

APO-Metformin XR

Contains the active ingredient metformin hydrochloride

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before 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. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine 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 this medicine is used for

APO-Metformin XR Tablets is 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.

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

Metformin 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.

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

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.

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

Your doctor may have prescribed this medicine for another reason.

Use in children

There is not enough information to recommend the use of this medicine for children.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing metformin.
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction 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 think you are having an allergic reaction, do not take any more of the medicine and

contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

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

- 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 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 this medicine 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 metformin 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.

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

Do not breastfeed if you are taking this medicine.

Your doctor will discuss with you the options of either breast-feeding or using metformin.

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 this medicine, talk to your doctor.

Before you start to take it

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

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

- kidney problems
- liver problems
- alcohol dependence
- current dehydration
- current infection
- pancreatitis (inflammation of the pancreas)
- thyroid problems
- heart or blood vessel problems, including heart failure.
- Before starting metformin, your doctor will ask you to have a blood test to check your kidney function.

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 metformin may also lead to serious side effects.

Your doctor may suggest you stop drinking or reduce the amount of alcohol you drink. You should also avoid taking other medicines that contain alcohol.

Tell your doctor if you are planning to have any operations or radiographic procedures.

If you have not told your doctor about any of the above, tell him/her 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 get without a prescription from your pharmacy, supermarket or health food shop.

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

- other medicines used to treat diabetes such as insulin, glitinides (repaglinide) and sulfonylureas (e.g. gliclazide, glibenclamide,)
- iodinated contrast agents (dyes)
- medicines that contain alcohol, such as cough and cold syrups
- corticosteroids such as prednisolone, prednisone and cortisone
- tetracosactrin, a medicine used in people with multiple sclerosis, and also 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 (metoprolol), calcium channel blockers (nifedipine, amlodipine) and ACE inhibitors (captopril, enalapril, fosinopril, lisinopril, perindopril, ramipril, quinapril andtrandolapril).
- some medicines used to treat asthma such as salbutamol and terbutaline
- diuretics, also called fluid, or water tablets, such as amiloride, bumetanide, frusemide,

- hydrochlorothiazide and spironolactone
- 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, including arthritis such as aspirin, diclofenac, meloxicam, naproxen and piroxicam
- medicines used to treat ulcers and reflux, such as cimetidine
- medicines used to prevent blood clots such as warfarin
- thyroid hormones, such as thyroxine.

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.

Other medicines not listed above may also interact with metformin.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take this medicine

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, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

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

The usual starting dose is 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 2 grams once per day.

The elderly and people with kidney problems may need smaller doses.

How to take it

Swallow the tablets whole with a full glass of water.

Do not break, crush or chew the tablets.

If you break, crush or chew the tablets, they will not work as well.

Metformin XR are modified 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 at about the same time each day.

Taking the tablets 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

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

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

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

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

If you forget to take it

If it is almost time to take 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 an unwanted side effect.

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)

If you think that you or anyone else may have taken too much of this medicine, 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.

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 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 this medicine

Things you must do

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

doctor and pharmacist that you are taking this one.

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

Tell your doctor that you are taking this medicine if you experience any of the following signs which may indicate a lifethreatening condition called lactic acidosis:

- muscle cramps
- stomach pain
- feeling weak
- problems breathing.

Tell your doctor if you plan to have any radiographic procedures requiring an injection of an iodinated contrast agent (dye).

Your doctor will advise you when to stop taking metformin before you have these procedures and when to start again.

If you become pregnant or plan to breastfeed while taking this medicine, tell your doctor immediately.

Visit your doctor regularly for check-ups.

Your doctor may want to check your kidneys, liver, heart and blood levels while you are taking 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.

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

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 an influenza, respiratory tract infection or urinary tract infection
- you are going to have surgery

- you are having an examination such as an X-ray or a scan requiring an injection of an iodinated contrast agent (dye).
- you become pregnant.

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.

Hypoglycaemia

Metformin does not normally cause hypoglycaemia (low blood sugar), although you may experience it while taking other medicines for diabetes such as insulin, sulfonylureas or glitinides. 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 Metformin XR than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Things you must not do

Do not take this medicine 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 stop taking your medicine or lower the dosage without checking with your doctor.

Do not skip any meals while taking metformin.

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.

Things to be aware of

After 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 metformin works.

Possible side effects

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

Metformin helps most people with (indication), 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 attention 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.

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:

- feeling sick (nausea), being sick (vomiting)
- diarrhoea
- stomach pain
- taste disturbance, loss of appetite
- skin reactions such as redness of the skin, itching or an itchy rash (urticaria).

The above list includes the more common side effects of your medicine, which disappear after the first few weeks. Taking metformin 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 (jaundice) and dark coloured urine.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

The below list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Symptoms of lactic acidosis (buildup 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 IT DOES OCCUR, LACTIC ACIDOSIS CAN BE FATAL. THE RISK OF LACTIC ACIDOSIS IS HIGHER IN THE ELDERLY, OR PEOPLE WITH POORLY CONTROLLED DIABETES, PROLONGED FASTING, CERTAIN HEART CONDITIONS, SEVERE LIVER OR KIDNEY PROBLEMS OR PEOPLE WHO DRINK ALCOHOL.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. It is very important that you speak to your doctor immediately if a side effect is severe, occurred suddenly or gets worse rapidly.

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.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it. If you take your medicine out of its original packaging it may not keep well.

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

Do not store any 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 tells you to stop taking this medicine or the expiry date has passed, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Metformin XR tablets looks like

New formulation

Metformin XR 500 contains 500 mg metformin hydrochloride as modified release tablets: White, capsule shaped uncoated tablet with XR 500 on one side and a plain on the other side.

It is available in blister packs of 120 tablets.

Metformin XR 1000 contains 1000 mg metformin hydrochloride as modified release tablets: White capsule shaped uncoated tablet with XR 1000 one side and a plain on the other side.

It is available in blister packs of 60 tablets.

Old formulation

Metformin XR 500 contains 500 mg metformin hydrochloride as modified release tablets: white to off-white capsule-shaped, unscored tablet; engraved "APO" on one side and "XR500" on the other side.

It is also available in blister of 120 tablets.

Metformin XR 1000 contains 1000 mg metformin hydrochloride as modified release tablets: white to off-white capsule-shaped biconvex tablet; engraved "MXR 1000" on one side and plain on the other side.

It is also available in blister of 60 tablets.

* Not all strengths, pack types and/or pack sizes may be

Ingredients

New formulation

Each modified release tablet contains either 500 mg or 1000 mg metformin hydrochloride as the active ingredient. It also contains the following inactive ingredients:

- hypromellose
- Povidone
- colloidal anhydrous silica
- magnesium stearate

Old formulation

Each modified release tablet contains either 500 mg or 1000 mg metformin hydrochloride as the active ingredient.

It also contains the following inactive ingredients:

- hypromellose
- methylcellulose
- colloidal anhydrous silica
- magnesium stearate.

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

Australian Registration Numbers

APO-Metformin XR 500 (blister):
AUST R 281211.

APO-Metformin XR 1000 (blister):
AUST R 281210.

Sponsor

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