

Metformin HCl 500mg, 850mg, 1000mg film-coated tablets (Metformin hydrochloride)

What is metformin hcl and what is it used for?

Metformin HCl belongs to a group of medicines called biguanides. These medicines are used in the treatment of type II diabetes, which is a form of diabetes that usually occurs later in life. In diabetes, the blood sugar level is too high and therefore, it needs to be lowered. Metformin HCl reduces the blood sugar level and is prescribed when a diet and more physical activity are not enough.

Metformin HCl reduces the production of glucose (sugar) in the liver, increases the sensitivity of cells to insulin, and improves the use of glucose in the body. It also slows down the absorption of glucose in the intestines, which slows down the spread of glucose throughout the body. Metformin HCl also has a favorable effect on the fatty acid and cholesterol metabolism in the body. In addition, the use of Metformin HCl reduces the risk of complications that often occur with diabetes, such as problems with the eyes, heart, brain, and feet.

Metformin HCl is used in the treatment of type II diabetes in adults, especially in patients who are overweight, when the blood sugar level cannot be adequately regulated with diet and physical activity alone. Metformin HCl can also be prescribed in combination with other blood sugar-lowering agents or insulin.

When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

if you are allergic to any of the substances in this medicine.

if you have uncontrolled diabetes with, for example, severe hyperglycemia (high blood glucose), nausea, vomiting, diarrhea, rapid weight loss, lactic acidosis (see "Risk of lactic acidosis" below), or ketoacidosis. Ketoacidosis is a condition in which so-called ketone bodies accumulate in the blood, which can lead to diabetic precoma. The symptoms include stomach pain, rapid and deep breathing, drowsiness, or an unusual fruity smell on the breath.

if you have severely reduced kidney function

in sudden-onset conditions that also reduce kidney function, Metformin HCl should not be used. Kidney function can be reduced by dehydration due to, among other things, diarrhea and/or vomiting, high fever, severe infections, and shock. if you have conditions that can lead to oxygen deficiency in tissues, such as reduced heart or lung function, recent heart attack, and shock in case of reduced liver function, acute alcohol poisoning, and excessive alcohol use.

When should you be extra careful with this medicine?

Risk of lactic acidosis Metformin HCl can cause the very rare but very serious side effect of lactic acidosis, especially if your kidneys do not work well. The risk of developing lactic acidosis is also increased in uncontrolled diabetes, severe infections, prolonged fasting or alcohol use, dehydration (see further information below), liver problems, and medical conditions in which a part of the body has insufficient oxygen (such as acute severe heart disease). If any of the above conditions apply to you, contact your doctor for further advice. Stop taking it and contact your doctor or the nearest hospital immediately if you experience one or more symptoms of lactic acidosis, as this condition can lead to a coma.

Symptoms of lactic acidosis include: vomiting, abdominal pain, muscle cramps, a general feeling of malaise with severe fatigue, difficulty breathing, decreased body temperature and heart rate. Lactic acidosis is a medical emergency and must be treated in the hospital.

Stop taking Metformin HCl temporarily if you have a condition that may be associated with dehydration (significant loss of body fluids), such as severe vomiting, diarrhea, fever, exposure to heat, or if you drink less fluid than usual. Contact your doctor for further advice.

Exercise extra caution when using Metformin HCl in situations where there is a chance of a reduction in kidney function, such as at the start of treatment for high blood pressure, at the start of using diuretics (water pills), or when using certain painkillers that also have anti-inflammatory and fever-reducing effects (NSAIDs). Reduced kidney function is more common in elderly patients. During treatment with Metformin HCl, your doctor will check your kidney function at least once a year, or more frequently if you are elderly and/or have a worsened kidney function.

If you need to take iodine-containing contrast agents for examination, these agents may cause a reduced kidney function, which increases the risk of the side effect lactic acidosis. Therefore, your doctor will ask you to stop taking Metformin HCl before an examination involving these contrast agents. Generally, you may resume taking Metformin HCl 48 hours after the examination.

If you are undergoing major surgery, you should stop taking Metformin HCl during and for a period after the procedure. Your doctor will decide when you should stop and when you should resume treatment.

During the use of Metformin HCl, it is important that you eat at regular times of the day. If you are on a diet due to your weight, it is important that you continue to follow this diet. Additionally, you should have regular laboratory tests for the control of diabetes.

If you are using other medications for diabetes. Metformin HCl alone cannot cause low blood sugar (hypoglycemia). Other medications for diabetes can cause this. If you use Metformin HCl in combination with one of these medications, your blood sugar level may become too low. Contact your doctor or pharmacist before using this medication.

Are you using any other medications?

If it is necessary for you to be injected with an iodine-containing contrast agent, for example, for an X-ray or a scan, you must stop taking Metformin HCl before or at the time of the injection. Your doctor will decide when you should stop and when you should resume treatment.

Metformin can cause decreased absorption of Vitamin B12, especially in patients undergoing prolonged treatment.

If you are using other medications in addition to Metformin HCl, have recently used them, or may use other medications in the near future, you may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust your Metformin HCl dose. It is particularly important to report the following:

- If you are using medications that increase urine production (diuretics).
- If you are using medications to treat pain and inflammation (NSAIDs and COX-2 inhibitors, such as ibuprofen and celecoxib).
- If you are using certain medications to treat high blood pressure (ACE inhibitors and angiotensin II receptor antagonists).
- If you are using certain adrenal cortical hormones (glucocorticosteroids); blood sugar levels may increase.
- If you are using certain medications to treat high blood pressure (ACE inhibitors and angiotensin II receptor antagonists).
- If you are using certain adrenal cortex hormones (glucocorticosteroids), it may increase blood sugar levels.
- If you are using certain medications used for breathing difficulties (bronchodilators, such as salbutamol, fenoterol, and terbutaline), it may increase blood sugar levels.

What should you be aware of when consuming alcohol?

Avoid excessive alcohol intake when using Metformin HCl, as this can increase the risk of lactic acidosis (see section 'When to be extra careful with this medicine?').

Pregnancy and breastfeeding: Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Pregnancy: The use of Metformin HCl is not recommended. If you are planning to become pregnant or think you are pregnant, discuss this with your doctor. Your doctor will interrupt treatment with Metformin HCl and switch you to insulin treatment.

Breastfeeding: Do not use Metformin HCl without consulting your doctor if you are breastfeeding.

Driving and using machinery: If you only use Metformin HCl and no other medicines for your diabetes, Metformin HCl has no effect on driving or using machinery. If you also use other medicines for your diabetes with Metformin HCl, your blood sugar level may sometimes become too low. In that case, your ability to actively participate in traffic or operate machinery may decrease.

How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, please contact your doctor or pharmacist.

Dosage

The following dosage applies to both the 500 mg, 850 mg and 1000 mg tablets. Your doctor will prescribe the dosage and determine whether you should use 500 mg, 850 mg or 1000 mg tablets. You must adhere closely to the prescribed dosage.

The usual dose is 1 tablet containing 500 or 850 mg of metformin hydrochloride 2 to 3 times a day. If necessary, your doctor may increase the dose and prescribe Metformin HCl 1000 mg. The dosage may be adjusted based on blood sugar levels after 10 to 15 days. The maximum dose is 3 g of metformin hydrochloride per day. If you have reduced kidney function, your doctor may prescribe a lower dose.

If you are taking other medications for your diabetes in addition to Metformin HCl, the usual dose is also 1 tablet containing 500 or 850 mg of metformin hydrochloride 2 to 3 times a day. Your doctor will prescribe the correct dose.

If your doctor has decided to switch you from another medication for your diabetes to Metformin, your doctor will stop treatment with the other medication. Metformin HCl can also be prescribed in combination with insulin. In this case, the usual dosage is 1 tablet containing 500 or 850 mg of metformin hydrochloride 2 to 3 times a day. Your doctor will adjust the dose of insulin based on blood sugar levels.

In general, it will be necessary to use Metformin HCl (1000 mg) for a longer period of time.

Elderly patients

Reduced kidney function is more common in elderly patients. If necessary, the doctor will adjust the dose of Metformin HCl in older patients based on kidney function.

Use in children

For children aged 10 years and adolescents, the usual starting dose is 1 tablet containing 500 or 850 mg of metformin hydrochloride. Your doctor may adjust the dosage if necessary. The maximum dose for children aged 10 years and adolescents is 4 tablets containing 500 mg of metformin hydrochloride (= 2 grams of metformin hydrochloride) per day, divided into 2 or 3 doses.

Children under 10 years of age should not use Metformin HCl because there is insufficient data on its use in children under 10 years of age.

Method of use: It is best to take Metformin HCl during or after a meal. Take the tablet by swallowing it with enough liquid (such as water). The daily dose is usually taken throughout the day.

Did you use too much of this medicine?: If you have taken too much of Metformin HCl, contact your doctor or pharmacist immediately.

Did you forget to use this medicine?: If you have missed a dose, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and continue with your normal dosing schedule. Do not take a double dose to make up for a missed dose.

If you stop using this medicine: If you suddenly stop using Metformin HCl without consulting your doctor, you may experience high blood sugar levels. Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

Possible side effects

Like any medicine, this medicine can have side effects, although not everyone gets them. Metformin HCl can cause the very rare but serious side effect of lactic acidosis (which can occur in up to 1 in 10,000 people, see section 'When to be extra careful with this medicine?'). If this happens, you should stop using this medicine immediately and contact a doctor or the nearest hospital immediately, as lactic acidosis can lead to coma.

The frequencies of the side effects mentioned below are classified as follows: **Very common:** in more than 1 in 10 patients: nausea, vomiting, diarrhea, abdominal pain, loss of appetite.

These side effects mainly occur at the beginning of treatment and in most cases disappear on their own. To prevent these symptoms, take the tablets during or after meals and divide them into 2 to 3 doses per day.

Common: in 1 to 10 out of 100 patients: taste disturbances.

How to store this medicine?

Store below 25°C.