

Package leaflet: Information for the user
Metformin 500mg or 850mg Film-Coated Tablets

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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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 Metformin Tablets are and what they are used for
2. What you need to know before you take Metformin Tablets
3. How to take Metformin Tablets
4. Possible side effects
5. How to store Metformin Tablets
6. Contents of the pack and other information

1. What Metformin Tablets are and what they are used for

Metformin belongs to a group of medicines called biguanides. Metformin is used for the treatment of "Type 2 diabetes" (non-insulin dependent diabetes).

How metformin works

- In type 2 diabetes, there is too much sugar (glucose) in your blood. This is because your body does not make enough insulin or because it makes insulin that does not work properly.
- Insulin is a hormone that allows your body tissue to take glucose from the blood and use it for energy or for storage for future use.
- Metformin works by improving the sensitivity of your body to insulin. It helps your body to use glucose in the normal way again.

Using this medicine

- This medicine is given when diet and exercise alone has not been able to control your blood sugar levels.
- Metformin can be given on its own. However, sometimes it is given with other medicines for diabetes or with insulin.
- In patients who are overweight, long-term use of metformin also helps to lower the risk of any problems related to diabetes.

2. What you need to know before you take Metformin Tablets

Do not take Metformin Tablets:

- if you are allergic to metformin or any of the other ingredients of this medicine (listed in section 6). An allergic reaction can include a rash, itching or shortness of breath.
- 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 pre-coma. 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 are a heavy drinker of alcohol (more than 21 units a week for a man or 14 units a week for a woman). A unit is equivalent to a small glass of wine, one shot or half a pint of beer

If any of the above applies to you, talk to your doctor, before you start taking this medicine.

Talk to your doctor or pharmacist before taking Metformin Tablets 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 Metformin Tablets 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

Metformin Tablets 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 diseases).

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

Stop taking Metformin tablets 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 Metformin tablets 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 Metformin tablets during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Metformin tablets.

Metformin Tablets on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take Metformin Tablets 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, visions disorders or difficulty in concentration, it usually helps to eat or drink something containing sugar.

During treatment with Metformin tablets, 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 Metformin Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

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

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 Metformin Tablets. 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 asthma)
- medicines that may change the amount of metformin tablets in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin; cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib).
- other medicines used to treat diabetes

Metformin Tablets with alcohol

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

During pregnancy, you need insulin to treat your diabetes. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This medicine is not recommended if you are breast-feeding or if you are planning to breast-feed your baby.

Driving and using machines

Metformin 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 Metformin together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, insulin, meglitinides). Symptoms of hypoglycaemia include weakness, dizziness, increased sweating, fast heart beat, vision disorders or difficulty in concentration. Do not drive or use machines if you start to feel these symptoms.

3. How to take Metformin Tablets

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

Metformin tablets 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.

Adults and the elderly

- The recommended starting dose is one or two 500mg tablets, or one 850mg tablet a day, which is gradually increased until the right dose is found for you.
- Do not take more than a total of six 500mg tablets, or three 850mg tablets, in one day.
- In most cases the symptoms can eventually be controlled with three 500mg tablets, or two 850mg tablets, a day.
- The daily doses should be divided into two or three doses.

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

Children

Not for use in children.

Monitoring

- Your doctor will perform regular blood glucose tests and will adapt your dose of Metformin Tablets to your blood glucose levels. Make sure that you talk to your doctor regularly. This is particularly important if you are an older person.
- Your doctor will also check at least once a year how well your kidneys work. You may need more frequent checks if you are an older person or if your kidneys are not working normally.

How to take Metformin tablets

Take Metformin 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)
- If you take two divided doses a day, take them in the morning (breakfast) and evening (dinner)
- If you take three divided doses a day, take them in the morning (breakfast), at noon (lunch) and in the evening (dinner)

If, after some time, you think that the effect of Metformin tablets is too strong or too weak, talk to your doctor or pharmacist.

If you take more metformin tablets than you should

Talk to a doctor or go to a hospital straight away. The following effects may happen:

- Unexpected weight loss, feeling very sick or being very sick, very fast breathing which you cannot stop, stomach pains or feeling cold. You may have something called 'lactic acidosis'. The doctor may use a method called 'haemodialysis' to remove the extra lactate and metformin from your body.

If you forget to take Metformin Tablets

Take them as soon as you remember. However, if it is almost time for the next dose, skip the missed dose. Then go on as before. Do not take a double dose to make up for the forgotten dose.

If you stop taking Metformin tablets

Keep taking this medicine until your doctor tells you to stop.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side-effects may occur:

Metformin may cause a very rare (may affect up to 1 user in 10,000) but very serious side effect called lactic acidosis (see section 'Warnings and precautions'). If this happens you must **stop taking Metformin tablets and contact a doctor or the nearest hospital immediately**, as lactic acidosis may lead to coma.

Very common: may affect 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 Metformin Tablets. It helps if you spread the doses over the day and if you take Metformin Tablets with or straight after a meal. If symptoms continue, stop taking Metformin Tablets and talk to your doctor.

Common: may affect up to 1 in 10 people

- changes in taste.

Very rare: may affect up to 1 in 10,000 people

- abnormalities in liver function tests or hepatitis (inflammation of the liver; this may cause tiredness, loss of appetite, weight loss, with or without yellowing of the skin or whites of the eyes). If this happens to you, **stop taking Metformin Tablets and talk to your doctor**.
- skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives).
- low vitamin B12 levels in the blood.

Reporting of side effects

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

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Keep this medicine in the package or container in which it was given to you. Do not transfer to another container.
- Do not use this medicine after the expiry date, which is stated on the blister and carton after EXP (month, year). The expiry date refers to the last day of that month.
- Do not use this medicine if you notice that the appearance of your medicine has changed. Talk to your pharmacist.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Metformin Tablets contain

The active substance is metformin hydrochloride.

The other ingredients are sodium starch glycollate (type A), maize starch, povidone K30, colloidal anhydrous silica, magnesium stearate, methylhydroxypropylcellulose, titanium dioxide E 171, propylene glycol E1520, polyethylene glycol 6000, and purified talc E553 b.

What metformin tablets look like and contents of the pack

Metformin 500mg tablets are white, film coated, round, biconvex tablets with MET 500 on one side and CP on reverse. Metformin 850mg tablets are white, film coated, round, biconvex tablets with MET 850 on one side and CP on reverse. They come in blister packs of 28 and 84 (500mg) tablets and 56 (850mg) tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder: Wockhardt UK Limited, Ash Road North, Wrexham, LL13 9UF, UK.
Manufacturer: CP Pharmaceuticals Limited, Ash Road North, Wrexham, LL13 9UF, UK.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: **0800 198 5000 (UK Only)**

Please be ready to give the following information:

Product name	Reference number
Metformin 500 mg Film-Coated Tablets	29831/0133
Metformin 850 mg Film-Coated Tablets	29831/0134

This is a service provided by the Royal National Institute of Blind People.

The leaflet was last revised in 05/2017