

GenRx Metformin

Contains the active ingredient, metformin (met-FOR-min) hydrochloride

For a copy of a large print leaflet, Ph: 1800 195 055

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.

This leaflet answers some common questions about metformin.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Keep this leaflet with your medicine.

You may want to read it again.

What metformin is used for

The name of your medicine is GenRx Metformin. It contains the active ingredient, metformin (as metformin hydrochloride).

Metformin is used to control blood glucose in patients with diabetes mellitus ("diabetes"), when diet and

exercise are not enough to control blood glucose.

There are two types of diabetes:

- type 1, also called insulin dependent diabetes
- type 2, also called non-insulin dependent diabetes mellitus (NIDDM) or maturity onset diabetes.

Metformin can be used in patients with type 2 diabetes where insulin alone is not enough to control blood glucose levels.

Metformin can also be used in patients with type 2 diabetes. It can be used alone or in combination with other medicines for treating diabetes.

How it works

Metformin belongs to a group of medicines called biguanides.

Metformin lowers high blood glucose by helping your body make better use of the insulin produced by your pancreas.

If your blood glucose is not properly controlled, you may experience hypoglycaemia (low blood glucose) or hyperglycaemia (high blood glucose).

People with type 2 diabetes are unable to make enough insulin or their body does not respond properly to the insulin it does make. This causes a build up of glucose in the blood, which can lead to serious medical problems with your heart, eyes, circulation or kidneys.

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

Your doctor may have prescribed metformin for another reason.

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

There is no evidence that this medicine is addictive.

Use in children

This medicine is not recommended for use in children, except those with insulin-resistant diabetes who are being treated in hospital.

Before you take metformin

When you must not take it

Do not take this medicine if you have had an allergic reaction to metformin, any other medicine containing a biguanide or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint pain or rash, itching or hives on the skin.

Do not take this medicine if you have any of the following conditions:

- type 1 diabetes that is well controlled by insulin alone
- type 2 diabetes that is already well controlled by diet alone

- diabetic ketoacidosis (a symptom of uncontrolled diabetes, in which substances called ketone bodies build up in the blood - you may notice this as an unusual fruity odour on your breath, difficulty breathing, confusion and frequent urination)
- severe liver disease
- excessive alcohol intake, binge drinking, alcohol dependence
- severe kidney disease or kidney failure
- dehydration, severe blood loss, shock
- a severe infection
- certain heart or blood vessel problems, including a recent heart attack or severe heart failure (when the heart fails to pump blood effectively)
- dehydration, severe blood loss, shock
- severe breathing difficulties
- blood clots in the lungs (symptoms include coughing, shortness of breath, chest pain and a fast heart rate)
- gangrene
- inflammation of the pancreas (pancreatitis), symptoms include severe upper stomach pain, often with nausea and vomiting.

Do not take this medicine if you plan to have any X-ray procedures requiring an injection of iodinated contrast (dye).

Using this type of dye while you are taking metformin may cause severe kidney problems and increase the risk of a serious condition called lactic acidosis. Your doctor will tell you when to temporarily stop taking the tablets before the X-ray and when it is safe to restart them.

Do not take this medicine if you are pregnant or plan to become pregnant.

The safety of metformin in pregnant women has not been established.

Insulin is more suitable for controlling blood glucose during

pregnancy. Your doctor will replace metformin with insulin while you are pregnant.

Do not take this medicine if you are breast-feeding.

Metformin 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 (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take this medicine if the packaging is torn, shows signs of tampering or if it does not look quite right.

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 or pharmacist.

Before you start to take it

Tell your doctor if you:

1. have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

2. have or have had any medical conditions, especially the following:

- kidney disease
- heart failure.

3. drink alcohol.

Alcohol can affect the control of your diabetes. Drinking excessive amounts of alcohol while you are being treated with metformin may also lead to serious side effects.

Your doctor may suggest you stop drinking or reduce the amount of alcohol you drink.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

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

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

- sulfonylureas, a group of medicines used to treat diabetes, such as gliclazide, glipizide, glimepiride
- repaglinide, another type of medicine used to treat diabetes
- some medicines used to treat high blood pressure and some heart conditions, including beta-blockers, calcium channel blockers and ACE inhibitors; some examples include metoprolol, nifedipine and enalapril
- medicines used to prevent blood clots such as warfarin
- diuretics, also called fluid tablets
- thyroid preparations such as thyroxine
- cimetidine, a medicine commonly used to treat reflux and ulcers
- glucocorticoids such as prednisone and cortisone
- beta-2-antagonists.

These medicines may be affected by metformin 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 can tell you if you are taking any of these medicines. They may also have more information on medicines to be careful with or avoid while taking metformin.

Other interactions not listed above may also occur.

How to take this medicine

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

They may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how many tablets you will need to take. This depends on your condition and whether or not you are taking any other medicines.

The usual dose of metformin for adults is 500 mg one to two times a day, up to a maximum of 1 g three times a day.

People over 65 years of age or those with kidney problems may need smaller doses.

Your doctor may increase or decrease the dose, depending on your blood glucose levels.

How to take it

Swallow the tablets with a glass of water.

When to take it

Take your medicine during or immediately after a meal, at about the same time each day.

This will reduce the chance of a stomach upset.

Taking your medicine 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 for

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

Metformin will help control your diabetes but will not cure it.

Therefore, you may have to take it for a long time.

Make sure you have enough to last over weekends and holidays.

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 you getting low blood sugar levels (hypoglycaemia).

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 Poisons Information Centre (Tel: 13 11 26 for Australia) for advice, or go to the Accident and Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much metformin.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much metformin you may feel sleepy, very tired, sick, vomit, have trouble breathing and have unusual muscle pain, stomach pain or diarrhoea. These may be early signs of a serious condition called lactic acidosis (build up of lactic acid in the blood).

You may also experience symptoms of hypoglycaemia (low blood glucose). This usually only happens if you take too much metformin together with other medicines for diabetes or with alcohol.

If you do experience any signs of hypoglycaemia, raise your blood glucose quickly by eating jelly beans, sugar or honey, drinking a

non-diet soft drink or taking glucose tablets.

While you are taking metformin

Things you must do

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

HYPOGLYCAEMIA

Metformin does not normally cause hypoglycaemia, although you may experience it if you take other medicines for diabetes such as sulfonylureas or repaglinide; or if you also use insulin.

Hypoglycaemia can occur suddenly. Initial signs may include:

- weakness, trembling or shaking
- sweating
- lightheadedness, dizziness, headache or lack of concentration
- irritability, tearfulness or crying
- hunger
- numbness around the lips and tongue.

If not treated promptly, these may progress to:

- loss of co-ordination
- slurred speech
- confusion
- fits or loss of consciousness.

If you experience any of the symptoms of hypoglycaemia, you need to raise your blood glucose immediately.

You can do this by doing one of the following:

- eating 5 to 7 jelly beans
- eating 3 teaspoons of sugar or honey
- drinking half a can of non-diet soft drink

- taking 2 to 3 concentrated glucose tablets.

Unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates such as plain biscuits, fruit or milk.

Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

HYPERGLYCAEMIA

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 treatments for your diabetes.

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less metformin than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Tell your doctor if you:

- become ill
- become dehydrated
- are injured
- have a fever
- have a serious infection
- are having surgery (including dental surgery).

Your blood glucose may become difficult to control at these times. You may also be more at risk of developing a serious condition called lactic acidosis. At these times, your doctor may replace metformin with insulin.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking metformin.

Tell your doctor immediately if you become pregnant.

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

Go to your doctor regularly for a check-up.

Your doctor may want to perform blood tests to check your kidneys, liver, heart and vitamin B12 level while you are taking this medicine.

Check your blood glucose levels regularly.

This is the best way to tell if your diabetes is being controlled properly.

Your doctor or diabetes educator will show you how and when to do this.

When you start treatment with metformin, it can take up to two weeks for your blood glucose levels to be properly controlled.

Carefully follow the advice of your doctor and dietician on diet, drinking alcohol and exercise.

Things you must not do

Do not skip meals while taking this medicine.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to.

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

Things to be careful of

If you have to be alert, for example when driving, be especially careful not to let your blood glucose levels fall too low.

Low blood glucose levels may slow your reaction time and affect your ability to drive or operate machinery. Drinking alcohol can make this worse. However, metformin by itself is unlikely to affect how you drive or operate machinery.

If you become sick with a cold, fever or flu, it is very important to continue taking metformin, even if you feel unable to eat your normal meal.

Your diabetes educator or dietician can give you a list of foods to use for sick days.

If you are travelling, it is a good idea to:

- wear some form of identification (e.g. bracelet) showing you have diabetes
- carry some form of sugar to treat hypoglycaemia if it occurs, for example, sugar sachets or jelly beans
- carry emergency food rations in case of a delay, for example, dried fruit, biscuits or muesli bars
- bring your medicine with you, so you don't miss any doses.

Side effects of metformin

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time, they are not.

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

Metformin helps most people with diabetes, but it may have unwanted side effects in a few people.

If you are over 65 years of age, report any side effects to your doctor immediately.

People over his age may have an increased chance of getting side effects.

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

Following is a list of possible side effects. Do not be alarmed by this list. You may not experience any of them.

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

- stomach upset such as feeling sick (nausea)
- taste disturbance, loss of appetite
- diarrhoea

- red skin rash.

These are generally mild side effects. Stomach upset and diarrhoea are common but usually short-lived. Taking your medicine with meals can help reduce nausea and diarrhoea. Skin rash has been reported rarely.

TELL YOUR DOCTOR IMMEDIATELY OR GO TO ACCIDENT AND EMERGENCY AT THE NEAREST HOSPITAL IF YOU NOTICE ANY OF THE FOLLOWING SYMPTOMS OF LACTIC ACIDOSIS (BUILD UP OF LACTIC ACID IN THE BLOOD):

- nausea, vomiting, stomach pain
- trouble breathing
- feeling weak, tired or generally unwell
- unusual muscle pain
- sleepiness
- dizziness or lightheadedness
- shivering, feeling extremely cold
- 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.

Other side effects not listed above may occur in some patients.

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

After taking this medicine

Storage

Keep your medicine in its original packaging until it is time to take them.

If you take the tablets out of their original packaging they may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, 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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product description

What GenRx Metformin looks like

500 mg tablets:

White, round, biconvex tablet, partially bisected and engraved

"APO" on one side and "M500" on the other side.

They are packaged in a blister pack of 100 tablets.

850 mg tablets:

White, capsule-shaped, biconvex tablet, engraved "APO" on one side and "850" on the other side.

They are packaged in a blister pack of 60 tablets.

Ingredients

Each tablet contains 500 mg or 850 mg of metformin hydrochloride as the active ingredient.

It also contains the following inactive ingredients:

- methylcellulose
- magnesium stearate
- croscarmellose sodium.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

GenRx Metformin 500 mg tablets: AUST R 78617.

GenRx Metformin 800 mg tablets: AUST R 78621.

Sponsor

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