

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FORMET 500.

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 risk of you taking FORMET 500 against the benefits it is expected to 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 want to read it again.

What FORMET 500 is used for

The name of your medicine is FORMET 500. It contains the active ingredient metformin hydrochloride. Metformin is used to control blood glucose in patients with diabetes mellitus, when diet and exercise are not enough to control blood glucose. There are two types of diabetes mellitus:

- Type I, also called insulin dependent diabetes
- Type II, also called non-insulin dependent diabetes mellitus (NIDDM) or maturity onset diabetes.

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

Metformin can also be used in patients with Type II diabetes mellitus. It can be used alone or in combination with other medicines for treating diabetes.

Your doctor may have prescribed FORMET 500 tablets for another reason.

Ask your doctor if you have any questions about why FORMET 500 was prescribed for you.

How FORMET 500 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). High blood glucose can lead to serious problems with your heart, eyes, circulation or kidneys. Low blood glucose can occur suddenly.

Signs may include:

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

If not treated promptly, these may progress to:

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

High blood glucose usually occurs more slowly than low blood glucose. Signs of high blood glucose may include:

- lethargy or tiredness
- headache
- thirst
- passing large amounts of urine
- blurred vision.

There is no evidence that FORMET 500 is addictive.

Before you take FORMET 500

When you must not take FORMET 500

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

Symptoms of an allergic reaction to these medicines 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.

If you are not sure if you have an allergy to metformin check with your doctor.

Do not take metformin if you have any of the following medical conditions:

- Type I diabetes mellitus that is well controlled by insulin alone
- Type II diabetes that is already well controlled by diet alone
- diabetic acidosis (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)
- excessive alcohol intake, binge drinking, alcohol dependence
- diabetic coma
- kidney failure or disease
- severe liver disease
- severe infection
- dehydration, severe blood loss, shock
- certain heart or blood vessel problems, including a recent heart attack or severe heart failure (when the heart fails to pump blood effectively)
- gangrene
- blood clots in the lungs (symptoms include coughing, shortness of breath, chest pain, and a fast heart rate)
- inflammation of the pancreas (pancreatitis), symptoms include severe upper stomach pain, often with nausea and vomiting.

If you are not sure if you have any of the above, ask your doctor.

Do not take FORMET 500 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 FORMET 500 for a certain period of time before and after the examination or 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 take FORMET 500 if you are pregnant or intend becoming pregnant. The safety of FORMET 500 in pregnant women has not been established.

Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will replace FORMET 500 with insulin while you are pregnant.

Do not take FORMET 500 if you are breastfeeding.

FORMET 500 is not recommended while you are breastfeeding. Your doctor will discuss the options available to you.

Do not take FORMET 500 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 FORMET 500 if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking FORMET 500, talk to your doctor or pharmacist.

Before you start to take it

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

Tell your doctor if you are breastfeeding or plan to breast-feed.

It is not known whether metformin passes into breast milk. Metformin is usually not recommended while you are breastfeeding. Your doctor will discuss the risks and benefits of taking metformin when breastfeeding.

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

- kidney disease
- heart failure
- high blood pressure
- recent heart attacks
- liver disease
- clots in the lung.

Tell your doctor if:

- you ever drink alcohol
- you do not eat regular meals
- you do heavy exercise or work
- you are ill or feeling unwell.

Alcohol, diet, exercise and your general health all strongly affect the control of your diabetes. Alcohol can affect the control of your diabetes. Drinking excessive amounts of alcohol while you are being treated with FORMET 500 may also lead to serious side effects. Your doctor may suggest you stop drinking or reduce the amount of alcohol you drink. Discuss these things with your doctor.

If you have not told your doctor, pharmacist or diabetes educator about any of the above, tell them before you start taking metformin.

Taking other medicines

Tell your doctor, pharmacist or diabetes educator 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 may hide the symptoms of low blood sugar (hypoglycaemia). These include:

alcohol

certain medicines used to treat high blood pressure e.g. betablockers.

Some medicines and FORMET 500 may interfere with each other. These include:

alcohol, including medicines such as cough and cold syrups which may contain alcohol tetracosactrin, a medicine used in people with multiple sclerosis, and in young children to treat some types of seizures (fits) danazol, a medicine used to treat endometriosis

chlorpromazine, a medicine used to treat schizophrenia and other mental illnesses NSAIDs (non-steroidal antiinflammatory drugs), medicines used to relieve pain, swelling and other symptoms of inflammation, such as aspirin, diclofenac, ibuprofen, meloxicam, naproxen or piroxicam

some medicines used to treat asthma such as salbutamol or terbutaline

cimetidine, a medicine used to treat reflux and ulcers

other medicines used to treat diabetes e.g. glibenclamide and insulin

beta blockers, medicines used to treat high blood pressure and angina nifedipine, a medicine used to treat high blood pressure and angina medicines used to prevent blood clots, also known as anticoagulants diuretics, also known as fluid tablets e.g. thiazides, frusemide

medicines used to treat thyroid gland problems

corticosteroids such as prednisolone and cortisone

oestrogen and progesterone in oral contraceptives

diazoxide, a medicine used to treat glaucoma (high dose) nicotinic acid used for the lowering of blood fats.

You may need different amounts of your medicine or you may need to take different medicines. Your doctor, pharmacist or diabetes educator can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while taking metformin.

Ask your doctor or pharmacist if you are not sure if you are taking any of these medicines.

How to take FORMET 500

Follow all directions given to you by your doctor, pharmacist or diabetes educator carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help. Your doctor will tell you how much to take and when to take it.

Take FORMET 500 exactly as directed by your doctor.

How much to take

The dose varies from patient to patient. Your doctor will decide the right dose for you.

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

Your doctor may increase or decrease the dose, depending on your blood glucose levels. FORMET 500 can be taken by children with diabetes that cannot be

controlled with insulin and who are being treated in hospital. Your child's doctor will decide the dose.

How to take it

Swallow the tablets with a glass of water.

When to take it

Take FORMET 500 during or immediately after a meal, at about the same time each day. This will reduce the chance of a stomach upset.

Do not skip meals while taking metformin.

How long to take it

Continue taking FORMET 500 for as long as your doctor recommends.

Make sure you keep enough FORMET 500 to last over weekends and holidays.

FORMET 500 will help control your diabetes but will not cure it. Therefore, you may have to take it for a long time.

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 (with food), 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. If you double a dose, this may cause low blood sugar (hypoglycaemia).

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to Accident & Emergency at your nearest hospital, if you think that you or anyone else may have taken too much FORMET 500.

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

If you take too much metformin together with other medicines for diabetes or alcohol, you may experience symptoms of low blood sugar (hypoglycaemia).

At the first signs of hypoglycaemia, raise your blood glucose quickly by eating jelly beans, sugar or honey, drinking non-diet soft drink or taking glucose tablets.

If not treated quickly, these symptoms may progress to loss of co-ordination, slurred speech, confusion, fits or loss of consciousness.

If you take too much metformin, you may feel sick, vomit, have trouble breathing and have stomach pain or diarrhoea. These may be the early signs of a serious condition called lactic acidosis.

If you experience any of these symptoms, immediately get medical help.

While you are using FORMET 500

Things you must do

Tell your doctor if:

- you become pregnant while you are taking metformin,
- you are about to start taking any new medicines
- you do not eat regular meals
- you do heavy exercise or work
- you are feeling unwell.

Diet and exercise and your general health all strongly affect the control of your diabetes. Discuss these with your doctor. If you have not told your doctor, pharmacist or diabetes educator about any of the above, tell them before you start FORMET 500.

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

Make sure that you, your friends, family and work colleagues can recognise the symptoms of low blood sugar and high blood sugar and know how to treat them.

HYPOGLYCAEMIA

If you experience any of the symptoms of low blood sugar, 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 ordinary (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.

Metformin does not normally cause low blood sugar (hypoglycaemia) unless you are also taking other medicines for diabetes such as insulin or sulfonylureas.

Some substances may hide the symptoms of hypoglycaemia. These include alcohol and certain medicines used to treat high blood pressure such as beta blockers.

HYPERGLYCAEMIA

If you experience any of the signs of high blood sugar (hyperglycaemia), contact your doctor immediately.

The risk of high blood sugar is increased in the following situations:

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

Tell your doctor if you become ill, seriously dehydrated (have lost a large amount of body fluids) or experience injury, fever, extra stress, infection or need surgery.

You are more at risk of developing a serious condition called lactic acidosis at these times. Your doctor may decide to change your treatment and use insulin instead of metformin. Make sure you 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.

Tell your doctor, dentist or anaesthetist that you are taking metformin before you have any surgery or X-ray procedures that require injection of contrast agents. Your doctor may decide that metformin should be stopped prior to these procedures.

Visit your doctor for regular checks of your eyes/feet/kidneys/heart/circulation/blood/ blood pressure.

See your doctor once a year for a check on your body's level of vitamin B12.

Carefully follow your doctor's and/or dietician's advice on diet, drinking alcohol and exercise.

Tell your doctor immediately if you notice the return of any symptoms you had before starting metformin.

These may include lethargy or tiredness, headache, thirst, passing large amounts of urine and blurred vision.

These may be signs that metformin is no longer working, even though you may have been taking it successfully for some time.

Things you must not do

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

Do not skip meals while taking metformin.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give FORMET 500 to anyone unconscious or with a diabetic coma.

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 are travelling, it is a good idea to:

- wear some form of identification 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
- keep FORMET 500 readily available.

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. If you have trouble eating solid food, use sugar-sweetened drinks as a carbohydrate substitute or eat small amounts of bland food.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FORMET 500.

FORMET 500 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 treatment 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.

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

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

- stomach upset such as feeling sick (nausea)
- diarrhoea
- skin rash.

These are generally mild side effects which usually occur during the first few weeks.

Taking FORMET 500 with meals can help reduce nausea and diarrhoea. Skin rash is rare; it is usually not serious and should go away in a few days.

Tell your doctor immediately or go to the accident and emergency department at your nearest hospital if you notice any of the following symptoms of lactic acidosis (high lactic acid in the blood):

- loss of appetite
- unexplained weight loss
- nausea (feeling sick)
- vomiting
- stomach pain
- trouble breathing
- rapid, shallow breathing
- feeling weak, tired, or uncomfortable
- sleepiness
- unusual muscle pain
- dizziness or lightheadedness
- slow heart beat.

You may need urgent medical attention if these symptoms occur. Lactic acidosis with metformin is rare and mostly happens to people who are ill or whose kidneys are not working properly.

Tell your doctor if you notice any other effects.

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

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

After using FORMET 500

Storage

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

If you take the tablets out of the pack they will not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store metformin or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.

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 using the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What FORMET 500 looks like

FORMET 500-Tablets 500 mg: white to off-white circular, biconvex, bevel-edged, film-coated tablets debossed with '500' on one side. Available in bottles.

Tablet Ingredients

Active Ingredient:

- Metformin hydrochloride

Excipients:

- sodium starch glycollate type A
- povidone
- maize starch
- magnesium stearate
- colloidal anhydrous silica
- hypromellose
- macrogol 6000
- purified talc
- titanium dioxide
- propylene glycol

Sponsor

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

Australian Registration Number
FORMET 500 500mg bottle AUST R
192236

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