

Patient leaflet according to the Pharmacists' Regulations (Preparations) – 1986

This medicine is dispensed with a doctor's prescription only

Metformin Galenicum 850 mg, Film coated tablets

Each film coated tablet contains 850 mg metformin hydrochloride.

For information regarding inactive ingredients and allergens in the medicine - see section 6 "Additional information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar to yours.

1. What is the medicine intended for?

The medicine is intended for the treatment of type 2 diabetes mellitus, particularly in overweight patients, when change in diet and exercise alone are not sufficient to stabilize blood glucose levels.

- In adults, **Metformin galenicum 850 mg** is indicated as monotherapy or in combination with other oral medicines for the treatment of diabetes or with insulin.
- In children from 10 years of age and adolescents, **Metformin galenicum 850 mg** is indicated as monotherapy or in combination with insulin.

A reduction of diabetic complications has been observed in overweight adult patients with type 2 diabetes treated with metformin as first-line therapy after diet failure.

Therapeutic group: Medicines to lower blood glucose levels. The active ingredient is part of the biguanide group.

Insulin is a hormone produced by the pancreas, that causes the body to absorb glucose (sugar) from the blood. Your body uses glucose to create energy or stores it for future use. If you have diabetes, your pancreas does not produce enough insulin or your body is unable to properly use the insulin it produces. This causes a high blood level of glucose.

Metformin galenicum 850 mg helps to reduce the blood level of glucose to as normal as possible.

If you are an overweight adult, taking **Metformin galenicum 850 mg** over a long period of time also helps to reduce the risk of complications associated with diabetes. There is a connection between **Metformin galenicum 850 mg** and a stable body weight or moderate weight loss.

2. Before using the medicine

Do not use the medicine if:

- you are hypersensitive (allergic) to the active ingredient (metformin) or to any of the other ingredients this medicine contains (see section 6).
- you have liver problems.
- You suffer from a severe impairment in kidney function.
- you have diabetes that is not balanced with, for example, severe hyperglycemia (high blood glucose levels), nausea, vomiting, diarrhea, rapid weight loss, lactic acidosis (see below 'risk for lactic acidosis') or ketoacidosis. Ketoacidosis is a condition in which substances called "ketone bodies" accumulate in the blood, which can lead to diabetic pre-coma. The symptoms include: abdominal pain, rapid and deep breathing, sleepiness or breath with an unusual fruity smell.
- you have lost too many body fluids (dehydration), for example due to prolonged or severe diarrhea or continuous vomiting. Dehydration may lead to kidney problems, which can

cause a risk of lactic acidosis (see section "Special warnings regarding the use of the medicine").

- you suffer from a severe infection such as an infection affecting the lungs/bronchial system/ your kidney. Severe infections may lead to kidney problems, which can increase the risk of lactic acidosis (see section "Special warnings regarding the use of the medicine").
 - you have severe heart failure or have recently had a heart attack, have severe circulatory problem (e.g., shock) or have breathing difficulties. These conditions may lead to a deficiency in the supply of oxygen to the body tissues, which can cause a risk of lactic acidosis (see section "Special warnings regarding the use of the medicine").
 - you consume large quantities of alcohol.
- If one or more of the above conditions apply to you, consult a doctor before starting treatment with this medicine.

Special warnings regarding the use of the medicine

Before the treatment with Metformin galenicum 850 mg, tell the doctor if:

- you are about to undergo an examination such as an x-ray or a scan, that requires the injection of a contrast agent containing iodine into your blood.
- you are about to undergo a major operation.

You should stop taking **Metformin galenicum 850 mg** for a certain period before and after the examination or operation. Your doctor will decide if you need a different treatment during this period. It is important to follow your doctor's instructions precisely.

Additional special warnings

Risk of lactic acidosis

Metformin galenicum 850 mg may cause a very rare but also very serious side effect called lactic acidosis, especially if your kidneys do not function properly. The risk of developing lactic acidosis also increases in the following situations: when diabetes is not balanced, severe infections, prolonged fasting, excessive alcohol intake, dehydration (see additional information below), liver problems and with any medical condition in which there is a decrease in the supply of oxygen to the body's organs (such as acute and severe heart disease).

If one or more of the above conditions apply to you, consult a doctor for further instructions.

Stop taking Metformin galenicum 850 mg for a short period, if you are suffering from a condition that can be related to dehydration (significant fluid loss) such as severe vomiting, diarrhea, fever, exposure to heat or if you consume less fluids than usual. Consult a doctor for further instructions.

Stop taking Metformin galenicum 850 mg and immediately refer to a doctor or to a hospital emergency room, if you experience some of the symptoms of lactic acidosis, since this condition may cause a coma. Symptoms of lactic acidosis include: vomiting, abdominal pain, muscle cramps, a general feeling of not being well accompanied by severe tiredness, breathing difficulties, decrease in body temperature and heartbeat. Lactic acidosis is a medical emergency and must be treated in a hospital.

Talk to your doctor promptly for further instructions if:

- You suffer from a genetically inherited disease affecting mitochondria (the energy-producing components within cells) such as MELAS syndrome (brain damage [Mitochondrial Encephalopathy], muscle damage [myopathy], Lactic acidosis and Stroke-like episodes) or Maternal inherited diabetes and deafness (MIDD).
- You have any of the following symptoms after starting treatment with metformin: seizures, declined cognitive abilities, difficulty with body movements, symptoms indicating nerve damage (e.g. pain or numbness), migraine and deafness.

If you need to undergo a major operation, you must stop taking **Metformin galenicum 850 mg** during and for some time after the procedure. Your doctor will decide when you should stop and when to restart the treatment with **Metformin galenicum 850 mg**.

Metformin galenicum 850 mg as a monotherapy does not cause hypoglycemia (blood glucose levels that are too low). However, if you are taking **Metformin galenicum 850 mg** together with other medicines to treat diabetes that can cause hypoglycemia (such as sulfonylurea, insulin, meglitinides), there is a risk of hypoglycemia. If you experience symptoms of hypoglycemia such as weakness, dizziness, excessive sweating, rapid heartbeat, visual disturbances or difficulty concentrating - drinking or eating foods containing sugar usually helps in this situation.

Tests and follow up

- Your doctor will perform regular blood glucose tests and adjust the dosage of **Metformin galenicum 850 mg** to your blood glucose levels. Make sure to speak to your doctor regularly. This monitoring is especially important in children, adolescents and the elderly.
- During treatment with **Metformin galenicum 850 mg** your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if there is a worsening in your kidney function.

Drug interactions

If you need to undergo an injection of a contrast agent containing iodine into your blood, for example for an x-ray or a scan, you should stop taking **Metformin galenicum 850 mg** before or during the injection. Your doctor will decide when you should stop and when to restart the treatment with **Metformin galenicum 850 mg**.

If you are taking, have recently taken or might take other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. You may need more frequent monitoring of blood glucose levels and kidney function or your doctor will need to adjust the dosage of **Metformin galenicum 850 mg**.

Tell the doctor or pharmacist especially if you are taking:

- medicines that increase the amount of urine (diuretics).
- medicines to treat pain and inflammation (NSAID and COX-2 inhibitors, such as ibuprofen, celecoxib).
- certain medicines to treat high blood pressure (angiotensin converting enzyme [ACE] inhibitors, angiotensin II receptor blockers).
- beta-2 receptor agonists such as salbutamol or terbutaline (to treat asthma).
- corticosteroids (to treat various conditions, such as severe skin inflammation or asthma).
- medicines that may alter the level of **Metformin galenicum 850 mg** in your blood, especially in case of impaired kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib).
- other medicines to treat diabetes.

Use of the medicine and food

Take the medicine with or immediately after a meal to avoid gastrointestinal side effects.

Use of the medicine and alcohol consumption

Avoid excessive alcohol consumption during treatment with **Metformin galenicum 850 mg**, as there may be an increased risk for lactic acidosis (see section "Special warnings regarding the use of the medicine").

Pregnancy and breast-feeding

Tell your doctor If you are pregnant, think you might be pregnant or are planning to become pregnant, in order for him to decide if any changes are needed to your treatment or to the monitoring of your blood glucose levels.

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

Driving and operating machinery

Metformin galenicum 850 mg alone does not cause hypoglycemia (too low a blood glucose level). Therefore, the medicine should not affect your ability to drive or operate machinery.

However, be careful if you are taking **Metformin galenicum 850 mg** together with other medicines to treat diabetes that may cause hypoglycemia (such as sulfonylurea, insulin, meglitinides). Symptoms of hypoglycemia include weakness, dizziness, increased sweating, rapid heartbeat, visual disturbances or difficulty concentrating.

Do not drive or operate machinery if you begin to feel these symptoms.

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and the manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only.

Metformin galenicum 850 mg is not a substitute for a healthy lifestyle. Follow the dietary instructions recommended by the doctor and take care to exercise regularly.

The acceptable dosage is:

Children 10 years of age and older and adolescents:

The starting dosage is usually 500 mg or 850 mg once a day. The maximum daily dosage is 2,000 mg a day divided into 2 or 3 doses. The treatment of children 10-12 years of age is recommended only if explicitly instructed by the doctor since the experience with that age group is limited.

Adults:

The accepted starting dosage is usually 500 mg or 850 mg 2-3 times a day. The maximum daily dose is 2,550 mg a day, divided into 3 doses.

If you suffer from impaired kidney function, the doctor may prescribe a lower dosage for you. If you are also being treated with insulin, the doctor will instruct you on how to start treatment with **Metformin galenicum 850 mg**.

The Metformin Galenicum 850 mg tablet should not be halved in order to divide the dose. When a dose of 500 mg is required, a medicine containing 850 mg of metformin which can be halved should be used (to obtain a dose of 425 mg), which may serve as an alternative for a 500 mg tablet.

Do not exceed the recommended dose.

How to take Metformin Galenicum 850 mg?

Take **Metformin Galenicum 850 mg** with or immediately after the meal, to avoid gastrointestinal side effects.

Swallow the tablet with a cup of water.

- If you are taking one dose a day, take it in the morning (with breakfast).
- If you are taking the medicine twice a day, take it in the morning (with breakfast) and in the evening (with supper).
- If you are taking the medicine 3 times a day, take it in the morning (with breakfast), at noon (with lunch) and in the evening (with supper).

Method of administration

No information is available regarding crushing or chewing.

To make swallowing easier, the tablet may, if necessary, be split for immediate use. Both halves should be swallowed together immediately after splitting.

If, after a while, you think that the effect of **Metformin Galenicum 850 mg** is too strong or weak, consult a doctor.

If you have accidentally taken a higher dosage

If you have taken an overdose, you may suffer from lactic acidosis. Symptoms of lactic acidosis are not specific such as vomiting, abdominal pain with muscle cramps, general unwell feeling accompanied by severe tiredness and breathing difficulties. Additional symptoms include a decrease in body temperature and heartbeat. **If you experience these symptoms, seek medical treatment immediately, since lactic acidosis may lead to a coma. Stop taking Metformin Galenicum 850 mg immediately and refer immediately to a doctor or to a hospital emergency room.**

If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine

If you forgot to take the medicine at the scheduled time, do not take a double dose to compensate for a forgotten dose. Take the next dose at the usual time.

Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of **Metformin Galenicum 850 mg** can cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Metformin Galenicum 850 mg may cause a very rare (an effect that appears in less than one user out of 10,000), but very severe side effect called lactic acidosis (see section 2 "Special warnings regarding the use of the medicine").

If this side effect occurs, **stop taking Metformin Galenicum 850 mg and refer immediately to a doctor or a hospital**, since lactic acidosis may cause a coma.

Very common side effects (effects that occur in more than one in ten users):

- Gastrointestinal disturbances, such as nausea, vomiting, diarrhea, abdominal pain and loss of appetite. These effects usually occur at the beginning of treatment with **Metformin Galenicum 850 mg**. You can alleviate these symptoms by dividing the dose throughout the day and also by taking **Metformin Galenicum 850 mg** with or immediately after a meal. **If the symptoms continue, stop taking Metformin Galenicum 850 mg and consult the doctor.**

Common side effects (effects that occur in 1-10 users out of 100):

- Changes in the sense of taste.
- Decreased or low vitamin B12 levels in the blood [symptoms may include extreme tiredness, a sore and red tongue (inflammation of the tongue - glossitis), a sensation of pins and needles (paresthesia) or pale or yellow skin]. Your doctor may conduct a number of tests in order to find out the cause of the symptoms as some of them may also be caused by diabetes or by other unrelated health problems.

Very rare side effects (effects that occur in less than one user out of 10,000):

- Lactic acidosis. A very rare but very severe complication, especially if your kidneys are not functioning properly. Symptoms of lactic acidosis are not specific (see section 2 "Special warnings regarding the use of the medicine").

- Abnormalities in liver function tests or jaundice (liver inflammation that may cause tiredness, loss of appetite, weight loss, with or without yellowing of the skin or the whites of the eyes). If you experience these symptoms, **stop taking Metformin Galenicum 850 mg and refer to your doctor.**
- Skin reactions such as skin redness (erythema), itching or an itchy rash (hives).

Children and adolescents

Limited data regarding children and adolescence has shown side effects similar in character and severity to those reported in adults.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult a doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link “Report side effects due to medicinal treatment” found on the Ministry of Health website homepage (www.health.gov.il) , which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** store below 25°C.
- Do not discard medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. Additional information

In addition to the active ingredient the medicine also contains:

Hydroxypropylmethyl cellulose, povidone K90, magnesium stearate, macrogol 400 and macrogol 6000.

What the medicine looks like and what the package contains

White to yellowish, biconvex, oval shaped film coated tablets debossed with a scoreline between M and B on one side and debossed with a scoreline on the other side.

The scoreline serves only to fractionate the tablet and facilitate swallowing, but not to divide into equal doses.

Each carton package contains 30 film coated tablets packed in blisters.

Name and address of the registration holder:

A.L.Medi-Market Ltd., 3 Hakatif street, Emek Hefer Industrial Park, 3877701

Name and address of the manufacturer:

Galenicum Health S.L.U., Sant Gabriel,50 08950 Esplugues de Liobregat, Barcelona, Spain

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