

GLUCOMIN 500MG TABLET

Metformin Hydrochloride 500mg

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What GLUCOMIN 500 is used for?

Metformin is used for the sort of diabetes called Type 2 diabetes or non-insulin-dependent diabetes mellitus.

GLUCOMIN 500 is used to treat patients with type 2 diabetes (also called 'non-insulin dependent diabetes') when diet and exercise alone have not been enough to control your blood glucose levels. It is used particularly in overweight patients.

Adults can take GLUCOMIN 500 on its own or together with other medicines to treat diabetes (medicines taken by mouth or insulin). Children 10 years and over and adolescents can take GLUCOMIN 500 on its own or together with insulin

How GLUCOMIN 500 works

- In type 2 diabetes, there is too much sugar (glucose) in your blood. This is because your body does not make enough insulin or because it makes insulin that does not work properly.
- Insulin is a hormone that allows your body tissue to take glucose

from the blood and use it for energy or for storage for future use.

- Metformin works by improving the sensitivity of your body to insulin. It helps your body to use glucose in the normal way again

Before you use GLUCOMIN 500

When you must not take it

Do not take Glucomin 500 :

- 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 are allergic (hypersensitive) to metformin or any of the other ingredients. you have recently had a heart attack or any other heart problems
- you have liver or kidney problems
- you have recently had a severe infection, injury or trauma (shock)
- you are dehydrated
- you are a heavy drinker of alcohol (more than 21 units a week for a man or 14 units a week for a woman). A unit is equivalent to a small glass of wine, one shot or half a pint of beer.

- you are pregnant, planning to get pregnant or are breast-feeding
- Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking metformin.

Before you start to take it

Take special care and check with your doctor or pharmacist before taking metformin if:

- You are elderly
- You are on a very low calorie diet (less than 1000 calories a day) or are fasting. This could increase the chances of you getting a very rare, but serious side effect called lactic acidosis.

Risk of lactic acidosis

GLUCOMIN 500 During treatment with 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 500 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 GLUCOMIN 500 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

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- 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 GLUCOMIN 500, 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.

Operations and tests while taking metformin

- The amount of sugar in your blood or urine should be checked regularly. Your doctor will also check your kidneys are working properly. This should be done at least once a year (more often if you are elderly or have kidney problems).
- If you are going to have an X-ray, tell your doctor you are taking metformin. If this involves having a dye injected, you must stop taking metformin.
- If you are going to have an operation that needs a general anaesthetic, tell your doctor you are taking metformin before the operation. Your doctor may stop you taking metformin for a couple of days before and after the operation

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicine. This includes medicines obtained without a prescription, including herbal medicines. This is because metformin can affect the way some other medicines work. Also, some medicines can affect the way metformin works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines for high blood pressure (hypertension) such as water tablets (diuretics), ACE inhibitors (such as enalapril)
- Medicines for asthma such as salbutamol or formoterol (beta-2-agonists)
- Medicines used for inflammation called steroids

How to take GLUCOMIN 500

How much to take

Adults with normal kidney function (GFR ≥ 90 mL/min) usually start with 500 mg or 850 mg GLUCOMIN 500 two or three times a day. The maximum daily dose is 3000 mg taken as 3 divided doses. If you take insulin too, your doctor will tell you how to start GLUCOMIN 500.

Patient w/ renal impairment (stage 2)

Max: 3,000 mg daily in 2-3 divided dose, (stage 3a) Max: 2,000 mg daily in 2-3 divided dose, (stage 3b) Max: 1,000 mg daily in 2-3 divided doses

When to take it

Try to take your medicine at the same time each day so that it becomes part of your daily routine.

How long to take it•

Keep taking metformin until your doctor tells you to stop. Do not stop taking metformin just because you feel better. If you stop your illness may get worse.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, with your next meal. However, if it is time for your next dose, do not take the missed dose.

Take only a single dose as usual.

- Do not take a double dose to make up for a forgotten dose

If you take too much (overdosage)

you have taken more GLUCOMIN 500 than you should have, you may experience lactic acidosis. Symptoms of lactic acidosis are vomiting, bellyache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. If this happens to you, you may need immediate hospital treatment, as lactic acidosis may lead to coma. Contact a doctor or the nearest hospital straight away. The doctor may use a method called 'haemodialysis' to remove the extra lactate and metformin from your body.

While you are using GLUCOMIN 500

Things you must do

- You need to eat carbohydrates regularly throughout the day. If your doctor has given you advice on your diet, you need to continue to follow this.
- Do not drink large amounts of alcohol or take medicines containing alcohol while taking metformin

Things you must not do

Do not take this medicine and talk to your doctor if you are pregnant, planning to get pregnant or are breast-feeding

Things to be careful of

Driving and using machines: GLUCOMIN 500 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.

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However, take special care if you take GLUCOMIN 500 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 heart beat, vision disorders or difficulty in concentration. Do not drive or use machines if you start to feel these symptoms

Side effects

Like all medicines, GLUCOMIN 500 can cause side effects, although not everybody gets them. The following side effects may occur:

Very common side effects (in more than 1 in 10 people)

- 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 GLUCOMIN 500. It helps if you spread the doses over the day and if you take GLUCOMIN 500 with or straight after a meal. If symptoms continue, stop taking GLUCOMIN 500 and talk to your doctor.

Common side effects (in less than 1 in 10 people)

- changes in taste.

Very rare side effects (in less than 1 in 10,000 people)

- lactic acidosis. This is a very rare but serious complication

particularly if your kidneys are not working properly.

Symptoms of lactic acidosis are vomiting, bellyache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. If this happens to you, you may need immediate hospital treatment, as lactic acidosis may lead to coma. Stop taking GLUCOMIN 500 immediately and contact a doctor or the nearest hospital straight away.

- 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 GLUCOMIN 500 and talk to your doctor.
- Skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives).
- low vitamin B12 levels in the blood.

Limited data in children and adolescents showed that adverse events were similar in nature and severity to those reported in adults.

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 You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website <http://nptra.moh.gov.my> (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and disposal of GLUCOMIN 500

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

A white to off white round shaped film coated tablet with breaking line on one side.

Ingredients

Active ingredient

- Metformin hydrochloride

Inactive ingredients

- Corn starch
- Magnesium stearate
- Hydroxylpropyl methylcellulose
- Polyethylene Glycol
- Propylene Glycol
- Talc
- Titanium dioxide
- Isopropyl alcohol
- Purified water

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- MAL number
MAL20116009AZ

**Manufacturer and Product
Registration Holder:**
Noripharma Sdn. Bhd.
Lot 5030, Jalan Teratai,
5 ½ Mile off Jalan Meru,
41050 Klang, Selangor.

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15/3/2024

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