

# GLUCOPHAGE® FILM-COATED TABLET

Metformin hydrochloride (500mg, 850mg, 1000mg)

## What is in this leaflet

1. What Glucophage is used for
2. How Glucophage works
3. Before you take Glucophage
4. How to take Glucophage
5. While you are taking it
6. Side effects
7. Storage and Disposal of Glucophage
8. Product Description
9. Manufacturer and Product registration holder
10. Date of revision

## 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 Glucophage works

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 take Glucophage

### - When you 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 severely reduced kidney function
- if you have uncontrolled diabetes, with e.g. severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis 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 your breath developing an unusual fruity smell.
- 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').
- Patients with known or suspected mitochondrial diseases such as Mitochondrial Encephalopathy with Lactic Acidosis and Stroke-like episodes (MELAS) syndrome and Maternal inherited diabetes and deafness (MIDD) must avoid Metformin due to risk of lactic acidosis exacerbation.
- 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 when you must stop and when to restart your treatment with Glucophage. 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 liver failure, uncontrolled diabetes, prolonged fasting, alcohol intake and concomitant use of medicinal products that affects renal function (see under 'Taking other medicines'). Symptoms of lactic acidosis are vomiting, stomachache (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.

# GLUCOPHAGE® FILM-COATED TABLET

Metformin hydrochloride (500mg, 850mg, 1000mg)

During treatment with Glucophage, 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.

## - 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. Your doctor will decide when you must stop and when to start your treatment with Glucophage.

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:

- Organic cation transporters (co-administration of metformin with verapamil, rifampicin or cimetidine may affect the levels of metformin)
- Sympathomimetic medicines including epinephrine and dopamine used to treat heart attacks and low blood pressure
- Medicinal products which affects kidney function such as Diuretics (used to remove water from the body by making more urine), NSAIDs (used in pain relief), ACE inhibitors (reduces blood pressure) daily dose is 3000 mg taken as 3 divided doses. If you take insulin too, your doctor will tell you how to start Glucophage. 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

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 you have taken more Glucophage that you should have, you may experience lactic acidosis.

## ***While you are using it***

### - Things you must do

Pregnancy and breast-feeding:

If you are pregnant, think you may be pregnant or are planning to have a baby, speak to your doctor in case any changes will be needed to your treatment or monitoring of your blood glucose levels. This medicine is not recommended if you are breast-feeding or if you are planning to breast-feed your baby.

- Glucocorticoid (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 this medicine 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

Paediatric population 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. GLUCOPHAGE® 500 mg film-coated tablet can be used in children from 10 years of age and adolescents.

### Adults with normal kidney function

(GFR > 90 mL/min) 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, 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 medicine, ask your doctor or pharmacist

### - If you take too much (overdose)

### - 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, are fasting 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,

# GLUCOPHAGE® FILM-COATED TABLET

Metformin hydrochloride (500mg, 850mg, 1000mg)

dizziness, increased sweating, fast heartbeat, vision disorders or difficulty in concentration. Do not drive or use machines if you start to feel these symptoms.

## Side effects

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

Very common side effects (may affect 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 (may affect up to 1 in 10 people)

- changes in taste.
- 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.

Very rare side effects (may affect up to 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, stomachache (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.

Lactic acidosis is a medical emergency and must be treated in a hospital.

- 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).

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 get 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 of Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [(Consumers → Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI))].

## Storage and Disposal of Glucophage

### - Storage

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

Do not use this medicine 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, & 1000mg:  
Store below 30°C

### - Disposal

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

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 & 120 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

- Active ingredient: metformin hydrochloride

- Inactive ingredients:

#### Glucophage 500 mg and 850 mg

Povidone K 30, Magnesium stearate and Hypromellose

#### Glucophage 1000 mg

Povidone K 30, Magnesium stearate, Hypromellose, Macrogol 400 and Macrogol 8000.

- MAL Number(s):

Glucophage 500 mg: MAL19992047AZ

Glucophage 850 mg: MAL19992048AZ

Glucophage 1000 mg: MAL06021194AZ

## Manufacturer

Merck Santé s.a.s.

2 rue du Pressoir

Vert 45400 Semoy, France

## Product Registration Holder

Merck Sdn Bhd (178145-V) B-23A-1,

Level 23A, The Ascent Paradigm

No.1, Jalan SS7/26A, Kelana Jaya,

47301 Petaling Jaya, Selangor, Malaysia

Date of Revision: 15/11/2025

Serial Number

NPRA (R1/5) 23122024/235