

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Metformin Hydrochloride 500mg Film Coated 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 is and what it is used for
2. What you need to know before you take Metformin
3. How to take Metformin
4. Possible side effects
5. How to store Metformin
6. Contents of the pack and other information

1 What Metformin is and what it is used for

Metformin belongs to a group of medicines called biguanides. It works by lowering your blood-sugar level. Metformin may be used alone or in combination with other medicines to treat diabetes (oral or insulin).

Metformin is used:

- To treat non-insulin dependent diabetes (also called type 2 diabetes) where diet and exercise alone has failed to control blood sugar levels, particularly if overweight.
- As the only treatment or in combination with insulin, for children aged from 10 years and adolescents.
- As an initial treatment to reduce complications associated with type 2 diabetes (non-insulin dependent diabetes), if you are an overweight adult and diet has failed to control your blood sugar levels.

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 (listed in section 6).
- You suffer from or have a history of serious diabetic complications such as loss of consciousness caused by either very high or very low blood sugar levels (diabetic coma), a lack of insulin which leads to high blood sugar levels, ketones in the urine and certain acids in the blood (ketoacidosis).
- You suffer from conditions which may cause a lack of oxygen supply to your body tissue (hypoxia) such as sudden heart failure (even if the condition is under control), insufficient oxygen passes from your lungs to your blood (respiratory failure), you have recently had a heart attack or have severe problems with your circulation such as shock.
- You suffer from kidney or liver problems.
- You regularly drink a lot of alcohol.
- You suffer from a loss or lack of water in the body (dehydration).
- You have a severe infection.

Warnings and precautions

Talk to your doctor before taking Metformin if:

- You are at risk of a build-up of lactic acid in the blood (lactic acidosis). Metformin may cause a very rare, but serious complication called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, prolonged fasting, excessive alcohol intake, dehydration, liver problems and any conditions where an area of the body is deprived of oxygen (such as heart failure or sudden heart attack). Symptoms of lactic acidosis can include being sick (vomiting), stomach pain, muscle cramps, a general feeling of not being well, severe tiredness, difficulty in breathing, reduced body temperature and heartbeat. **If you experience any of these symptoms, you should seek medical advice immediately as lactic acidosis may lead to coma.**

- You suffer from kidney problems, particularly if you are elderly.
- You suffer from heart failure.
- You are due to have major surgery as you must stop taking your Metformin 48 hours before having an anesthetic.
- This medicine is intended for a child.
- You continuously use Metformin. It may reduce your vitamin B12 level and should be annually monitored by your doctor.
- You are taking insulin or other oral antidiabetic medicines e.g. sulfonylureas or meglitinides (see “Other medicines and Metformin” section) as there is a risk of low blood sugar levels (hypoglycaemia).
- You are to undergo diagnostic tests (using iodinated contrast media). You may need to stop taking your Metformin.

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.

Other medicines and Metformin

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

Other medicines which may interact with or be affected by Metformin:

- Other medicines used to treat diabetes, such as glibenclamide (known as sulfonylureas), meglitinides or insulin (antidiabetics).
- Medicines used to treat fluid retention or high blood pressure, such as furosemide (diuretics)
- Medicines to thin the blood, such as warfarin (anticoagulants).
- Cimetidine, for stomach ulcers and indigestion.
- Medicines for inflammatory and allergic conditions, such as betamethasone (glucocorticoids).
- Medicines used to treat life-threatening allergies (anaphylaxis) such as epinephrine (sympathomimetics).
- Medicines that may change the amount of Metformin in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib).

Taking Metformin with food and drink and alcohol

- These tablets should be taken with or after food.
- You should continue your diet, ensuring a regular intake of carbohydrates throughout the day. If you are overweight, you should continue with your energy-restricted diet.
- Alcohol and alcohol-containing medicines should be avoided whilst taking Metformin.

Pregnancy and breast-feeding

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

Pregnancy

If you are pregnant, it is recommended that your diabetes is treated with insulin instead of Metformin.

Breast-feeding

If you are breast-feeding, the use of this medicine is not recommended as Metformin is passed into breast milk.

Driving and using machines

Metformin should not affect your ability to drive or operate machinery. However, there is a risk of low blood sugar levels (hypoglycaemia) when Metformin is taken in combination with other antidiabetic medicines e.g. sulfonylureas, insulin or meglitinides (see “Other medicines and Metformin” section).

3 How to take Metformin

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

- These tablets are to be taken orally.
- These tablets should be taken with or after food.

Adults

- The recommended starting dose is 500mg or 850mg, two or three times a day.
- The maximum dose is 3000mg per day taken in 3 divided doses.
- After 10-15 days, your dose should be adjusted according to your blood sugar levels.
- If you are transferring from another oral medicine used to treat diabetes to Metformin, the other medicine must be stopped before starting treatment with Metformin.
- Metformin may be taken in combination with insulin. Your dose of insulin will be adjusted according to your blood sugar levels.

Elderly

Your doctor will monitor your condition if you have kidney problems and adjust your dose of Metformin accordingly.

Use in children

- Metformin can be used as the only treatment or in combination with insulin, for children aged from 10 years and adolescents.
- The recommended starting dose is 500mg or 850mg once a day.
- The maximum recommended dose is 2000mg per day, taken as 2 or 3 divided doses.
- After 10-15 days, your dose should be adjusted according to your blood sugar levels.

If you have taken more Metformin than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you. An overdose of Metformin may lead to a build-up of lactic acid in the blood (lactic acidosis) (see Section 2 "Warnings and precautions").

If you forget to take your Metformin

Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, do **not** take a double dose to make up for a forgotten dose.

If you stop taking Metformin

It is important that you keep taking Metformin for as long as your doctor has told you to.

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

4 Possible side effects

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

Seek medical advice immediately if you develop the following symptoms:

- Allergic reactions: swelling of the face, throat or tongue, difficulty breathing or dizziness
- A build-up of lactic acid in the blood (lactic acidosis) (see Section 2, "Warnings and precautions")

Very common side effects (may affect more than 1 in 10 people)

- Feeling sick (nausea) or being sick (vomiting)
- Diarrhoea
- Stomach pain
- Loss of appetite

These side effects usually occur at the start of treatment and are of short duration. They may be avoided by taking Metformin in 2 or 3 daily doses with or after food.

Common side effects (may affect up to 1 in 10 people)

- Taste disturbance
- 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 (may affect up to 1 in 10,000 people)

- Skin rashes (erythema)
- Severe itching (pruritus)

- Skin rashes with the formation of wheals (urticaria)
- Abnormal liver function test (detected through blood test). Resolves after stopping treatment with Metformin

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 the Yellow Card Scheme at 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

- Keep this medicine out of the sight and reach of children.
- Do not take Metformin after the expiry date, which is stated on the carton/blister after EXP. The expiry date refers to the last day of that month.
- Store below 25°C, in the original package in order to protect from light.
- Medicines should not be disposed of via wastewater or household waste. 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 contains:

Each film-coated tablet contains 500mg of Metformin Hydrochloride.

The other ingredients are: povidone K30, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate, sodium starch glycollate, ethyl cellulose 7 cps, hypromellose, propylene glycol and titanium dioxide (E171).

What Metformin looks like and the contents of the pack:

Metformin 500mg are approximately 12mm, white, round, convex, film-coated tablets marked 17 LG on one side.

Metformin is available in:

Metformin Tablets are available in packs of 28, 50, 56, 84, 100 or 500 tablets.

Not all pack sizes may be marketed.

Product Licence Number:

PL 52574/0005

Marketing Authorisation Holder:

HFA Holdings Limited.

Wharley Hall Barston Lane Hampton in Arden West Midlands B92 0HS.

Manufacturer:

Pacific Pharmaceuticals Limited

30th KM Multan road Lahore.

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