

NEW ZEALAND CONSUMER MEDICINE INFORMATION

METFORMIN MYLAN

Metformin hydrochloride, Film coated tablets, 500 & 850 mg



What is in this leaflet

This leaflet answers some common questions about Metformin Mylan.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Metformin Mylan against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Metformin Mylan is used for

Metformin Mylan is used to control blood glucose (the amount of sugar in the blood) in people with type 2 diabetes mellitus.

This type of diabetes is also known as non-insulin-dependent diabetes mellitus (NIDDM) or maturity onset diabetes.

Metformin Mylan is used when diet and exercise are not enough to control your blood glucose.

It can be used alone, or together with other medicines for treating diabetes.

Metformin Mylan contains the active ingredient metformin hydrochloride. It belongs to a group of medicines called biguanides.

It works by reducing liver glucose (sugar) production, increasing insulin sensitivity in the muscles and

delaying the absorption of glucose from the intestinal tract.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

This medicine does not cause hypoglycaemia (low blood sugar) and is not expected to affect your ability to drive a car or operate machinery. However there is a risk of hypoglycaemia when Metformin Mylan is used in combination with other antidiabetic medicines (see Taking other medicines).

Metformin Mylan is not recommended for use in children.

Before you take Metformin Mylan

When you must not take it

Do not take Metformin Mylan if you have an allergy to:

- any medicine containing metformin hydrochloride or a class of medicines called biguanides
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Metformin Mylan if you have any of the following:

- diabetes mellitus that is well controlled by diet alone
- type 1/juvenile diabetes mellitus that is uncomplicated and well controlled by insulin
- diabetic ketoacidosis (symptoms of uncontrolled diabetes, include loss of appetite, stomach pain, difficulty breathing, tired and muscle pain)
- diabetic pre-coma
- kidney failure/problems
- dehydration
- severe infection
- shock
- heart failure
- recent heart attack or chest pain (myocardial infarction)
- severe lung problems, such as shallow/difficulty breathing (respiratory failure)
- gangrene
- severe blood loss
- blockage of lung artery
- inflammation of the pancreas
- serious bacterial infection of the blood (sepsis)
- severe liver disease
- excessive alcohol intake or alcoholism
- a history of lactic acidosis

Do not take Metformin Mylan if you need to have major surgery or an examination such as an X-ray or a scan requiring an injection of iodinated contrast (dye). You must stop taking Metformin Mylan for a certain period of time before and after the examination or the surgery. Your doctor will decide whether you need any other treatment for this time. It is important that you follow your doctor's instructions precisely.

Do not breast-feed if you are taking this medicine. Metformin Mylan is not recommended while you are

breastfeeding. Your doctor will discuss the options available to you.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- heart failure
- kidney failure
- lactic acidosis

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you drink alcohol.

Alcohol can affect the control of your diabetes. Drinking excessive amounts of alcohol while you are being treated with Metformin Mylan may also lead to serious side effects. Your doctor may suggest you stop drinking or reduce the amount of alcohol you drink.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Metformin Mylan.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Metformin Mylan may interfere with each other. These include:

- other antidiabetic agents, such as sulfonylureas, repaglinide and insulin
- alcohol and alcohol-containing medications, such as cough and cold syrups
- medicines used to prevent the formation of blood clots, such as warfarin
- some medicines used to treat high blood pressure and other heart conditions, including ACE-inhibitors, beta-blockers, and calcium channel blockers, such as nifedipine
- thiazide diuretics, also called fluid tablets, a medicine used to treat high blood pressure, such as bendrofluazide
- cimetidine, a medicine used to treat reflux and ulcers
- corticosteroids – steroids that reduce inflammation throughout the body
- medicines used to treat thyroid conditions

These medicines may be affected by Metformin Mylan or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Metformin Mylan

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many Metformin Mylan tablets to take, and for how long.

The usual doses are shown below but your doctor may decide to adjust them to your individual needs.

The initial dose of Metformin Mylan is 500 mg once or twice a day, and if necessary, the dose increased over a few weeks up to 1 g three times per day (this is the maximum recommended daily dose).

The elderly and people with kidney problems may need smaller doses.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take Metformin Mylan during or immediately after food.

This will reduce the chance of a stomach upset.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well. Most people will need to take Metformin Mylan on a long-term basis.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of

developing lactic acidosis and unwanted side effects.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Metformin Mylan. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose are associated with the development of lactic acidosis and may include feeling unwell, aching/tender muscles, difficulty breathing, sleepiness, drowsiness and stomach pain.

While you are taking Metformin Mylan

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Metformin Mylan.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery. Metformin must be stopped 48 hours before elective major surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests (*blood glucose test, renal function tests and blood vitamin B12 level measurements*) from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take Metformin Mylan to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, the signs of low blood sugar (hypoglycaemia) may become less clear, and delayed hypoglycaemia can occur. In addition, there is an increased risk of lactic acidosis in acute alcohol intoxication (particularly in the case of fasting/malnutrition and liver disease)

Things that would be helpful for diabetes

Make sure that you, your friends, family and work colleagues can recognise the symptoms of both hypoglycaemia and hyperglycaemia and know how to treat them.

Recognising and treating hypoglycaemia (low blood sugar levels)

Metformin Mylan does not normally cause hypoglycaemia, although you may experience it if you take metformin in combination with other anti-diabetic medications.

Hypoglycaemia can rapidly occur, with symptoms including:

- shakiness
- sweating and chills
- irritability
- confusion
- fast heart beat
- lightheaded or dizziness
- blurred or impaired vision
- headaches
- weakness or fatigue
- tingling or numbness of the lips or tongue
- hunger or nausea

If you experience any of these symptoms, you need to raise your blood glucose levels immediately.

You can do this by doing one of the following:

- eating 5 to 7 jelly beans
- eating 3 teaspoons of honey or sugar
- taking 2 to 3 concentrated glucose tablets

Unless you are within 15 minutes of your next meal, follow this with extra carbohydrates, such as plain biscuits, fruit or milk.

Recognising and treating hyperglycaemia (high blood sugar levels)

If you notice the return of any of the signs of hyperglycaemia, contact your doctor immediately. Your doctor may need to consider additional or other medicines to treat your diabetes.

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less metformin than prescribed
- interaction between medications
- too little exercise
- eating excess carbohydrates

The symptoms of hyperglycaemia include:

- frequent urination
- increased thirst
- ketoacidosis can develop without adequate treatment, (symptoms include

shortness of breath,
nausea, vomiting and fruity
breath)

Some self-help measures suggested below may help your condition. Your doctor or pharmacist can give you more information about these measures.

Beneficial lifestyle measures include:

- regular exercise
- healthy diet that includes plenty of fruit and vegetables
- limit alcohol intake and quit smoking
- maintain healthy weight

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Metformin Mylan.

This medicine helps most people with diabetes, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- diarrhoea
- feeling sick/unwell (nausea)
- vomiting
- stomach pain
- loss of appetite
- taste disturbances
- skin reactions such as redness, rash/burning or itchiness

They are usually mild and short-lived. Taking Metformin Mylan at the correct time (with meals) can help to reduce some of these side effects, such as nausea, stomach pain and diarrhoea.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following symptoms of lactic acidosis (build-up of lactic acid in the blood):

- nausea and vomiting
- abdominal/stomach pain
- weak
- aching/tender muscles
- shivering/cold
- dizziness
- difficulty breathing
- sleepiness/drowsiness
- slow heart beat

Lactic acidosis is a very rare but serious side effect requiring urgent medical attention or hospitalisation. Although rare, if lactic acidosis does occur it can be fatal. The risk of lactic acidosis is higher in the elderly, those whose diabetes is poorly controlled, those with prolonged fasting, those with certain heart conditions, those who drink alcohol and those with kidney or liver problems.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects (for example, reduced blood vitamin B12 levels) can only be found when your doctor does tests from time to time to check your progress.

After taking Metformin Mylan

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Metformin Mylan or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Metformin Mylan 500 mg tablets are white, round, normal convex, film coated tablet, plain on both sides.

Metformin Mylan 850 mg tablets are white, round, normal convex, film coated tablets that are plain on both sides.

Ingredients

Metformin Mylan contains either 500 mg or 850 mg of metformin hydrochloride as the active ingredient.

It also contains:

- magnesium stearate
- povidone
- hypolose
- hypromellose
- macrogols

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: 0800 579 811

Date of Information

25 February 2021
(Based on datasheet dated 25
February 2021)