delaying intestinal glucose absorption.
- Glibenclamide causes acute lowering of blood glucose by stimulating the release of insulin by the pancreas.

Before you take GLUCOMIN-G

- When you must not use it

- If you are allergic (hypersensitive) to Glibenclamide, metformin hydrochloride or any of the other ingredients of Glucomin-G.
- If you have kidney or liver function problems.
- Stop temporarily, if you need to have any type of x-ray or CT scan using a dye that is injected into your veins or if you need surgery.
- If you suffer from type 1 diabetes mellitus (i.e. insulin-dependent) or if you have severe loss of diabetes control with either pre-coma or ketosis (a condition caused by substances called 'ketone bodies' accumulating in the blood; you may notice that your breath has an unusual fruity odour)
- If you have a severe infection (for example an infection of the air passages or an urinary tract infection).
- If you are breast-feeding.
- If you drink alcohol excessively (either every day or only from time to time)
- 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).
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blood and which can lead to diabetic pre-coma. Symptoms of acidosis may include stomach pain, abnormal breathing and drowsiness (if severe).

- Before you start to use it.

Risk of lactic acidosis

GLUCOMIN-G 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 GLUCOMIN-G 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 GLUCOMIN-G 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.

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During treatment with Glucomin-G 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 doctor if you have

- Heart disease or a history of heart attack or stroke
- If you have liver or kidney disease, congestive heart failure, a severe infection, dehydrated, or if you drink large amounts of alcohol.
- If you are pregnant or planned to become pregnant during treatment
- You must stop taking Glucomin-G for a certain period of time before and after you are pregnant or plan to become pregnant the examination or the surgery. Your doctor will decide whether you need any other treatment for this time. It is important that you follow your doctor's instructions precisely.

Risk of lactic acidosis

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Stop taking Glucomin-G 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

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Stop taking Glucomin-G 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.

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- stomach ache (abdominal pain)
- muscle cramps
- a general feeling of not being well with severe tiredness
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Lactic acidosis is a medical emergency and must be treated in a hospital.

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

Taking other medicines

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

While taking Glucomin-G, you should not use any of the following medicines:

- Miconazole (used to treat certain yeast infections)
- Iodinated contrast agents(used for X-ray or scan)

Special precautions may be required if you take Glucomin-G and any of the following medicines at the same time:

- Angiotensin-converting enzyme inhibitors (used to treat variety of cardiovascular conditions, such as high blood pressure, and some other diseases)

- Diuretics (used to remove water from the body by increasing urine production)
- Beta-blockers (used to treat a high blood pressure and some other cardiovascular diseases)
- Beta-2 agonists (used to treat asthma, such as ritodrine, salbutamol or terbutaline)
- Bosentan (used to treat pulmonary hypertension)
- Corticosteroids and tetracosactide (used to treat a variety of conditions, e.g severe inflammation of the skin or in asthma)
- Certain painkillers (non-steroidal anti-inflammatory drugs, such as phenylbutazone)
- Fluconazole (used to treat certain yeast infections)
- Chlorpromazine (a medicine used to treat mental illness)
- Desmopressin (generally used to reduce urine production)
- Danazol (used to treat *endometriosis*, a condition where the tissue lining of the uterus is formed outside the uterus.)

Special precautions may include self-monitoring of blood glucose, blood tests and modification of dosage.

Avoid medicines containing alcohol as alcohol can increase certain side-effects such as lactic acidosis and lower blood sugar level.

How to take GLUCOMIN-G

How much to take it

Take exactly the amount the doctor told you. If you are not sure please check with your doctor or pharmacist. Follow the directions on your prescription label. The recommended starting dose is 500mg/2.5 mg or 500mg/5 mg twice daily with meals.

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Swallow the tablet whole with a glass of water.

- When to take it

GLUCOMIN-G must be taken with meals.

- How long to take it

Your doctor will give you an instruction how long you can take this medicine.

If you forget to take it

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take as soon as you remember it and then take the next dose at the right time

If you take too much (overdose)

You may experience an increase in side effects and its severity. Contact your doctor if you take more tablets than you should do.

GLUCOMIN-G overdose can cause life-threatening hypoglycemia. Overdose may also cause lactic acidosis.

While you are using GLUCOMIN-G

- Things you must not do

Avoid drinking alcohol. It can lower your blood sugar and may increase the risk of lactic acidosis while you are taking GLUCOMIN-G

- Things you must do

- Your blood sugar will need to be checked often, and you may need other blood tests with your doctor. Visit your doctor regularly. Know the signs of low blood sugar (Hypoglycemia) and how to recognize them: headache, hunger, weakness, sweating, tremor, irritability, or trouble concentrating.

- Keep a source of sugar available in case you have symptoms of low blood sugar. Sugar sources include orange juice, glucose gel, candy, or milk.

If you travel, exercise more than usual, drink alcohol, or skip meals. These things can affect your glucose levels and your dose needs may also change. Ask your doctor how to adjust your dose if needed. Do not change your medication dose or schedule without your doctor's advice.

Side effects

All medicines including GLUCOMIN-G can cause allergic reactions. You should contact your doctor immediately if you experience any of the following symptoms after taking GLUCOMIN-G:

- Taste disturbance
- Abnormal urea(crystalline compound which soluble in water formed from ammonia and carbon dioxide and is usually found in urine) and creatinine(a waste product from meat protein in the diet and from the muscles of the body . It will be removed from the blood by the kidneys) levels in the blood, which show changes in the way the kidneys are working.
- A crisis forms of porphyria [porphyria hepatica (caused by a disturbance in liver metabolism such as occurs following hepatitis, poisoning by heavy metals and certain enemas) or porphyria cutanea (patient develop liver disease and rashes on parts of their bodies exposed to the sun e.g. On the knuckles or face)] this may occur in patients with particular enzyme disorder.

- Reduction in the number of white blood cells, which makes infections more likely.
- Reduction in blood platelets (cells which help in blood cloth)which increases risk of bleeding or bruising
- Skin reactions including itching, hives, and skin rash.
- Lactic acidosis (too much acid in the body) due to the buildup of lactic acid in the body. This is very rare, but serious complication, particularly if your kidneys are not working properly. The risk of lactic acidosis is also increased with uncontrolled diabetes, prolonged fasting or alcohol intake.
- Severe reduction in the number of white blood cells (agranulocytosis), anemia due to extensive breakdown of the red blood cells (haemolytic anaemia), lack or insufficient number of new blood cells produced by the bone marrow (bone marrow aplasia) and very severe reduction in the number of blood cells (pancytopenia, this can make the skin look pale, can cause weakness or breathlessness, can increase the risk of bleeding or bruising or make infections more likely)
- Abnormalities in liver function tests or inflammation of the liver (hepatitis; this can 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 Glucomin-G and talk to your doctor.
- Excessive skin sensitivity to sun, serious allergic reactions of the skin or blood vessels.
- Intolerance to alcohol (with symptoms such as general feeling discomfort, redness of face, rapid heartbeat)
- Decreased vitamin B12 levels in the blood.

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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.

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

Storage and disposal of GLUCOMIN_G

Storage

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

GLUCOMIN-G 500MG/2.5MG:

A beige coloured oblong shaped film coated tablet

GLUCOMIN-G 500MG/5MG:

A yellow coloured oblong shaped film coated tablet

- Ingredients
- Active ingredient

Metformin Hydrochloride,
Glibenclamide

- Inactive ingredients

Microcrystalline Cellulose, Povidone,
Isopropyl Alcohol Purified water,
Croscarmellose sodium, Magnesium stearate,
Hydroxypropylmethylcellulose
Polyethylene Glycol
Propylene Glycol
Magnesium stearate
Talc
Titanium Dioxide
Yellow Iron Oxide
Red Iron Oxide
Isopropyl alcohol
Purified water

MAL NO

GLUCOMIN-G 500MG/2.5MG:

MAL14125124AZ

GLUCOMIN-G 500MG/5MG

MAL14125166AZ

Manufacturer and Product Registration Holder

Noripharma Sdn. Bhd. (792633-A)

Lot 5030 Jalan Teratai,

5 1/2 Mile off Jalan Meru,

41050 Klang,

Selangor Darul Ehsan, Malaysia.

Date of Revision

15/04/2024

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