

Package leaflet: Information for the user
Metformin EQL 500 mg and 850 mg film-coated tablets

metforminhydrochloride

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 EQL is and what it is used for
2. What you need to know before you use Metformin EQL
3. How to use Metformin EQL
4. Possible side effects
5. How to store Metformin EQL
6. Contents of the pack and other information

1. What Metformin EQL is and what it is used for

Metformin EQL contains metformin, a drug used to treat diabetes. It belongs to a group of medicines called biguanides.

Insulin is a hormone produced in the pancreas that helps the body absorb glucose from the blood. The body uses glucose to produce energy or stores it for future needs. If you have diabetes, the pancreas does not produce enough insulin or the body cannot use the insulin that is produced well enough. It leads to high blood glucose levels. Metformin EQL helps to lower blood glucose levels to a level as close to the normal level as possible.

If you are adult and overweight, taking Metformin EQL for a long time may also help reduce the risk of complications associated with diabetes. Metformin EQL is linked to either a stable body weight or a small weight loss.

Metformin EQL is used to treat patients with type 2 diabetes (also called "non-insulin-dependent diabetes") when diet and exercise alone are not enough to control blood glucose levels, especially in obese patients.

Adults can take Metformin EQL as a single treatment or together with other medicines to treat diabetes (oral or insulin-based medicines).

Children 10 years of age or older and adolescents may take Metformin EQL as a single treatment or together with insulin

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

Do not take Metformin EQL:

- if you are allergic (hypersensitive) to metformin or to any of the other ingredients of this medicine (listed in section 6).
- if you have liver problems
- if you have severe renal impairment

- if you have uncontrolled diabetes with eg severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhea, rapid weight loss, lactic acidosis (see 'Risk of lactic acidosis' below) or ketoacidosis. Ketoacidosis is a condition where substances called ketone bodies accumulate in the blood, which can lead to diabetic precoma. Symptoms include stomach pain, rapid and deep breathing, sleepiness or the fact that your breath has a different, fruity odor.
- if the body has lost too much water (dehydration), eg. due to prolonged or severe diarrhea, or if you have vomited several times in a row. Dehydration can lead to kidney problems, which can cause lactic acidosis (see “Warnings and precautions”).
- if you have a severe infection, eg. an infection that affects the lungs, trachea or kidneys. Severe infections can lead to kidney problems, which can cause lactic acidosis (See “Warnings and precautions”).
- if you are being treated for acute heart failure or have recently had a heart attack, if you have severe circulatory problems (such as shock) or difficulty breathing. This can lead to oxygen deficiency in the tissue, which can cause lactic acidosis (see “Warnings and precautions”).
- if you drink a lot of alcohol

If any of this apply to you, do not take this medicine without talking to a doctor.

You must consult a doctor

- you need to undergo an examination, such as an X-ray examination or computed tomography, which means that you get contrast agents containing iodine injected into the blood
- you must undergo a major surgery

You must stop taking Metformin EQL for some time before and after the examination or surgery. The doctor will decide if you need any other treatment during this time. It is important that you follow the doctor's instructions carefully.

Warnings and precautions

Risk of lactic acidosis

Metformin EQL can cause the very rare but very serious side effect of lactic acidosis, especially if your kidneys are not working properly. The risk of developing lactic acidosis is also increased in uncontrolled diabetes, severe infections, prolonged fasting or alcohol intake, dehydration (see more information below), liver problems and conditions where part of the body has reduced oxygen supply (including acute severe heart disease).

If any of the above applies to you, talk to your doctor for further details.

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.

Stop taking Metformin EQL for a shorter time if you have a condition that may be associated with dehydration, such as severe vomiting, diarrhea, fever, exposure to heat or drinking less fluid than normal. Talk to your doctor for further guidance.

Stop taking Metformin EQL and contact your doctor or nearest hospital immediately if you get any of the symptoms of lactic acidosis as the condition may lead to coma.

The symptoms of lactic acidosis include:

- vomiting
- abdominal pain (stomach pain)
- muscle cramps

- a general feeling of not feeling good and pronounced fatigue
- hard to breathe
- lowered body temperature and heart rate

Lactic acidosis is an acute medical condition that must be treated in hospitals.

If you are going to undergo a major surgery, you must stop taking Metformin EQL during the operation and a certain time after it. The doctor will decide when to stop taking Metformin EQL and when to start taking it again.

Metformin EQL itself does not cause hypoglycaemia (too low blood sugar) but if you take Metformin EQL with other anti-diabetic medicines that can cause hypoglycaemia (eg sulfonylureas, insulin, meglitinides), there is a risk of hypoglycaemia. If you get symptoms of hypoglycaemia, such as weakness, dizziness, increased sweating, rapid heart rate, visual disturbances or difficulty concentrating, it usually helps to eat or drink something that contains sugar.

During treatment with Metformin EQL, your doctor will check your kidney function at least once a year or more often if you are elderly and/or if your kidney function is impaired.

Other medicines and Metformin EQL

If you need an injection in the blood with iodine-containing contrast agents, for example, in X-ray or computed tomography, you must stop taking Metformin EQL before or at the time of injection. Your doctor will decide when to stop taking Metformin EQL and when to start taking it again.

Tell your doctor if you are taking, have recently taken or might take other medicines. You may need to do more blood sugar and kidney function tests, or your doctor may need to adjust the dose of Metformin EQL. It is especially important that you mention the following:

- medicines that increase urine production (diuretics).
- medicines used to treat pain and inflammation (NSAIDs and COX 2 inhibitors such as ibuprofen and celecoxib).
- some medicines used to treat 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 skin inflammation or asthma).
- medicines that can change the amount of Metformin EQL in your blood, especially if you have impaired renal function (eg verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib).
- other medicines used to treat diabetes

Metformin EQL with alcohol

Avoid large alcohol intake while taking Metformin EQL as alcohol may increase the risk of lactic acidosis (see section “Warnings and precautions”).

Pregnancy and breast-feeding

During a pregnancy, you need insulin to treat your diabetes. Tell your doctor if you are or think you are pregnant or plan to become so that he or she can change your treatment.

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 EQL alone does not cause hypoglycaemia (too low in blood glucose). This means that it does not affect your ability to drive or use machines.

However, you should be especially careful if you are taking Metformin EQL with other anti-diabetic medicines that may cause hypoglycaemia (eg sulfonylureas, insulin, meglitinides). Symptoms of hypoglycaemia include weakness, dizziness, increased sweating, rapid heart rhythm, visual disturbances or concentration difficulties. Do not drive or use machines if you experience such symptoms.

3. How to take Metformin EQL

Always take Metformin EQL as your doctor has told you. Ask your doctor or pharmacist if you are not sure.

Metformin EQL cannot replace the beneficial effects of a healthy lifestyle. Continue to follow any dietary advice that your doctor has given you and exercise regularly.

Recommended dose

Children 10 years of age or older and adolescents usually start with 500 mg or 850 mg Metformin EQL once a day. The maximum daily dose is 2000 mg divided into two or three doses. Treatment of children aged 10-12 years is only recommended according to your doctor's instructions, as the experience in this age group is limited.

Adults usually start with 500 mg or 850 mg Metformin EQL two or three times a day. The maximum daily dose is 3,000 mg divided into three doses.

If you have impaired kidney function, your doctor may print a lower dose.

If you are also taking insulin, your doctor will tell you how to start treatment with Metformin EQL.

Controls

- Your doctor will take regular blood glucose tests and adjust your dose of Metformin EQL to the blood glucose level. You must talk to your doctor regularly. This is especially important for children and adolescents or if you are older.
- Your doctor will also examine your kidney function at least once a year. You may need more frequent controls if you are older or your kidneys are not working properly.

How to take Metformin EQL

Take Metformin EQL during or after a meal. In this way you avoid side effects that affect the digestive tract.

The tablets should not be crushed or chewed. Swallow each tablet with a glass of water.

- If you take a dose a day, take it in the morning (breakfast).
- If you take two doses a day, take one dose in the morning (breakfast) and one in the evening (dinner).
- If you take three doses a day, take one dose in the morning (breakfast), one in the middle of the day (lunch) and one in the evening (dinner).

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

If you take more Metformin EQL than you should

If you have taken too much of Metformin EQL, lactic acidosis may occur. The symptoms of lactic acidosis are unspecific, such as vomiting, stomach pain with muscle cramps, general feeling of sickness with great fatigue and difficulty breathing. Additional symptoms are lowered body temperature and decreased heart rate. **If you experience any of these symptoms, you should immediately seek medical care as lactic acidosis may lead to coma. Stop taking Metformin EQL immediately and contact your doctor or nearest hospital straight away.**

If you forget to take Metformin EQL

Do not take a double dose to make up for a forgotten dose. Take the next dose at the time you would normally have taken it.

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 EQL can cause it very rarely (may occur in up to 1 user in 10,000), but very serious side effect is lactic acidosis (see section “Warnings and precautions”). If this happens to you, **you must stop taking Metformin EQL and immediately contact a doctor or nearest hospital** as lactic acidosis may lead to coma.

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

- Food digestion problems, e.g. nausea, vomiting, diarrhea, stomach pain and loss of appetite. These side effects usually occur at the beginning of Metformin EQL therapy. It helps if you distribute the doses over the day and if you are taking Metformin EQL during or immediately after a meal. **If symptoms persist, stop taking Metformin EQL and talk to your doctor.**

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

- Taste disturbances.

Very rare side effects (may affect up to 1 in 10,000 users)

- Lactic acidosis. This is a very rare but serious complication, which may occur especially if the kidneys are not working properly. Symptoms of lactic acidosis are non-specific (see section “Warnings and precautions”).
- Abnormalities in liver function test or liver inflammation (this may cause fatigue, loss of appetite, weight loss, with or without yellowing of the skin or whites of the eyes). If this happens to you, stop taking this medicine and contact your doctor.
- Skin reactions such as skin redness, itching or hives.
- Low level of vitamin B12 in the blood.

Children and adolescents

Limited information shows that the type and severity of side effects are similar for children and adolescents as for adults.

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 national reporting system listed in [Appendix V](#)**.^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Metformin EQL

Keep this medicine out of the sight and reach of children.

No special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton or bottle after EXP. The expiry date refers to the last day of that month.

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 EQL contains

Metformin EQL 500 mg

- The active substance is metforminhydrochloride. One film-coated tablet Metformin EQL 500 mg contains 500 mg metforminhydrochloride corresponding to 390 mg metformin base.
- The other excipients are sodiums starch glycolate, povidone, maize starch, colloidal anhydrous silica, magnesium stearate, titanium dioxide (E171), talc, macrogol, propyleneglycol, hypromellose, water.

Metformin EQL 850 mg

- The active substance is metforminhydrochloride. One film-coated tablet Metformin EQL 500 mg contains 850 mg metforminhydrochloride corresponding to 662,9 mg metformin base.
- The other excipients are sodiums starch glycolate, povidone, maize starch, colloidal anhydrous silica, magnesium stearate, titanium dioxide (E171), talc, macrogol, propyleneglycol, hypromellose, water.

What Metformin EQL looks like and contents of the pack

Metformin EQL 500 mg

Metformin EQL 500 mg film-coated tablets are white, round with a diameter of 11 mm, height of 6.0 mm, convex and marked 500 on one side.

The tablets are marketed in plastic bottle with child-protective cap, containing 105, 300, 330 and 400 tablets.

Metformin EQL 850 mg

Metformin EQL 850 mg film-coated tablets are white, round with diameter of 13,5 mm, height of 7.1 mm, convex and marked 850 on one side.

The tablets are marketed in plastic bottle containing 105 and 210 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden:	Metformin EQL 500 mg och 850 mg filmdragerade tabletter
Iceland:	Metformin EQL 500 mg och 850 mg filmuhúðaðar töflur

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