Metformin 1000 mg Prolonged Release Tablets
Metformin hydrochloride

This medicine is intended for adults only.

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

1. What this medicine is and what it is used for

Metformin 1000mg prolonged release tablets called Metformin for short throughout this leaflet, contain the active ingredient metformin hydrochloride and belong to a group of medicines called biguanides, used in the treatment of Type 2 diabetes (non-insulin-dependent) diabetes mellitus.

Metformin 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 overweight, have high blood glucose levels after a meal or developed diabetes during pregnancy.

Metformin is used for the treatment of Type 2 diabetes when diet and exercise alone have not been enough to control blood glucose (sugar). Metformin is a hormone that enables body tissues to take glucose from the blood and use it for energy or to store it for future use. People with Type 2 diabetes do not make enough insulin in their pancreas or their body does not react properly to the insulin it makes. 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. Metformin makes the body more sensitive to insulin and helps return to normal the way your body uses glucose.

Metformin is also used with either a stable body weight or modest weight loss.

Metformin 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.

2. What you need to know before you take Metformin

Do not take Metformin

- If you are allergic to metformin or any of the other ingredients of this medicine (see section 4). An allergic reaction may cause a rash, itching or redness/flushing.
- If you have severe liver or kidney problems, (see section 6.7).
- If you have uncontrolled diabetes, with, for example, severe high blood pressure, high blood glucose, nausea, vomiting, diarrhea, rapid weight loss, lactic acidosis (see section “Lactic acidosis (below) or ketosis”). Ketosis is a condition in which substances called "ketones" accumulate in the blood and which can lead to diabetic coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or confusion developing an unusual fruity smell.
- If you have severe liver problems.
- If you have severe kidney problems, such 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 section “Warning and precautions”).

Other medicines and Metformin

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

If you take Metformin, 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 Metformin should be reduced to the risk of developing Type 2 diabetes.

You may see some remains of your 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.

3. How to take Metformin

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

For treatment of Type 2 diabetes, you can take Metformin for you to take it on its own, or in combination with an oral antidiabetic medicine or insulin.

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

3.1 Recommended dosage

Children and adolescents (up to and including 16 years of age) under 160 cm (5 foot 3 inches) in height and weighing less than 50 kg (0.11 pounds) should be started on an initial dose of 500 mg Metformin daily. After you have been taking Metformin for about 2 weeks, your doctor may increase your blood sugar and adjust the dose. The maximum daily dose is 2000 mg of Metformin.

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

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.

If you take more Metformin than you should

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. Symptoms of lactic acidosis are non-specific, such as vomiting, tarry loo, fatigue and muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. Further symptoms are reduced body temperature and heartbeat. If you experience some of these symptoms, you should immediately seek medical attention, as lactic acidosis may lead to coma. Stop taking Metformin immediately and contact a doctor or the nearest hospital straight away.

If you forget to take Metformin

Take the missed dose as soon as you remember it, unless it’s nearly time for your next dose. Do not take a double dose to make up for the forgotten dose.

If you stop taking Metformin

Tell your doctor if you stop taking Metformin, tell your doctor or pharmacist if you are pregnant or breast-feeding. If you think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Metformin taken on its own does not cause 'hypos' (symptoms of low blood sugar) or hypoglycaemia, so there is no need to take precautions such as carrying food or sweets. However, if a patient is taking this medicine and any other antidiabetic medicines or insulin, he or she should consult with his or her doctor and/or pharmacist about the need for precautionary measures when driving or using machines.

4. Possible side effects

Medicines can cause the amount of Metformin in your blood, especially if you have reduced kidney function (such as warfarin, nimodipine, simvastatin, itraconazole, trimethoprim, valproate, zidovudine, citalopram, diazepam).

Metformin with food

The tablets should be swallowed whole with a glass of water or immediately after meals.

Avoid excessive alcohol intake while taking Metformin since this may increase the risk of lactic acidosis (see section “Warnings and precautions”).

Pregnancy and breast-feeding

Do not take Metformin if you are pregnant. If you think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Metformin taken on its own does not cause ‘hypos’ (symptoms of low blood sugar or hypoglycaemia), so there is no need to take precautions such as carrying food or sweets. However, if a patient is taking this medicine and any other antidiabetic medicines or insulin, he or she should consult with his or her doctor and/or pharmacist about the need for precautionary measures when driving or using machines.

Other possible side effects are listed by frequency as follows:

Very common

(>10%)

Common

(up to 1 in 10 people)

Uncommon

(up to 1 in 100 people)

Rare

(up to 1 in 10,000 people)

Very rare

(up to 1 in 100,000 people)

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. See section "Reporting of side effects."