

Glucomin 850mg Tablet

Metformin Hydrochloride 850mg

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What Glucomin 850 is used for?

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

How Glucomin 850 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 850

When you must not take it

- 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 severe circulation problems or difficulty in breathing
- you have liver or kidney problems
- you have had serious problems with your diabetes in the past called diabetic ketoacidosis. When you have this you lose weight quickly, feel sick (nausea) or are sick (vomiting).
- you have recently had a severe infection, injury or trauma (shock)
- you are dehydrated

- you are going to have an X-ray where you will be injected with a dye
- 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
- 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).

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 850 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 applies to you, talk to your doctor for further instructions.

Stop taking Glucomin 850 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 <product name> 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 Glucomin 850 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

If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, you must stop taking Glucomin 850 before or at the time of injection. Your doctor

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will decide when you must stop and when to restart your treatment with Glucomin 850.

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 Glucomin 850. It is especially important to mention the following:

- 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).
- corticosteroids (used to treat a variety of conditions, such as severe inflammation of the skin or in asthma).
- medicines that may change the amount of Glucomin in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib).
- other medicines used to treat diabetes. Glucomin with alcohol
Avoid excessive alcohol intake while taking Glucomin since this may increase the risk of lactic acidosis.

Glucomin with alcohol

Avoid excessive alcohol intake while taking Glucomin 850 since this may increase the risk of lactic acidosis

Pregnancy and breast-feeding

During pregnancy, you need insulin to treat your diabetes. Tell your doctor if you are, you think you might be or are planning to become pregnant, so that he or she may change your treatment. This medicine is not recommended if you are

breast-feeding or if you are planning to breast-feed your baby.

Driving and using machines

Glucomin 850 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 Glucomin 850 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

How to take Glucomin 850

How much to take

- Swallow the tablets whole with a glass of water.
- Do not crush or chew the tablets.
- Take metformin with or after food. This lowers the chance of getting an upset stomach.

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Adults

- The usual starting dose is one tablet 2 or 3 times a day. Your doctor will tell you when to take this
- After 10 to 15 days, your doctor may slowly increase your dose until the right dose for you is reached. This will help lower the chances of getting side effects such as feeling sick
- (nausea) or being sick (vomiting).
- The maximum daily dose is six 500mg tablets or three 850mg tablets.

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Elderly

- Your doctor may give you a much lower starting dose as there is a risk of kidney problems.

Teenagers and children aged 10 years or older

- The usual starting dose is one tablet each day. Your doctor will tell you when to take this

- After 10 to 15 days, your doctor may slowly increase your dose until the right dose is reached. This will help lower the chances of getting side effects such as feeling sick (nausea) or being sick (vomiting).
- The maximum daily dose is four 500mg tablets or two 850mg tablets.

Children aged under 10 years

Metformin is not recommended for use in children under 10 years old.

Taking metformin with insulin

- If your doctor wants you to take metformin with insulin the usual starting dose of metformin is one tablet 2 or 3 times a day.
- The insulin dose will change depending on your blood sugar level

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)

- If you take too many tablets tell your doctor or go to the nearest hospital straight away. Remember to take the pack and any remaining tablets with you. This is so the doctor knows what you have taken

The following effects may happen if you take too much metformin: unexpected weight loss, feeling very sick or being very sick, very fast breathing which you cannot stop, stomach pains or feeling cold. You may

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have something called lactic acidosis. The doctor may use a method called 'haemodialysis' to remove the extra lactate and metformin from your body.

While you are using Glucomin 850

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

- Metformin on its own does not usually affect your ability to drive.
- However, if you also take other medicines which lower blood sugar you may feel faint, dizzy, weak or shaky. If this happens, do not drive or use any tools or machines.

Side effects

Like all medicines, Glucomin 850 can cause side effects, although not everybody gets them. The following side effects may occur: Glucomin 850 may cause a very rare (may affect up to 1 user in 10,000), but very serious side effect called lactic acidosis. If this happens you must stop taking Glucomin 850 and contact a doctor or the nearest hospital immediately, as lactic acidosis may lead to coma.

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 850. It helps if you spread the doses over the day and if you take Glucomin 850 with or straight after a meal. If symptoms continue, stop taking Glucomin 850 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 non-specific (see section 'Warning and precautions')
- 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 850 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.

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 850

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 oblong shaped film coated with breaking line on one side.

MAL No

MAL19021004AZ

Manufacturer and Registration Holder

Noripharma Sdn. Bhd.
Lot 5030, Jalan Teratai,
5 ½ Mile off Jalan Meru,
41050 Klang, Selangor.

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