

METFORMIN XR MYLAN

metformin hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Diaformin XR and Diaformin XR 1000.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Diaformin XR or Diaformin XR 1000 against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor, pharmacist or diabetes educator.

Keep this leaflet with your medicine.

You may need to read it again.

What Diaformin XR and Diaformin XR 1000 are used for

Diaformin XR and Diaformin XR 1000 are used to control blood glucose (sugar) in people with Type 2 diabetes mellitus, especially in those who are overweight. It is used when diet and exercise are not enough to control high levels of blood glucose.

Diaformin XR and Diaformin XR 1000 can be used alone, or in combination with other medicines for treating diabetes.

TYPE 2 DIABETES MELLITUS

Type 2 diabetes mellitus is also called non-insulin dependent diabetes mellitus (NIDDM) or maturity onset diabetes.

Insulin is a hormone that enables body tissues to take up glucose from the blood and to use it for energy or fat storage for future use.

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 (hyperglycaemia), which can lead to serious medical problems.

Long-term hyperglycaemia can lead to heart disease, blindness, kidney damage, poor blood circulation and gangrene.

Signs of hyperglycaemia may include:

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

How Diaformin XR and Diaformin XR 1000 works

Diaformin XR and Diaformin XR 1000 belongs to a group of medicines called biguanides. It lowers high blood glucose levels by:

- improving your body's sensitivity to insulin and restoring the way it normally uses glucose
- reducing the amount of glucose your liver makes
- delaying the amount of glucose your intestine absorbs

Ask your doctor if you have any questions about why Diaformin XR or Diaformin XR 1000 has been prescribed for you.

Diaformin XR and Diaformin XR 1000 are not recommended in children as its safety and effectiveness have not been established in this age group.

Diaformin XR and Diaformin XR 1000 are available only with a doctor's prescription.

There is no evidence that Diaformin XR or Diaformin XR 1000 is addictive.

After the active ingredient metformin is absorbed into your body, you may see the empty tablet shell in your faeces (bowel motions). This is normal and does not affect the way Diaformin XR and Diaformin XR 1000 works.

Before you take Diaformin XR or Diaformin XR 1000

When you must not take it

Do not take Diaformin XR and Diaformin XR 1000 if you are allergic to:

- medicines containing metformin or any other biguanide
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not take Diaformin XR and Diaformin XR 1000 if you have any of the following medical conditions:

- type 1 diabetes mellitus that is well controlled by insulin alone
- type 2 diabetes that is already well controlled by diet alone
- serious complications with your diabetes or any type of metabolic acidosis such as lactic acidosis, diabetic ketoacidosis (a symptom of uncontrolled diabetes, in which substances called ketone bodies accumulate in the blood – you may notice this as an unusual fruity odour on your breath)
- kidney failure or severe kidney disease
- dehydration (for instance due to persistent or severe vomiting or diarrhoea)
- shock from severe injury or blood loss
- severe liver disease
- acute alcohol intoxication, chronic alcohol dependence
- certain heart or blood circulation problems, including a recent heart attack or heart failure (when the heart fails to pump blood effectively)
- blood clots in the lungs (symptoms include coughing, shortness of breath, chest pain and a fast heart rate), severe breathing difficulties
- inflammation of the pancreas (symptoms include severe upper stomach pain, often with nausea and vomiting) if associated with severe infection or hypoxia (lack of oxygen)
- a severe infection or gangrene.

Do not take Diaformin XR and Diaformin XR 1000 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 Diaformin XR and Diaformin XR 1000 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 take this medicine if you are pregnant or plan to become pregnant.

Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will replace Diaformin XR or Diaformin XR 1000 with insulin while you are pregnant.

Do not take Diaformin XR and Diaformin XR 1000 if 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 Diaformin XR or Diaformin XR 1000, ask your doctor.

Before you start to take it

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

Before starting Diaformin XR or Diaformin XR 1000 your doctor will ask you to have a blood test to check your kidney function.

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

- kidney problems
- liver problems
- heart or blood vessel problems including heart failure.

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 Diaformin XR or Diaformin XR 1000 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 him/ her before you start taking Diaformin XR or Diaformin XR 1000.

Taking other medicines

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

Some medicines and Diaformin XR or Diaformin XR 1000 may interfere with each other. These include:

- other medicines used to treat diabetes
- iodinated contrast agents (dyes)
- medicines that contain alcohol, such as cough and cold syrups
- corticosteroids such as prednisone or cortisone
- 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
- medicines used to treat high blood pressure and some heart conditions, such as beta-blockers, calcium channel blockers or ACE inhibitors
- some medicines used to treat asthma such as salbutamol or terbutaline
- diuretics, also called fluid tablets
- chlorpromazine, a medicine used to treat schizophrenia and other mental illnesses
- NSAIDs (non-steroidal anti-inflammatory drugs), medicines used to relieve pain, swelling and other symptoms of inflammation, such as aspirin, diclofenac, ibuprofen, meloxicam, naproxen or piroxicam
- cimetidine, used to treat ulcers and reflux
- medicines used to prevent blood clots such as warfarin.
- medicines that are substrates/ inhibitors of organic cation transporters - OCT 1 such as verapamil; OCT 2 such as dolutegravir, crizotinib, olaparib, daclatasvir or vandetanib
- medicines that are inducers of OCT 1 such as rifampicin
- medicines that may increase the risk of lactic acidosis when concomitantly used with metformin hydrochloride such as topiramate and other carbonic anhydrase inhibitors

These medicines may be affected by Diaformin XR or Diaformin XR 1000 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 also have more information on medicines to be careful with or avoid while taking Diaformin XR or Diaformin XR 1000.

How to take Diaformin XR and Diaformin XR 1000

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

Diaformin XR comes in two strengths:

Diaformin XR metformin 500 mg and Diaformin XR 1000 metformin 1000 mg tablets.

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

The usual starting dose is 1 tablet (500 mg) once daily with the evening meal. Your doctor may increase the dose slowly, depending on your blood glucose levels.

The maximum recommended dose is 4 tablets (2 grams) once per day.

Elderly patients and people with kidney problems may need smaller doses.

How to take it

Swallow the tablets whole with a glass of water.

Do not break, crush or chew the tablets.

If you break, crush or chew Diaformin XR or Diaformin XR 1000, they will not work as well. Diaformin XR and Diaformin XR 1000 are extended release tablets. This means they have a special coating which allows the active ingredient, metformin, to be released slowly over time.

When to take it

Take your medicine everyday with the evening meal.

Taking Diaformin XR or Diaformin XR 1000 during or with your evening meal will reduce the chance of a stomach upset.

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 for

Keep taking Diaformin XR and Diaformin XR 1000 for as long as your doctor recommends.

Diaformin XR and Diaformin XR 1000 will help control diabetes but will not cure it. Most people will need to take Diaformin XR or Diaformin XR 1000 for long periods of time.

When you start treatment with Diaformin XR or Diaformin XR 1000, it can take up to some weeks for your blood glucose levels to be properly controlled.

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 you missed.

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) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Diaformin XR or Diaformin XR 1000. Do this even if there are no signs of discomfort or poisoning.

If you take too much Diaformin XR or Diaformin XR 1000, you may feel 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 Diaformin XR or Diaformin XR 1000 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 non-diet soft drink or taking glucose tablets.

While you are taking Diaformin XR or Diaformin XR 1000

Things you must do

If you are about to be started on any new medicine, remind your doctor and

pharmacist that you are taking Diaformin XR or Diaformin XR 1000.

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

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

HYPOGLYCAEMIA

Diaformin XR or Diaformin XR 1000 does not normally cause hypoglycaemia (low blood sugar), although you may experience it while taking other medicines for diabetes such as insulin or sulfonylureas.

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

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

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less Diaformin XR or Diaformin XR 1000 than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Tell your doctor if any of the following happen:

- you become ill
- you become dehydrated (for instance due to persistent or severe diarrhoea or recurrent vomiting)
- you are injured
- you have a fever

- you have a serious infection such as influenza, respiratory tract infection or urinary tract infection
- you are having major surgery
- you are having an examination such as an X-ray or a scan requiring an injection of an iodinated contrast agent (dye).

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 Diaformin XR or Diaformin XR 1000 with insulin.

Visit your doctor regularly for check-ups.

Your doctor may want to check your kidneys, liver, heart and vitamin B12 levels while you are taking Diaformin XR or Diaformin XR 1000.

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.

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

Things you must not do

Do not use Diaformin XR or Diaformin XR 1000 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 skip meals while taking Diaformin XR or Diaformin XR 1000.

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, Diaformin XR and Diaformin XR 1000 by itself is unlikely to affect how you drive or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Diaformin XR and Diaformin XR 1000.

Diaformin XR and Diaformin XR 1000 helps most people with diabetes but it may have unwanted side effects in some 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.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

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

- feeling sick (nausea)
- vomiting
- diarrhoea
- stomach pain
- taste disturbance

- loss of appetite
- skin reactions such as redness of the skin, itching or an itchy rash (urticaria).

These are generally mild side effects which disappear after the first few weeks. Taking Diaformin XR or Diaformin XR 1000 with meals can help reduce nausea and diarrhoea.

Tell your doctor as soon as possible if you notice any of the following:

- symptoms of liver disease such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, yellowing of the skin and eyes and dark coloured urine

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 heartbeat.

LACTIC ACIDOSIS 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 side effects (e.g. reduced vitamin B12 level) can only be found when your doctor does tests from time to time to check your progress.

After using Diaformin XR and Diaformin XR 1000

Storage

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

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

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

Do not store Diaformin XR or Diaformin XR 1000 or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep Diaformin XR or Diaformin XR 1000 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

Diaformin XR comes in two strengths:

Diaformin XR and Diaformin XR 1000 tablets.

- Diaformin XR is a white to off-white, capsule-shaped, biconvex tablet, debossed "500" on one side. It is available in blister packs of 120 tablets.
- Diaformin XR 1000 is a white to off-white, capsule-shaped, biconvex tablet, debossed on one side with "1000". It is available in blister packs of 60 tablets.

Ingredients

The active ingredient in Diaformin XR and Diaformin XR 1000 is metformin hydrochloride.

Each extended release tablet contains 500 mg or 1000 mg of metformin hydrochloride.

The tablets also contain the following inactive ingredients:

- croscarmellose sodium
- hypromellose
- microcrystalline cellulose (500 mg only)
- magnesium stearate.

The tablets do not contain sucrose, lactose, gluten, tartrazine or any other azo dyes.

Diaformin XR and Diaformin XR 1000 tablets contain trace amounts of sulfites.

Supplier

Diaformin XR and Diaformin XR 1000 are supplied in Australia by:

Alphapharm Pty Ltd
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

Australian registration numbers:

Diaformin XR -

AUST R 120868

Diaformin XR 1000 -

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