

Title: Metformin 500/850mg PIL

Ref: SIG/MET/500/850

Date: 28/10/15 (Modified) 11/05/23

Size (mm): 260(H) x 162(W)

Minumum point size: 8pt

Typefaces:
Arial Roman
Arial Bold

Colours (Printed)

Black
Process

TRIM

PACKAGE LEAFLET: INFORMATION FOR THE USER

**METFORMIN 500 mg TABLETS and
METFORMIN 850 mg TABLETS**

Metformin Hydrochloride

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 Tablet is and what it is 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 tablet is and what it is used for

These tablets are available in two different strengths and your doctor will have decided which is the most suitable for you. Each tablet contains either 500 mg or 850 mg of the active ingredient, metformin hydrochloride.

Metformin is one of a group of medicines called oral hypoglycaemics, which work by reducing the level of sugar in the blood.

Metformin Tablets are used for the treatment of a type of diabetes which usually only occurs in adults, and is not severe enough to need insulin, but which does not respond to dietary measures alone. In some patients metformin may be used in combination with other anti-diabetic medicines called sulphonylureas.

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)
- If you have uncontrolled diabetes, with e.g. 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 unusual fruity odour of the breath.
- If you have problems with your liver
- If you have severely reduced kidney function.
- If you have an acute or chronic disease which could cause decreased oxygen supply (hypoxia), like heart failure, respiratory failure or a recent heart attack or you have breathing problems. 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 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 dehydrated (feeling extremely thirsty) or have severe diarrhoea or you have vomited several times in a row. Dehydration may lead to kidney problems, which can put you at risk for lactic acidosis (see "Warning and precautions")

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 blood stream.
- 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 instruction precisely.

Warnings and precautions

Risk of lactic acidosis

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

Metformin on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take metformin 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 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.

Other medicines and Metformin Tablets

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

Tell your doctor or pharmacist 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. 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 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 tablet with Alcohol

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

Continued, please turn over

<i>Title:</i> Metformin 500/850mg PIL
<i>Ref:</i> SIG/MET/500/850
<i>Date:</i> 28/10/15 (Modified) 11/05/23
<i>Size (mm):</i> 260(H) x 162(W)

Minimum point size: 8pt

Typefaces:
Arial Roman
Arial Bold

Colours (Printed)



— TRIM

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, speak to your doctor in case any changes will be needed to your treatment or monitoring of your blood glucose levels. This medicine is not recommended if you are breast-feeding or if you are planning to breast-feed your baby.

Driving and using machinery

Metformin Tablets taken on their own should not affect your ability to drive or operate machinery, but if you are also taking them with another medicine (sulphonylureas or insulin) to lower blood sugar levels, it is possible the combined effect of these medicines may make some patients feel faint or dizzy. If this happens do not drive or operate machinery until you feel better.

3. How to take Metformin Tablets

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

The Metformin tablet 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:

Adults: usually starts with 500 mg or 850 mg Metformin 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 Metformin tablets.

Children 10 years and over and adolescents: usually start with 500 mg or 850 mg Metformin tablet 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.

Monitoring

- Your doctor will perform regular blood glucose tests and will adapt your dose of metformin 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 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 the tablet 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 is too strong or too weak, talk to your doctor or pharmacist.

If you take more Metformin Tablets than you should

If you have taken more metformin than you should have, you may experience lactic acidosis.

Symptoms of lactic acidosis are non-specific such as vomiting, bellyache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. Further symptoms are reduced body temperature and heart beat. **If you experience some of these symptoms, you should seek immediate 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 Tablets

Do not take a double dose to make up for the forgotten dose. Take the next dose at usual time. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Metformin Tablets can cause side effects, although not everybody gets them.

Serious side effects:

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.

Other side effects:

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

Common side effects (in less than 1 in 10 people)

- Changes in taste
- decreased or low vitamin B12 levels in the blood (symptoms may include extreme tiredness (fatigue), a sore and red tongue (glossitis), pins and needles (paraesthesia) or pale or yellow skin). Your doctor may arrange some tests to find out the cause of your symptoms because some of these may also be caused by diabetes or due to other unrelated health problems.

Very rare side effects (in less than 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 and talk to your doctor.
- skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives)

Children and adolescents: Limited data in children and adolescents showed that adverse events were similar in nature and severity to those reported in adults.

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 Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Metformin Tablets

Keep out of the sight and reach of children - preferably in a locked cupboard or cabinet.

Do not store above 25°C. Store the tablets in the original blister pack.

Do not take the tablets after the expiry date shown on the carton.

The expiry date refers to the last day of that month. If your doctor tells you to stop taking the tablets, please take any unused medicine back to your pharmacist to be destroyed. Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Metformin Tablet contains

Each tablet contains either 500 mg or 850 mg of the active ingredient, metformin hydrochloride. The tablets also contain sodium starch glycolate, maize starch, povidone, colloidal anhydrous silica, magnesium stearate, hypromellose, titanium dioxide (E171), propylene glycol, macrogol 6000 and purified talc.

What Metformin Tablets look like and contents of the pack.

Metformin Tablets are round, white, film-coated tablets. The 500 mg strength tablets are marked with "500" on one side and the 850 mg strength tablets are marked with "850" on one side.

They are available in blister packs containing 28, 56 or 84 tablets (500 mg) and 28, 42, 56 or 84 tablets (850 mg).

Not all pack sizes are marketed.

Marketing Authorisation Holder:

Marketing Authorisation Holder: RxFarma, Colonial Way, Watford, Hertfordshire, WD24 4YR, United Kingdom

Manufacturer: RX Farma Limited, Unit 3, Colonial Way, Watford, Hertfordshire, WD24 4YR, United Kingdom

Product licence numbers

Metformin 500mg Tablets - PL 36722/0030

Metformin 850mg Tablets - PL 36722/0031

For any information about this medicine, please contact the Marketing Authorisation Holder.

The Leaflet was last reviewed in May 2023

If you would like this leaflet in a different format, please contact the licence holder at the above address.