

Metformin Generic Health

metformin hydrochloride

500 mg and 850 mg tablets

What is in this leaflet

Please read this leaflet carefully before you start using Metformin Generic Health.

This leaflet answers some common questions about Metformin Generic Health. 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 Generic Health 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 Generic Health is used for

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

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

Metformin Generic Health is used when diet and exercise have not been enough to control your blood glucose.

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

Metformin Generic Health contains the active ingredient metformin hydrochloride which

belongs to a group of medicines called biguanides.

It works by reducing liver glucose (sugar) production, improving insulin sensitivity in the muscles and slowing down the absorption of glucose from the intestinal tract.

Your doctor may have prescribed Metformin Generic Health for another reason.

Ask your doctor if you have any questions about why Metformin Generic Health has been prescribed for you.

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

Metformin Generic Health is not recommended for use in children.

Before you take Metformin Generic Health

When you must not take it

Do not take Metformin Generic Health 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:

- difficulty in breathing or wheezing
- shortness of breath
- swelling of the face, tongue, lips, or other parts of the body
- hives on the skin, rash, or itching.

Do not take Metformin Generic Health 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 Generic Health if you require an injection of iodinated contrast (dye) for a major surgery or an examination such as an X-ray or a scan. You must stop taking Metformin Generic Health 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 Metformin Generic Health. Metformin Generic Health is not recommended while you are breastfeeding. Your doctor will discuss the options available to you.

Do not take this Metformin Generic Health tablets 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 using Metformin Generic Health, talk to your doctor.

Before you start to use it

Tell your doctor if

- **you have allergies to any other medicines, foods, preservatives or dyes.**
- **you have or have had any of the following medical conditions:**
 - heart failure
 - lactic acidosis
 - kidney failure
- **you drink alcohol.** Alcohol can affect the control of diabetes. Drinking excessive amounts of alcohol while you are taking Metformin Generic Health may also lead to serious side effects. Your doctor may suggest you stop drinking or reduce your alcohol intake.
- **you are breast-feeding or are pregnant or plan to become pregnant.** Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start using Metformin Generic Health.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy,

supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Metformin Generic Health.

Some medicines may interfere with Metformin Generic Health. These include:

- other antidiabetic agents, such as sulfonylureas, repaglinide
- alcohol and alcohol- containing medications, such as cold and cough 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 classes of medicines called ACE-inhibitors, beta-blockers, and calcium channel blockers such as nifedipine
- thiazide diuretics such as bendrofluazide, also called water tablets, a medicine used to treat high blood pressure
- cimetidine, a medicine used to treat reflux and ulcers
- corticosteroids – steroids that reduce inflammation
- medicines used to treat thyroid conditions

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

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Metformin Generic Health.

How to take Metformin Generic Health

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 pack, printed on the pharmacist label or in this leaflet, ask your doctor or pharmacist for help.

How much to take

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

Your doctor may decide to adjust the dose according to your individual needs and therefore may differ from the usual dose shown below.

The initial dose of Metformin Generic Health is 500 mg once or twice a day, and if deemed necessary, the dose is 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.

When to take it

Take one tablet daily at about the same time every day. This will also help you remember when to take it.

Swallow the tablets during or immediately after food with a full glass of water. This will reduce the chance of a stomach upset.

How long to take it

Continue taking your medicine for as long as your doctor tells you. This medicine helps to control your diabetes, 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 Generic Health 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 unwanted side effects and developing lactic acidosis.

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.

While you are taking Metformin Generic Health

Things you must do

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Metformin Generic Health.

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 anaesthetist or surgeon that you are taking Metformin Generic Health. It may affect other medicines used during surgery. Metformin must be stopped 48 hours before, during and for 48 hours after an elective major surgery.

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

Tell your doctor that you are taking this medicine if you are about to have any blood tests.

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 give Metformin Generic Health to anyone else, even if they have the same condition as you.

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

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

Things to be careful of

Be careful when drinking alcohol while you are taking this medicine. Signs of low blood sugar (hypoglycaemia) may become less clear when drinking alcohol. Alcohol can also cause a delayed hypoglycaemia. In addition, there is an increased risk of lactic acidosis in acute alcohol intoxication (particularly in the case of fasting/malnutrition and liver disease).

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 you take Metformin Generic Health in combination with other antidiabetic medicines (see *Taking other medicines*). It is possible that their combined effects could make you feel faint, dizzy, or weak. If this happens you should not drive or operate any machinery until you have recovered.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Metformin Generic Health.

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

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Metformin Generic Health.

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 adverse 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 brief. Taking Metformin Generic Health, with meals, at the correct time 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):

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

Lactic acidosis is a very rare but serious side effect requiring urgent medical attention or hospitalisation. In rare occasions, 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 who drink alcohol, those with certain heart conditions, and those with liver or kidney problems.

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

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. Tell your doctor if you notice any other effects.

After taking Metformin Generic Health

Storage

Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the pack they may not keep well.

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

Heat and dampness can destroy medicines, so do not store Metformin Generic Health in the bathroom or near a sink. Do not leave it in the car or on a windowsill.

As with all medicines, you should store them out of the reach of children. 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 they have passed their expiry date, ask your pharmacist what to do with any unused medicine.

Product description

What it looks like

Metformin Generic Health 500mg Film Coated Tablets are white to off white, round, bevelled edged biconvex with '500' embossed on one side.

Metformin Generic Health 850 mg Film Coated Tablets are white to off white, round, bevelled edged biconvex with '850' embossed on one side.

Ingredients

Active ingredient(s):

- metformin hydrochloride

Inactive ingredients:

- Colloidal silicon dioxide
- Hypromellose E- 15
- Macrogol 6000
- Magnesium stearate
- Maize starch
- Povidone
- Propylene glycol
- Purified talc
- Purified water
- Sodium starch glycolate
- Titanium dioxide.

Sponsor details

Metformin Generic Health is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd
P O Box 45 027
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Phone: (09) 835 0660

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