

Package leaflet: Information for the patient

Metformin Mylan 500 mg film-coated tablets
Metformin Mylan 850 mg film-coated tablets
Metformin Mylan 1000 mg 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 Mylan is and what it is used for.
2. What you need to know before you take Metformin Mylan.
3. How to take Metformin Mylan.
4. Possible side effects.
5. How to store Metformin Mylan.
6. Contents of the pack and other information.

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

What Metformin Mylan is

Metformin Mylan contains the active substance metformin hydrochloride, a medicine to treat diabetes. It belongs to a group of medicines called biguanides.

Insulin is a hormone produced by the pancreas that makes your body take in glucose (sugar) from the blood. Your body uses glucose to produce energy or stores it for future use.

If you have diabetes, your pancreas does not make enough insulin or your body is not able to use properly the insulin it produces. This leads to a high level of glucose in your blood. Metformin Mylan helps to lower your blood glucose to as normal a level as possible.

If you are an overweight adult, taking Metformin Mylan over a long period of time also helps to lower the risk of complications associated with diabetes.

Metformin Mylan is associated with either a stable body weight or modest weight loss.

What Metformin Mylan is used for

Metformin Mylan is used to treat patients with type 2 diabetes (also called 'non-insulin dependent diabetes') when diet and exercise alone have not been enough to control your blood glucose levels. It is used particularly in overweight patients.

Adults can take Metformin Mylan on its own or together with other medicines to treat diabetes (medicines taken by mouth or insulin).

Children 10 years and over and adolescents can take Metformin Mylan on its own or together with insulin.

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

Do not take Metformin Mylan

- if you are allergic to metformin or any of the other ingredients of this medicine (listed in section 6)
- if you have liver problems
- if you have severely reduced kidney function.
- if you have uncontrolled diabetes, with, for example, 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 can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
- if you lost too much water from your body (dehydration), such as due to long-lasting or severe diarrhoea, or if you have vomited several times in a row. Dehydration may lead to kidney problems, which can put you at risk for lactic acidosis (see 'Warnings and precautions' below)
- 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' below)
- if you are treated for heart failure or have recently had a heart attack, have severe problems with your circulation (such as shock) or have breathing difficulties. This may lead to a lack in oxygen supply to tissue which can put you at risk for lactic acidosis (see 'Warnings and precautions' below)
- if you drink a lot of alcohol

If any of the above applies to you, talk to your doctor before you start taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Metformin Mylan

Risk of lactic acidosis

Metformin Mylan 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 Mylan 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 Mylan 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.

You need to eat carbohydrates regularly throughout the day. If your doctor has given you advice on your diet, you need to continue to follow this.

Metformin Mylan on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take Metformin Mylan together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulfonylureas, insulin, meglitinides), there is a risk of hypoglycaemia. If you experience symptoms of hypoglycaemia such as weakness, dizziness, increased sweating, fast heart beating, visions disorders or difficulty in concentration, it usually helps to eat or drink something containing sugar.

If you need to have major surgery you must stop taking Metformin Mylan during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Metformin Mylan.

Your doctor should check how your kidneys are working before treatment with this medicine, especially if you have heart failure that is being controlled by medicine.

During treatment with Metformin Mylan, 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.

Children and adolescents

Metformin Mylan is not recommended for use in children under 10 years of age. **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.**

Other medicines and Metformin Mylan

Tell your doctor 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 Mylan. 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

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

Metformin Mylan with alcohol

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

Pregnancy and breast-feeding

During pregnancy, you need insulin to treat your diabetes. Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby, so that he or she may change your treatment.

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

Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Metformin Mylan on its own does not cause hypoglycaemia (a blood glucose level which is too low). This means that it will not affect your ability to drive or use machines.

However, take special care if you take Metformin Mylan together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulfonylureas, insulin, meglitinides). Symptoms of hypoglycaemia include weakness, dizziness, increased sweating, fast heart beat, vision disorders or difficulty in concentration. **Do not** drive or use machines if you start to feel these symptoms.

3. How to take Metformin Mylan

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

Metformin Mylan 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.

The recommended dose in adults is 500 mg or 850 mg Metformin Mylan two or three times a day. The maximum daily dose is 3000 mg taken as 3 divided doses.

If you take insulin too, your doctor will tell you how to start Metformin Mylan.

Use in children 10 years of age and over and adolescents

Children 10 years and over and adolescents usually start with 500 mg or 850 mg **Metformin Mylan** 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 Mylan 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.

Method of administration

Take the tablets 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).

The 1000 mg tablet can be divided into equal doses.

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

If you take more Metformin Mylan than you should

If you have taken more Metformin Mylan than you should have, you may experience lactic acidosis. Symptoms of lactic acidosis are vomiting, bellyache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, - and difficulty in breathing. If this happens to you, you may need immediate hospital treatment, as lactic acidosis may lead to coma. Contact a doctor or the nearest hospital straight away.

If you forget to take Metformin Mylan

Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

If you stop taking Metformin Mylan

If you suddenly stop taking Metformin Mylan your blood glucose level may rise. Speak to your doctor before stopping this medicine.

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.

If you think you may have any of the following side effects, stop taking this medicine immediately and go to your nearest hospital emergency room straight away.

These side effects are very rare (may affect up to 1 in 10,000 people) lactic acidosis.

This is a very rare but very serious side effect (see section “Warnings and precautions”) Lactic acidosis may lead to coma

- 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).

Very common side effects (may affect 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 Mylan. It helps if you spread the doses over the day and if you take the tablets with or straight after a meal. **If symptoms continue, stop taking Metformin Mylan and talk to your doctor.**

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

- changes in taste.

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

- skin reactions such as redness of the skin (erythema), itching or an itchy rash (urticaria)
- low vitamin B₁₂ levels in the blood.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Metformin Mylan

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

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

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Metformin Mylan contains

The active substance is metformin (as hydrochloride).

Each 500 mg tablet contains 500 mg metformin hydrochloride equivalent to metformin base 390 mg.

Each 850 mg tablet contains 850 mg metformin hydrochloride equivalent to metformin base 662.9 mg.

Each 1000 mg tablet contains 1000 mg metformin hydrochloride equivalent to metformin base 780 mg.

The other ingredients are:

Core: povidone K-30, magnesium stearate,

Film-coating: hypromellose, hydroxypropyl cellulose and macrogol 400 and 8000.

What Metformin Mylan looks like and contents of the pack

500 mg: White, round, normal convex, film-coated tablets plain on both sides.

850 mg: White, round, normal convex, film-coated tablets plain on both sides.

1000 mg: White, oval, film coated tablet, debossed “MF” and “3” on either side of the breakline on one side and “G” on the other side.

Metformin Mylan tablets are packed in blister packs (PVC aluminium) containing 10, 15, 20, 28, 30, 40, 50, 56, 60, 84, 90, 100, 120 and 180 tablets and bottles (high density polyethylene) with caps (polypropylene) containing 30, 100, 180, 200, 300, 400, 500 and 1000 tablets.

Metformin Mylan 850 mg and 1000 mg film-coated tablets are also packed in multipacks of 180 comprising of 2 cartons each containing 90 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Limited t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Manufacturer:

McDermott Laboratories Ltd, t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Generics [UK] Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

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

Member State	Name of medicinal product
Austria	Arcamet 850 mg & 1000 mg Filmtabletten
Belgium	Metformine Mylan 500 mg filmomhulde tabletten Metformine Mylan 850 mg filmomhulde tabletten Metformine Mylan 1000 mg filmomhulde tabletten
Czech Republic	Metformin Mylan
Denmark	Mitforgen
France	METFORMINE MYLAN PHARMA 500 mg, comprimé pelliculé METFORMINE MYLAN PHARMA 850 mg, comprimé pelliculé METFORMINE MYLAN PHARMA 1000 mg, comprimé pelliculé sécable
Germany	Metformin dura 500mg/850mg/1000mg Filmtabletten
Ireland	Metformin Mylan
Portugal	Metformina Mylan
Slovakia	Metformin Mylan
Spain	Metformina MYLAN 500 mg comprimidos recubiertos con película Metformina MYLAN 850 mg comprimidos recubiertos con película EFG Metformina MYLAN 1000 mg comprimidos recubiertos con película EFG
Sweden	Mitforgen
The Netherlands	Metformine HCl Mylan 500mg 850mg 1000mg, filmomhulde tabletten
United Kingdom	Metformin hydrochloride 500mg 850mg 1000mg film-coated tablets

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