

PACKAGE LEAFLET: INFORMATION FOR THE USER
GLUCOPHAGE® SR 1000mg Tablets
(metformin hydrochloride)

This medicine is available as the above name but will be referred to as Glucophage SR throughout this leaflet. This medicine is available in other strengths and all strengths will be referred to throughout the remainder of this leaflet.

This medicine is intended for **adult** patients only

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Glucophage SR is and what it is used for
2. What you need to know before you take Glucophage SR
3. How to take Glucophage SR
4. Possible side effects
5. How to store Glucophage SR
6. Content of the pack and other information

1. What Glucophage SR is and what it is used for

Glucophage SR prolonged release tablets contain the active ingredient metformin hydrochloride and belong to a group of medicines called biguanides, used in the treatment of Type 2 (non-insulin dependent) diabetes mellitus.

Glucophage SR is used together with diet and exercise to lower the risk of developing Type 2 diabetes in overweight adults, when diet and exercise alone for 3 to 6 months have not been enough to control blood glucose (sugar). You are at high risk of developing Type 2 diabetes if you have additional conditions like high blood pressure, age above 40 years, an abnormal amount of lipids (fat) in the blood or a history of diabetes during pregnancy.

The medicine is particularly effective if you are aged below 45 years, are very overweight, have high blood glucose levels after a meal or developed diabetes during pregnancy.

Glucophage SR is used for the treatment of Type 2 diabetes when diet and exercise changes alone have not been enough to control blood glucose (sugar). Insulin is a hormone that enables body tissues to take glucose from the blood and to use it for energy or for storage for future use. People with Type 2 diabetes do not make enough insulin in their pancreas or their body does not respond properly to the insulin it does make. This causes a build-up of glucose in the blood which can cause a number of serious long-term problems so it is important that you continue to take your medicine, even though you may not have any obvious symptoms. Glucophage SR makes the body more sensitive to insulin and helps return to normal the way your body uses glucose.

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

Glucophage SR 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.

Polycystic ovary syndrome (PCOS) is a health condition that affects a woman's hormone levels, menstrual cycle, and ability to have children. Glucophage SR is used in women with PCOS to stimulate ovulation (release of an egg from the ovaries), and subsequently the chance of getting pregnant, alone or together with other treatment options.

2. What you need to know before you take Glucophage SR

Do not take Glucophage SR if:

- you are allergic to metformin or to any of the other ingredients of this medicine (listed in section 6). An allergic reaction may cause a rash, itching or shortness of breath.
- you have liver problems
- you have severely reduced kidney function
- you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see 'Risk of lactic acidosis' below) 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.
- you have lost too much water from your body (dehydration). Dehydration may lead to kidney problems, which can put you at risk for lactic acidosis (see 'Warnings and precautions').

- 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 'Warnings and precautions').
- you have been treated for acute heart problems or have recently had a heart attack or have severe circulatory problems or breathing difficulties. This may lead to a lack in oxygen supply to tissue which can put you at risk for lactic acidosis (see 'Warnings and precautions').
- you are a heavy drinker of alcohol.
- you are under 18 years of age.

Warnings and precautions

Risk of lactic acidosis.

Glucophage SR may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration (see further information below), liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease).

If any of the above apply to you, talk to your doctor for further instructions.

Stop taking Glucophage SR for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking Glucophage SR and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma.

Symptoms of lactic acidosis include:

- vomiting
- stomach ache (abdominal pain)
- muscle cramps
- a general feeling of not being well with severe tiredness
- difficulty in breathing
- reduced body temperature and heartbeat

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

Talk to your doctor promptly for further instructions 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 any of these symptoms after starting metformin: seizure, declined cognitive abilities, difficulty with body movements, symptoms indicating nerve damage (e.g. pain or numbness), migraine and deafness.

If you need to have major surgery you must stop taking Glucophage SR during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Glucophage SR.

During treatment with Glucophage SR, 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.

If you are older than 75 years, treatment with Glucophage SR should not be started to lower the risk of developing type 2 diabetes.

You may see some remains of the tablets in your stools. Do not worry - this is normal for this type of tablet.

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.

Other medicines and Glucophage SR

If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, you must stop taking Glucophage SR before or at the time of injection. Your doctor will decide when you must stop and when to restart your treatment with Glucophage SR.

Tell your doctor if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of Glucophage SR. It is especially important to mention the following:

- Medicines which increase urine production (diuretics (water tablets) such as furosemide).