

GLUCOPHAGE XR TABLET

Metformin Hydrochloride (500mg & 750mg)

What is in this leaflet

1. What Glucophage XR is used for
2. How Glucophage XR works
3. Before you use Glucophage XR
4. How to take Glucophage XR
5. While you are using Glucophage XR
6. Side effects
7. Storage and disposal of Glucophage XR
8. Product description
9. Manufacturer and product registration holder
10. Date of revision

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 for the treatment of 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 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 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 use Glucophage XR

When you must not use 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.
- you have ketosis (this is a symptom of uncontrolled diabetes in which substances called 'ketone bodies' accumulate in the blood – you may notice that your breath has an unusual, fruity odour).
- you have long-term kidney or liver problems.
- 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 kidney problems).
- 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 anaesthetic, 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.

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, beclometasone.
- 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 anaesthetics.

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 Glucophage XR 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
Do not take Glucophage XR if you are pregnant or breast feeding. Ask your doctor or pharmacist for advice before taking any medicine.

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 hypoglycaemia, 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, Glucophage XR 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 (affects more than 1 person in 10):

- Diarrhoea, nausea, vomiting, stomach ache or loss of appetite.
- These undesirable effects occur most frequently during initiation of therapy and resolve spontaneously in most cases.

Common (affects less than 1 person in 10, but more than 1 person in 100):

- Taste disturbance

Very rare (affects less than 1 person in 10,000):

- Decreased vitamin B12 levels
- Skin rashes including redness, itching and hives.

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 disposal of Glucophage XR

Storage

Keep Glucophage XR tablets out of the reach and sight of children. Do not use them 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

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

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.

Ingredients:

Each prolonged release tablet contains 500 or 750 milligrams of the active ingredient metformin hydrochloride. The other ingredients are magnesium stearate, carmellose sodium and hypromellose. The 500 milligram tablet also contains microcrystalline cellulose.

MAL number:

Glucophage XR 500mg Tablet:
MAL07050002A

Glucophage XR 750mg Tablet:
MAL10033141A

Manufacturer

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

Product Registration Holder

Merck Sdn Bhd (178145-V)
Level 3, Menara Sunway Annexe,
Jalan Lagoon Timur
Bandar Sunway
46150, Petaling Jaya
Selangor Darul Ehsan

Date of Revision

3/12/2014

Serial number

BPFK(R4/2)261114/00057