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

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 it. 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.

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.

Do not take Glucophage
- if you are allergic (hypersensitive) to metformin or any of the other ingredients of this medicine (see ‘What Glucophage contains’ in section 6)
- if you have liver problems
- if you have severely reduced kidney function
- if 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 ketoacidosis. 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 ‘Warnings and precautions’).
- 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 ‘Warnings and precautions’).
- if you are treated for acute 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 ‘Warnings and precautions’).
- 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.

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.

Warnings and precautions

Risk of lactic acidosis

Glucophage 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 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 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.

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

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, vision disorders or difficulty in concentration, it usually helps to eat or drink something containing sugar.

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.

Other medicines and Glucophage

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 before or at the time of injection. Your doctor will decide when you must stop and when to restart your treatment with Glucophage.

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. It is especially important to mention the following:
- medicines which increase urine production (diuretics).
- medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib).
- certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists).
- 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 asthmatic.
• medicines that may change the amount of Glucophage in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolastatin, ranolazine, trimethoprim, vancomycin, isavuconazole, crizotinib, olaparib).
• other medicines used to treat diabetes.

Glucophage with alcohol
Avoid excessive alcohol intake while taking Glucophage since this may increase the risk of lactic acidosis (see section ‘Warnings and precautions’).

Pregnancy and breast-feeding
During pregnancy, you need insulin to treat your diabetes. Tell your doctor if you think you might be or are thinking of becoming 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.

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, meglinilides). Symptoms of hypoglycaemia include weakness, dizziness, increased sweating, fast heartbeat, vision disorders or difficulty in concentration. Do not drive or use machines if you start to feel these symptoms.

3. 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.

Recommended dose
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 have reduced kidney function, your doctor may prescribe a lower dose.

If you take insulin too, your doctor will tell you how to start Glucophage.

Monitoring
• 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 are working. These measures will help to protect the environment.

How to take Glucophage
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) and evening (dinner).
• If you take two divided doses, you may take them in the morning (breakfast) and evening (dinner).
• If you take three divided doses, you may 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.

Monitoring
• 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 are working. These measures will help to protect the environment.

4. Possible side effects
Like all medicines, Glucophage can cause side effects, although not everybody gets them. The following side effects may occur:
Glucophage may cause a very rare (may affect up to 1 in 10,000), but very serious side effect called lactic acidosis (see section ‘Warnings and precautions’). If this happens you must stop taking Glucophage and contact a doctor or the nearest hospital immediately, as lactic acidosis may lead to coma.

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 without 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.
• low vitamin B12 levels in the blood.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Ireland
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie
United Kingdom
Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard
By reporting side effects you can help provide more information on the safety of this medicine.

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

This medicinal product does not require any special storage conditions.

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.

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.

6. Contents of the pack and other information
What Glucophage contains
• The active substance is metformin hydrochloride.
• The other ingredients are povidone K 30, magnesium stearate, hypromellose.

What Glucophage looks like and contains of the pack
Glucophage 500 mg film-coated tablets are white, circular, 11 mm in diameter and 5.7 mm high, convex, engraved with GL 500. The tablets are supplied in blister packs of 1 (x10), 9, 20, 21, 30, 40, 50, 56, 60, 84, 90, 100, 120, 200, 500, 600 or 1000 tablets and in plastic bottles with child-resistant caps of 21, 30, 40, 50, 60, 100, 120, 300, 400, 500, 600 or 1000 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Merck Serono Limited
Bedfont Cross, Stanwell Road
Feltham, Middlesex
TW14 8NX
United Kingdom
Manufacturer
Merck S.L.
Poligono Merck
Mollet Del Vallès 08100 Barcelona Spain

This medicinal product is authorised in the Member States of the EEA under the following names:
Glucophage: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Finland, France, Germany, Greece, Iceland, Ireland, Latvia, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Sweden, United Kingdom
Merckformin: Hungary

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