

Glumet Forte Tablet 850mg[®]

Metformin Hydrochloride (850mg)

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What Glumet Forte Tablet 850mg is used for

Glumet Forte Tablet 850mg contains the active ingredient metformin hydrochloride and belongs to a group of medicines called biguanides, used in the treatment of diabetes.

Glumet Forte Tablet 850mg 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 Glumet Forte 850mg on its own or together with other medicines to treat diabetes (medicines taken by mouth or insulin).

Children from 10 years of age and adolescents can take Glumet Forte 850mg on its own or together with insulin.

How Glumet Forte Tablet 850mg works

Glumet Forte Tablet 850mg works by improving the sensitivity of your body to insulin. 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. Glumet Forte Tablet 850mg help to lower your blood glucose to as normal a level as possible.

If you are an overweight adult, taking Glumet Forte Tablet 850mg over a long period of time also helps to lower the risk of complications associated with diabetes. Glumet Forte Tablet 850mg is associated with either a stable body weight or modest weight loss.

Before you use Glumet Forte Tablet 850mg

When you must not use it

Do not take Glumet Forte Tablet 850mg if:

- You are allergic (hypersensitivity) to metformin or any of the other ingredients in this medicine (listed in *Product Description*).
- You have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, dehydration, rapid weight loss 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 include stomach pain, fast and deep breathing, sleepiness, or unusual fruity odour of the breath.

- You lost too much water from your body (dehydration), such as due to long-lasting or severe diarrhoea, or if you have vomited several times in a row. Dehydration may lead to kidney problems, which can put you at risk for lactic acidosis. (see '*Take special care with Glumet Forte Tablet 850mg*').
- You are treated for heart failure or have recently had a heart attack, have severe problems with your circulation (such as shock) or have breathing difficulties. This may lead to a lack in oxygen supply to tissue which can put you at risk for lactic acidosis (see '*Take special care with Glumet Forte Tablet 850mg*').
- You drink a lot of alcohol.

If any of the above applies to you, talk to your doctor, before you start taking this medicine.

- Before you start to use it

Make sure you ask your doctor for advice, if you have heart failure, liver problem and inadequate vitamin B₁₂ or calcium intake or absorption.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

Take special care with Glumet Forte Tablet 850mg.

Please note the following particular risk of lactic acidosis.

Glumet Forte Tablet 850mg may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of lactic acidosis is also increased with liver failure, uncontrolled diabetes,

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prolonged fasting, alcohol intake and concomitant use of medicinal products that affect renal function (see under 'Taking other medicines')

Symptom of lactic acidosis include:

- Vomiting
- Stomach ache (abdominal pain) with muscle cramps
- A general feeling of not being well with severe tiredness.
- Difficulty in breathing

If this happens to you, you may need immediate hospital treatment, as lactic acidosis may lead to coma.

Stop taking Glumet Forte Tablet 850mg immediately and contact a doctor or the nearest hospital straight away.

- Taking other medicines

Glumet Forte Tablet 850mg on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take Glumet Forte Tablet 850mg together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas), there is a risk of hypoglycaemia such as weakness, dizziness, increased sweating, fast heart beating, visions disorders or difficulty in concentration, you may eat or drink something containing sugar.

If you need to have an injection of contrast medicines that contain iodine into your bloodstream, for example for examinations such as X-ray or scan, you must stop taking Glumet Forte Tablet 850mg for a certain period of time before and after the examination. Your doctor will decide when you must stop and

when to start your treatment with Glumet Forte Tablet 850mg.

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. 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 which increase urine production (diuretics).
- Medicines used to treat pain and inflammation (NSAIDs and COX-2 inhibitors).
- Medicines for high blood pressure such as ACE inhibitors (such as enalapril, perindopril, quinapril), water tablets (diuretics), and beta-blockers.
- 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 metformin in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib).
- Other medicines to treat diabetes.
- Insulin secretagogues or insulin.
- Cephalexin (antibiotic).
- Medicinal products which increase metformin plasma concentration; Amiloride, cimetidine, digoxin, glycopyrrolate, morphine, morphine sulphate liposome, quinidine, quinine, ranitidine, vancomycin or enalapril maleate

with metformin may cause metformin toxicity.

- Linezolid or moclobemide or selegiline may result in excessive hypoglycaemia, depression and seizures.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking metformin.

How to use Glumet Forte Tablet 850mg

- How much to use

Always take Glumet Forte Tablet 850mg as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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.
- The maximum daily dose is 3g.

Combination with insulin

Metformin and insulin may be used in combination therapy to achieve better blood glucose control. Metformin is given at the usual starting dose of one tablet 2-3 times daily, while insulin dosage is adjusted on the basis of blood glucose measurements.

Elderly

Metformin dosage should be adjusted depends on the condition of the kidney.

Child and Adolescents

This medicine can be used in children from 10 years of age and adolescent.

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- 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.
- The maximum daily dose is 2g.

Glumet Forte Tablet 850mg once daily given during meals or after meals.

After 10 to 15 days, your doctor will adjust the dose on the basis of blood glucose measurements.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Use Glumet Forte Tablet 850mg for the duration that doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up the missed tablet. Take the next doses at the correct time.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or

poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

- 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.

- Things you must not do

Do not drink large amounts of alcohol or take medicines containing alcohol while taking metformin. Alcohol may increase the risk of lactic acidosis especially if you have liver problems, are fasting or if you are undernourished. This also applies to medicines that contain alcohol.

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Glumet Forte Tablet 850mg to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Metformin on its own does not usually affect your ability to drive. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

You should be aware of the warning symptoms which include muscle cramps, abdominal pain, breathlessness and a feeling of being very weak and unwell. If you develop these symptoms, you must tell your doctor immediately.

Particular caution is recommended when prescribing to children aged between 10-12 years old and elderly.

Side effects

Like all medicines, Glumet Forte Tablet 850mg can cause side effects, although not everybody gets them.

Metabolism and nutrition disorders:

Very rare: Lactic acidosis and decreased or low vitamin B12 levels in the blood. 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.

Nervous system disorders:

Common: Change in taste

Gastrointestinal disorders:

Very common: Digestive problems such as diarrhoea, feeling sick (nausea), vomiting, abdominal pain and loss of appetite. These side effects most often happen at the beginning of the treatment with Glumet Forte 850mg. It helps if you spread the doses over the day and if you take Glumet Forte 850mg with or straight after a meal. If symptoms

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continue, stop taking Glumet Forte 850mg and talk to your doctor.

Hepatobiliary disorders:

Very rare: Isolated reports of liver function tests abnormalities or inflammation of kidney (hepatitis) resolving upon metformin discontinuation.

Skin and subcutaneous tissue disorders:

Very rare: Abnormal redness and inflammation of the skin (erythema), itching (pruritus) and hives (urticaria).

Paediatric population:

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

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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 Glumet Forte Tablet 850mg

- Storage

Keep all medicines out of reach of children. Do not take this medicine after the expiry date stamped on the pack.

Store below 30°C. Protect from light.

- Disposal

Medicines should not be disposed of via waste water 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

White to off white, round, film-coated tablet with Pharmaniaga icon on one side and plain on the other.

- Ingredients

-Active ingredient(s):
Metformin hydrochloride

- Inactive ingredients:

Purified water, Aerosil, Starch (Maize starch), Opadry II White, Sodium starch Glycolate, Magnesium Stearate, Kollidon 30.

- MAL number:

MAL06091502AZ

Manufacturer and Product Registration Holder

Pharmaniaga Manufacturing Berhad (198001006232),
No. 11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

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