

GLUCOPHAGE FILM COATED TABLETS

Metformin (500mg,850mg,1000mg)

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What glucophage is used for

Glucophage contains metformin, a medicine to treat diabetes. It belongs to a group of medicines called biguanides.

Glucophage 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 Glucophage 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 Glucophage on its own or together with insulin.

How does Glucophage work

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. Glucophage helps to lower your blood glucose to as normal a level as possible.

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

Before you use Glucophage

When must not take it

Do not take Glucophage

- if you are allergic (hypersensitive) to metformin or any of the other ingredients of this medicine (see *Product Description, Ingredients*)
- if you have kidney or liver problems
- if you have uncontrolled diabetes, with e.g. 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
- if 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 Glucophage').
- if you have a severe infection, such as an infection affecting your lung or bronchial system or your kidney. Severe infections may lead to kidney problems, which can put you at risk for lactic acidosis (see 'Take special care with Glucophage').
- if 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 Glucophage' below)
- if 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 take it

Make sure you ask your doctor for advice, if

- you need to have an examination such as X-ray or scan involving the injection of contrast medicines that

contain iodine into your bloodstream

- you need to have major surgery
- You must stop taking Glucophage for a certain period of time before and after 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.

Take special care with Glucophage

Please note the following particular risk of lactic acidosis.

Glucophage may cause a very rare, but serious complication called lactic acidosis, particularly if your kidneys are not working properly. The risk of lactic acidosis is also increased with uncontrolled diabetes, prolonged fasting or alcohol intake. 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 Glucophage immediately and contact a doctor or the nearest hospital straight away.

Glucophage on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take Glucophage together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, insulin, meglitinides), there is a risk of hypoglycaemia. If you experience symptoms of hypoglycaemia such as weakness, dizziness, increased sweating, fast heart beating, visions disorders or difficulty in concentration, it usually helps to eat or drink something containing sugar.

Taking other medicines

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 Glucophage for a certain period of time before and after the examination.

Tell your doctor if you take any of the following medicines and Glucophage at the same time. You may need more frequent blood glucose tests or your doctor may adjust the dosage of Glucophage:

- diuretics (used to remove water from the body by making more urine).
- 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)
- other medicines used to treat diabetes

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

How to take Glucophage

Always take Glucophage exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Glucophage cannot replace the benefits of a healthy lifestyle.

Continue to follow any advice about diet that your doctor has given you and get some regular exercise.

How much to take

Children 10 years and over and adolescents usually start with 500 mg or 850 mg Glucophage once a day.

The maximum daily dose is 2000 mg taken as 2 or 3 divided doses.

Treatment of children between 10 and 12 years of age is only recommended on specific advice from your doctor, as experience in this age group is limited.

Adults usually start with 500 mg or 850 mg Glucophage 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 Glucophage.

When to take it

Take Glucophage with or after a meal. This will avoid you having side effects affecting your digestion.

Do not crush or chew the tablets.

Swallow each tablet with a glass of water.

- If you take one dose a day, take it in the morning (breakfast)
- If you take two divided doses a day, take them in the morning (breakfast) and evening (dinner)
- If you take three divided doses a day, take them in the morning (breakfast), at noon (lunch) and in the evening (dinner)

If, after some time, you think that the effect of Glucophage is too strong or too weak, talk to your doctor or pharmacist.

How long to take it

The treatment duration is not limited and depends on the severity of the disease. The duration of therapy will be determined by your doctor. Stopping treatment must be discussed with your doctor. Your doctor will perform regular blood glucose tests and will adapt your dose of Glucophage to your blood glucose levels. Make sure that you talk to your doctor regularly. This is particularly important for children and adolescents or if you are an older person. Your doctor will also check at least once a year how well your kidneys work. You may need more frequent checks if you are an older person or if your kidneys are not working normally.

If you forget to take it

Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time. If you have any further questions on the use of this product, ask your doctor or pharmacist

If you take too much (overdose)

If you have taken more Glucophage 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.

While you are using Glucophage

Things you must do

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.

Things you must not do

Taking Glucophage with food and drink:

Do not drink alcohol when you take this medicine. Alcohol may increase the risk of lactic acidosis especially if you have liver problems or if you are undernourished. This also applies to medicines that contain alcohol.

Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to. Do not give this medicine to anyone else, even if they have the same condition as you. Do not stop taking Glucophage, or change the dosage, without checking with your doctor

Things to be careful of

Driving and using machines:
Glucophage 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 Glucophage 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, Glucophage 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 Glucophage. It helps if you spread the doses over the day and if you take Glucophage with or straight after a meal. If symptoms continue, stop taking Glucophage 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 Glucophage 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 Glucophage 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→Reporting).

Storage and disposable of

Glucophage

Storage

Keep out of the reach and sight of children. If a child is treated with Glucophage, parents and caregivers are advised to oversee how this medicine is used.

Do not use Glucophage after the expiry date which is stated on the carton or the bottle or the blister after 'EXP'. The expiry date refers to the last day of that month.

Glucophage 500mg & 850mg:
Store below 25°C.

Glucophage 1000mg:
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

Glucophage 500 mg

Glucophage 500 mg film-coated tablets are white, circular and convex
Pack sizes: 50, 100 & 500 tablets in blister packs.

Not all pack sizes may be marketed

Glucophage 850 mg

Glucophage 850 mg film-coated tablets are white, circular and convex
Pack sizes: 50, 100 & 500 tablets in blister packs.

Not all pack sizes may be marketed

Glucophage 1000 mg

Glucophage 1000 mg film-coated tablets are white, oval, biconvex film-coated tablets with a score line on both sides with « 1000 » engraved on one side. The tablet can be divided into equal halves.

Pack sizes: 30, 50, 60, 100, 120, 500 tablets in blister packs.

Not all pack sizes may be marketed

Ingredients

The active substance is metformin hydrochloride.

Glucophage 500 mg

One film-coated tablet of Glucophage 500 mg contains 500 mg metformin hydrochloride corresponding to 390 mg metformin base.

The other ingredients are povidone K 30, magnesium stearate, hypromellose.

Glucophage 850 mg

One film-coated tablet of Glucophage 850 mg contains 850 mg metformin hydrochloride corresponding to 662.9 mg metformin base.

The other ingredients are povidone K 30, magnesium stearate, hypromellose.

Glucophage 1000 mg

One film-coated tablet of Glucophage 1000 mg contains 1000 mg metformin hydrochloride corresponding to 780 mg metformin base.

The other ingredients are povidone K 30, magnesium stearate, hypromellose, Macrogol 400 and Macrogol 8000.

MAL NO.:

Glucophage 500 mg:

MAL19992047AS

Glucophage 850 mg:

MAL19992048AS

Glucophage 1000 mg:

MAL06021194A

Manufacturer

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