

# GLUCOPHAGE XR TABLET

Metformin Hydrochloride (500mg, 750mg & 1000mg)

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## What Glucophage XR is used for

Glucophage XR prolonged release tablets contain the active ingredient metformin hydrochloride and belong to a group of medicines called biguanides, used in the treatment of diabetes. Glucophage XR is used to delay the onset and treat Type 2 (non-insulin dependent) diabetes mellitus when diet and exercise changes alone have not been enough to control blood glucose (sugar).

## How Glucophage XR 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 XR makes the body more sensitive to insulin and helps return to normal the way your body uses glucose.

Glucophage XR is associated with either a stable body weight or modest weight loss.

Glucophage XR Prolonged Release Tablets are specially made to release the drug slowly in your body and therefore are different to many other types of tablet containing metformin.

## Before you take Glucophage XR

### When you must not take it

Do not take Glucophage XR if:

- you are allergic to metformin or to any of the other ingredients which are listed later on in the leaflet.
- If you have lactic acidosis [too much lactic acid in the blood (see "Risk of 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 of acidosis may include stomach pain, abnormal breathing and drowsiness (if severe).
- If you are known to suffer from a genetically inherited disease affecting mitochondria (the energy-producing components within cells) such as MELAS syndrome (Mitochondrial Encephalopathy, myopathy, Lactic acidosis and Stroke-like episodes) or Maternal inherited diabetes and deafness (MIDD).
- You have severely reduced kidney function.
- you have had serious complications with your diabetes or other serious conditions which resulted in rapid weight loss, nausea, vomiting or dehydration.
- you have a severe infection or have recently suffered a severe injury.
- you have been treated for heart problems or have recently had a heart attack or have severe circulatory problems or breathing difficulties.
- you are a heavy drinker of alcohol.
- you are under 18 years of age.

Take special care with Glucophage XR. After you have started taking your medicine:

- If you have diabetes you should have your blood or urine tested for sugar regularly. You should return to your doctor at least once a year to check the function of your kidneys (more often if you are elderly or if you have severely reduced kidney

function).

- If you start to lose weight unexpectedly or suffer severe nausea or vomiting, uncontrolled rapid breathing or abdominal pains, stop taking the medicine and tell your doctor straight away. This can be a sign of a rare, but serious, complication with your diabetes called 'lactic acidosis' which means there is too much acid in the blood (see also 'Side effects'). You may see some remains of the tablets in your stools. Do not worry- this is normal for this type of tablet.

### Before you start to take it

If you need to have an X-ray examination involving the injection of a dye, tell the doctor that you take

Glucophage XR as you may need to stop taking it for a few days afterwards.

Tell your doctor if you are going to have an operation under general anesthetic, as you may need to stop taking Glucophage XR for a couple of days before and after the procedure. You should continue to follow any dietary advice that your doctor has given you and you should make sure that you eat carbohydrates regularly throughout the day. Do not stop taking this medicine without speaking to your doctor.

Take special care with Glucophage XR

**Please note the following particular risk of lactic acidosis.** Glucophage XR 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

During treatment with Glucophage, your doctor will check your kidney function at least once a year or more

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription. If you are taking any of the following medicines, your blood sugar levels may need to be checked more often, and your dose adjusted:

- Steroids such as prednisolone, mometasone, beclomethasone.
- Diuretics (water tablets) such as furosemide.
- Sympathomimetic medicines including epinephrine and dopamine used to treat heart attacks and low blood pressure.

Epinephrine is also included in some dental anesthetics.

**How to take Glucophage XR**

Your doctor may prescribe Glucophage XR for you to take on its own, or in combination with other oral antidiabetic medicines or insulin.

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow the tablets whole with a glass of water, do not chew.

How much to take

Usually you will start treatment with 500 milligrams Glucophage XR daily. After you have been taking Glucophage XR for about 2 weeks, your doctor may measure your blood sugar and adjust the dose. The maximum daily dose is 2000 milligrams of Glucophage XR.

When to take it

Normally, you should take the tablets once a day, with your evening meal. In some cases, your doctor may recommend that you take the tablets twice a day. Always take the tablets with food.

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

If you forget to take it

Take it as soon as you remember with some food. Do not take a double dose to make up for a forgotten dose.

If you take too much (overdose)

If you take extra tablets by mistake you need not worry, but if you have unusual symptoms, contact your doctor. If the overdose is large, lactic acidosis is more likely and this is a medical emergency requiring treatment in hospital

**While you are using Glucophage XR**

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.

Things you must not do

You should avoid drinking alcohol and using alcohol-containing medicines as this will increase the risk of lactic acidosis.

Things to be careful of

Glucophage XR taken on its own does not cause ‘hypos’(symptoms of low blood sugar or hypoglycemia, such as faintness, confusion and increased sweating) and therefore should not affect your ability to drive

or use machinery. You should be aware, however, that Glucophage XR taken with other antidiabetic medicines can cause hypos, so in this case you should take extra care when driving or operating machinery.

**Side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you notice any of the following, stop taking Glucophage XR and see your doctor immediately:

- unexpected weight loss
- very severe nausea or vomiting
- very fast breathing which you cannot stop
- stomach pains or feeling cold

These can be signs of serious problems with your diabetes and may mean you have a very rare side effect called “lactic acidosis” (too much acid in the blood). If this happens, see a doctor as you will need treatment straight away.

Other possible side effects are listed by frequency as follows:

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

- Diarrhea, nausea, vomiting, stomachache or loss of appetite.

These undesirable effects occur most frequently during initiation of therapy and resolve spontaneously in most cases.

Common side effects (may affect up to 1 in 10 people):

- Taste disturbance
- 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 problems.

Very rare side effects (may affect up to 1 in 10,000 people):

- Skin rashes including redness, itching and hives.

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](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

### **Storage and disposal of Glucophage XR**

#### Storage

Keep this medicine tablets out of the reach and sight of children. Do not use this medicine after the expiry date that is printed on the pack after “Use before:”. The expiry date refers to the last day of that month. Protect from moisture, freezing and excessive heat. Store below 30°C.

#### Disposal

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

### **Product description**

#### What it looks like

The 500 milligram tablets are white to off-white and biconvex tablet with ‘500’ on one side.

The 750 milligram tablets are white to off-white and biconvex tablet with ‘750’ on one side and ‘MERCK’ on the other side.

The 1000 milligram tablets are white to off-white and biconvex tablet with ‘1000’ on one side and ‘MERCK’ on the other side.

#### MAL Number:

Glucophage XR 500mg Tablet:

MAL07050002AZ

Glucophage XR 750mg Tablet:

MAL10033141AZ

Glucophage XR 1000mg Tablet:

MAL15065037AZ

### **Manufacturer**

Merck Santé s.a.s.  
2 rue du Pressoir vert  
45400 Semoy France

### **Product Registration Holder**

B-23A-1, Level 23A, The Ascent  
Paradigm No.1, Jalan SS7/26A,  
Kelana Jaya, 47301 Petaling Jaya,  
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