

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you start to take these tablets. Keep it until all the prescribed course of Metformin generichealth 1000 has been finished, as you may want to read it again. This leaflet may not contain all the information about this medicine that you would like to know. It does not take the place of talking to your doctor, pharmacist or diabetes educator.

If you have any concerns about taking this medicine, please talk to your doctor or pharmacist or diabetes educator. All medicines have risks and benefits. Your doctor has weighed the risks of you taking Metformin generichealth 1000 against the benefits expected for you.

What is in your medicine?

- Metformin generichealth 1000: Each film coated tablet contains 1000 mg of the active ingredient metformin hydrochloride.
- Other inactive ingredients. Sodium starch glycollate, maize starch, povidone, colloidal anhydrous silica, magnesium stearate, hypromellose, titanium dioxide (E171), propylene glycol, macrogol 6000 and purified talc.

What is your medicine for?

Metformin generichealth 1000 is one of the groups of medicines called oral hypoglycaemics, which work by reducing the level of sugar in the blood in people with diabetes mellitus.

Diabetes mellitus is a condition in which the blood glucose levels are not adequately controlled.

There are two types of diabetes:

- Type 1 which is called insulin dependent diabetes or juvenile onset diabetes, when insulin alone is not enough to control blood glucose levels.
- Type 2 which is called Non insulin Dependent Diabetes Mellitus (NIDDM) or maturity onset diabetes.

People with type 2 diabetes are not able to make enough insulin or respond normally to the insulin their bodies make. When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems including kidney damage, amputation and blindness.

Diabetes is also closely linked to heart disease. The main goal of treating diabetes is to lower your blood sugar to a normal level. High blood sugar can be lowered by diet and exercise, by a number of medicines taken by mouth, and by insulin injections.

Metformin generichealth 1000 tablets are used for the treatment of type 2 diabetes which usually only occurs in adults and does not need insulin but does not respond to diet and exercise.

Metformin generichealth 1000 is especially useful in people who are overweight and in whom diet and exercise alone are not enough to lower high blood glucose levels (hyperglycaemia).

Metformin generichealth 1000 can be used alone, or in combination with other medicines for treating diabetes. Metformin generichealth 1000 can also be used in patients with type 1 diabetes mellitus where insulin alone is not enough to control blood glucose levels.

Metformin generichealth 1000 is not recommended for use in children, except for those with insulin-resistant diabetes who are being treated in hospital.

Before you take your medicine

Make sure that it is safe for you to take Metformin generichealth 1000. Do not take Metformin generichealth 1000 if you answer YES to any of the following questions. If you are not sure, then ask your doctor or pharmacist.

- Are you allergic to any of the ingredients in this medicine?
- Do you have type 1 diabetes mellitus that is well controlled by insulin alone?
- Do you have type 2 diabetes that is already well controlled by diet alone?
- Are you suffering from 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)?
- Are you allergic to any other medicines, foods, dyes or preservatives?
- Do you drink alcohol excessively or suffer from alcohol dependence? Alcohol can affect the control of your diabetes. Drinking excessive amounts of alcohol while you are being treated with Metformin generichealth 1000 may also lead to serious side effects. Your doctor may suggest you stop drinking or reduce the amount of alcohol you drink.
- Do you have any problem with your liver or kidneys?
- Do you have a heart disorder such as heart failure or have you suffered a heart attack recently?
- Are you, or could you be, pregnant? Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will replace Metformin generichealth 1000 with insulin while you are pregnant.
- Are you breast-feeding? Metformin generichealth 1000 is not recommended while you are breastfeeding. Your doctor will discuss with you the other options of treatment.
- Are you likely to have surgery or a scan involving the use of X-rays, including dental surgery within the next few days? Some types of X-ray procedures require an injection of iodinated contrast (dye). Using this type of dye while you are taking Metformin generichealth 1000 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 you have any problems with your circulation causing, for example, frequent cramp in your calves or leg ulcers that do not heal?
- Do you have a fever or are you ill in any other way?
- Are you on a special diet?
- Are you suffering from an excessive loss of body water?
- Do you have breathing problems?
- Do you suffer from the symptoms of blood clots in the lungs? (Symptoms include coughing, shortness of breath, chest pain and a fast heart rate.)
- Are you suffering from severe blood loss or shock?
- Are you suffering from gangrene?
- Are you suffering from inflammation of the pancreas? (Symptoms include severe stomach pain often with nausea and vomiting.)

Patients who are already on insulin should only be started on a course of treatment with Metformin generichealth 1000 in hospital.

Metformin generichealth 1000 should not be taken by children, except for those with insulin-resistant diabetes who are being treated in hospital.

Other Medicines

Other medicines, including some you could buy without a prescription, may interact with these tablets. If you are taking or intend to take any other medicine during treatment with Metformin generichealth 1000, check with your doctor or pharmacist that it is safe to do so.

This is particularly important in the case of:

- other antidiabetic drugs (eg. insulin, guar gum), sulphonylureas such as gliclazide (eg. Diamicron Glyade), glipizide (eg. Minidiab, Melizide), glimepiride (eg. Amaryl, Dimirel), repaglinide (Novonorm);
- anti-inflammatory pain killers such as salicylates or pyrazolones;
- medicines used to treat high blood pressure and some heart conditions (beta blockers, calcium channel blockers and ACE inhibitors, eg. metoprolol (Betaloc, Minax), nifedipine (Adalat, Adefin), enalapril (Renitec), Lisinopril (Zestril);
- cimetidine (Tagamet Magicul) a medicine used to treat reflux and ulcers;
- corticosteroids such as prednisone (Panafort, Sone) and Cortisone (Cortate);
- tablets that thin the blood (anticoagulants such as warfarin. Coumarin, Marevan);
- fluid tablets (thiazide diuretics such as Moduretic, Aprinox, Arnizide);
- thyroid preparations such as thyroxine (Oroxine);
- contrast media given as injections when you undergo examination using X-rays; for example Ultravist. One ingredient called "propylene glycol" may cause allergic reactions.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have more information on medicines to be careful with or to avoid while taking Metformin generichealth 1000.

Do not take Metformin generichealth 1000 after the expiry date printed on the pack has passed.

Do not take Metformin generichealth 1000 if the foil seal is broken or the pack shows signs of tampering.

How does Metformin generichealth 1000 work?

Metformin generichealth 1000 belongs to a group of medicines called biguanides. Metformin generichealth 1000 lowers high levels of blood glucose by helping your body to 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).

HYPOGLYCAEMIA

Hypoglycaemia (low blood glucose) can occur suddenly. Initial signs include:

- Weakness, trembling or shaking;
- Sweating;
- Light-headedness, 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.

HYPERGLYCAEMIA

Hyperglycaemia (high blood glucose) usually occurs more slowly than hypoglycaemia. Signs of hyperglycaemia may include:

- Lethargy or tiredness;
- Headache;
- Thirst;
- Passing large amounts of urine;
- Blurred vision;

Long term hyperglycaemia can lead to serious problems with your heart, eyes, kidneys or blood circulation.

Taking your medicine

Your doctor or pharmacist will have told you about this, and you should always follow their instructions carefully. The dose varies from patient to patient. The usual starting dose is one 500 mg tablet once or twice a day with breakfast and the evening meal. Your doctor may increase or decrease the dose depending on your blood glucose levels. The maximum recommended dose is 1000 mg three times a day.

Elderly patients may need smaller doses.

If your child has diabetes which is resistant to insulin and is being treated in hospital, your child's doctor will decide the dose.

The tablets should be taken with a glass of water during or after meals. This will lessen the chance of a stomach upset. Do not chew

the tablets but swallow them whole. The 500mg tablet may be divided in half along the breakline, if advised by your doctor.

Metformin generichealth 1000 will help control diabetes but will not cure it. Most people need to take Metformin generichealth 1000 for long periods of time.

What to do if you forget to take Metformin generichealth 1000

If you miss a dose, take it as soon as you remember (with food) unless it is nearly time for the next dose. If it is nearly time for the next dose skip the missed dose. Never double-up on the next dose to make up for the one missed.

What should you do if you take too many Metformin generichealth 1000

If you swallow too many tablets or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away or call the Poisons Information Centre (telephone 131126). Do this even if there are no signs of discomfort or poisoning.

If you take too much Metformin generichealth 1000, you may feel sleepy, very tired, and 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 generichealth 1000 together with other medicines for diabetes or with alcohol.

While taking your medicine

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

If you plan to have surgery (including dental surgery) or anaesthesia inform your doctor, dentist or anaesthetist that you are taking Metformin generichealth 1000 tablets.

If you do experience any signs of hypoglycaemia (low blood glucose), raise your blood glucose quickly by taking one of the following:

- 5-7 jelly beans
- 3 teaspoons of sugar or honey
- Half a can of non-diet soft drink
- 2-3 concentrated glucose tablets.

Unless you are within 10-15 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 generichealth 1000 dose not normally cause hypoglycaemia although you may experience it while taking other medicines for diabetes such as insulin or sulphonylureas.

If you experience any of the signs of hyperglycaemia (high blood glucose), contact your doctor immediately. The risk of hyperglycaemia is increased in the following situations:

- Uncontrolled diabetes;
- Illness, infection or stress;

- Taking less Metformin generichealth 1000 than prescribed;
- Taking certain other medicines;
- Too little exercise;
- Eating more carbohydrates than usual.

Tell your doctor if any of the following happen:

- You become ill;
- You become dehydrated;
- You are injured;
- You have a fever;
- You have a serious infection;
- You are having surgery (including dental surgery);
- You are having X-ray procedures that require injection of contrast agents.

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 generichealth 1000 with insulin.

Before starting any new medicines, tell your doctor or pharmacist that you are taking Metformin generichealth 1000.

If you become pregnant while taking Metformin generichealth 1000 tell your doctor immediately. **Visit your doctor regularly for check ups.**

Your doctor may want to check your kidneys, liver, heart, blood and vitamin B₁₂ levels while you are taking Metformin generichealth 1000.

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.

When you start treatment with Metformin generichealth 1000, it can take up to three weeks for your blood glucose levels to be properly controlled. Prolonged treatment with Metformin generichealth 1000 can deplete reserves of Vitamin B₁₂ and this may cause anaemia. Regular blood tests for kidney function and Vitamin B₁₂ should therefore be carried out.

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 Metformin generichealth 1000.
- Do not stop taking Metformin generichealth 1000 or change the dose without checking with your doctor.
- Do not give Metformin generichealth 1000 to anyone else even if they have the same condition as you.
- Do not use Metformin generichealth 1000 to treat any other condition unless your doctor tells you to.

Things to be careful of:

Metformin generichealth 1000 tablets on their own should not affect your ability to drive, but if you are also taking other medicines which lower the blood sugar it is possible that their combined effects could make you feel faint, dizzy, weak or jittery.

If this happens you should not drive or operate any machinery until you have recovered. If you are 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.

If you become sick with cold, fever or flu, it is very important to continue eating your normal meals.

Your diabetes educator can give you a list of foods to eat on sick days. When you are travelling, it is a good idea to:

- Wear some form of identification (eg. 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 enough Metformin generichealth 1000 with you, so you don't miss any doses.

Side effects

Any medicine can have side effects. Metformin generichealth 1000 is usually well tolerated, but sometimes can cause stomach upsets such as feeling sick (nausea), vomiting, diarrhoea, loss of appetite or a metallic taste.

If such side effects do occur, they often get better after the first few weeks. Taking Metformin generichealth 1000 with meals can help reduce nausea and diarrhoea.

Rarely, skin reactions may occur. If you notice a red skin rash ask your doctor for advice about continuing with the tablets.

Report any side effects to your doctor promptly. If you are over 65 years of age, you may have an increased chance of getting side effects.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- stomach or abdominal pain, nausea, vomiting;
- muscle pains, feeling weak, tired or generally unwell, have breathing problems, confusion or drowsiness, dizziness or light-headedness, shivering, feeling extremely cold, slow heart beat.
In this case you must contact your doctor immediately or go to the nearest hospital accident and emergency department since these symptoms may indicate the uncommon but serious condition of lactic acidosis. Lactic acidosis is a very rare but serious side effect requiring urgent medical treatment in hospital. The risk of lactic acidosis is higher in some people, including the elderly, those taking doses greater than 2000 mg a day, those drinking excessive amounts of alcohol and people with kidney problems.

If you think you have any other side effects from taking this medicine, please tell your doctor or pharmacist.

Storing your medicine

- Do not take the tablets after the expiry date on the label.
- Do not keep the tablets above 25°C.

- Store the tablets in their original blister pack in a cool dry place.
- Keep all medicines out of reach of children - preferably in a locked cupboard or medicine cabinet.
- Do not store Metformin generichealth 1000 or any other medicine in the bathroom or near a sink. Heat and dampness can destroy some medicines.
- Do not leave Metformin generichealth 1000 in the car or on window sills.

If your doctor tells you to stop taking Metformin generichealth 1000, or your tablets have reached their expiry date, ask your pharmacist what to do with any that are left over.

Presentation

10000 mg Tablet AUST R 164469

White, capsule-shaped film-coated tablets, with a breakline on one side, in blister packs of 10, 30, 60 and 90 tablets. The tablets are gluten free.

Sponsor

Generic Health Pty Ltd
Level 1, 1102 Toorak Rd
CAMBERWELL VIC 3124

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