

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about APX-METFORMIN.

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 risks and benefits. Your doctor has weighed the risk of you taking APX-METFORMIN 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 APX-METFORMIN is used for

The name of your medicine is APX-METFORMIN. It contains the active ingredient metformin hydrochloride.

Metformin is used to control blood glucose (the amount of sugar in the blood) in patients with diabetes mellitus, when diet and exercise are not enough to control blood glucose.

Metformin can be used in patients with Type II diabetes mellitus in adults and children over 10 years of age. It is especially useful in those who are overweight, when diet and exercise are not enough to lower blood glucose levels (hyperglycaemia). For adult patients, metformin can be used alone, or in combination with other oral diabetic medicines or in combination with insulin in insulin requiring Type II diabetes.

Ask your doctor if you have any questions about why APX-METFORMIN was prescribed for you.

Your doctor may have prescribed APX-METFORMIN tablets for another reason.

APX-METFORMIN is only available with a doctor's prescription.

There is no evidence that APX-METFORMIN is addictive.

How APX-METFORMIN works

Metformin belongs to a group of medicines called biguanides. Metformin lowers high blood glucose (hyperglycaemia) 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.

Before you take APX-METFORMIN

When you must not take it

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 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
- Any type of metabolic acidosis such as lactic acidosis, 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)
- severe liver disease
- excessive alcohol intake, binge drinking, alcohol dependence
- kidney failure or disease
- dehydration, severe blood loss, shock
- severe infection
- certain heart or blood vessel problems, including a recent heart attack or severe heart failure (when the heart fails to pump blood effectively)
- severe breathing difficulties
- blood clots in the lungs (symptoms include coughing, shortness of breath, chest pain, and a fast heart rate)
- gangrene
- inflammation of the pancreas (pancreatitis), symptoms include severe upper stomach pain, often with nausea and vomiting.

Do not take APX-METFORMIN 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 APX-METFORMIN 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 APX-METFORMIN if you are pregnant or intend becoming pregnant.

The safety of APX-METFORMIN in pregnant women has not been established.

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

Do not take APX-METFORMIN if you are breastfeeding.

APX-METFORMIN is not recommended while you are breastfeeding. Your doctor will discuss the options available to you.

Do not take APX-METFORMIN 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 APX-METFORMIN if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking APX-METFORMIN, 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 breastfeed.

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 APX-METFORMIN 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 APX-METFORMIN may interact with each other. These include:

- other medicines to treat diabetes
- 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
- some medicines used to treat high blood pressure and some heart conditions, including beta-blockers, calcium channel blockers and ACE inhibitors
- medicines used to prevent blood clots, such as warfarin
- diuretics, also known as fluid tablets e.g. thiazides, frusemide
- 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, a medicine used to treat reflux and ulcers
- corticosteroids such as prednisolone and cortisone
- some medicines used to treat asthma such as salbutamol or terbutaline
- medicines that are substrate/ 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 OTC 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.

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 APX-METFORMIN

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 APX-METFORMIN 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.

APX-METFORMIN 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 APX-METFORMIN 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 APX-METFORMIN for as long as your doctor recommends.

Make sure you keep enough APX-METFORMIN to last over weekends and holidays.

APX-METFORMIN 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 APX-METFORMIN.

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 APX-METFORMIN

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 APX-METFORMIN.

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

APX-METFORMIN does not normally cause hypoglycaemia, although you may experience it if you take other medicines for diabetes such as sulfonylureas or repaglinide; or if you also use insulin.

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 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.

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.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking APX-METFORMIN.

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

If you become pregnant while taking APX-METFORMIN, tell your doctor immediately.

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 APX-METFORMIN with insulin.

Visit your doctor regularly for check-ups.

Your doctor may want to perform blood tests to check your kidneys, liver, heart and vitamin B12 level while you are taking APX-METFORMIN.

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 APX-METFORMIN, it can take up to two weeks for your blood glucose levels to be properly controlled.

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

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 APX-METFORMIN 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 sick with a cold, fever or flu, it is very important to continue eating your normal meals.

Your diabetes educator or dietician can give you a list of foods to eat on a sick day.

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 APX-METFORMIN readily available.

Lifestyle measures that help reduce heart disease risk

By following these simple measures, you can further reduce the risk from heart disease.

- Quit smoking and avoid secondhand smoke
- Limit alcohol intake
- Enjoy healthy eating by:
 - eating plenty of vegetables and fruit;
 - reducing your saturated fat intake (eat less fatty meats, full fat dairy products, butter, coconut and palm oils, most take-away foods, commercially-baked products)
- Be active. Progress, over time, to at least 30 minutes of moderate intensity physical activity on 5 or more days each week. Can be accumulated in shorter bouts of 10 minutes duration. If you have been prescribed anti-angina medicine, carry it with you when being physically active
- Maintain a healthy weight
- Discuss your lifestyle and lifestyle plans with your doctor
- For more information and tools to improve your heart health, call Heartline, the Heart Foundation's national telephone information service, on 1300 36 27 87 (local call cost)

Know warning signs of heart attack and what to do:

- Tightness, fullness, pressure, squeezing, heaviness or pain in your chest, neck, jaw, throat, shoulders, arms or back
- You may also have difficulty breathing, or have a cold sweat or feel dizzy or light headed or feel like vomiting (or actually vomit).

If you have heart attack warning signs that are severe, get worse or last for 10

minutes even if they are mild, call triple zero (000). Every minute counts.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking APX-METFORMIN.

APX-METFORMIN 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)
- vomiting
- diarrhoea
- stomach pain
- taste disturbance
- loss of appetite
- skin reactions such as redness of the skin, itching or itchy rash (urticaria).

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

Taking APX-METFORMIN 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):

- 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 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 APX-METFORMIN

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 APX-METFORMIN looks like

- 500 mg tablet – oblong, white tablet, marked with M|O on one side and ‘ > ’ on the other APX-METFORMIN 500 mg tablets are available in bottles and blister packs containing 100 tablets
- 850 mg tablet – round, white tablet, marked with MO on one side and ‘ > ’ on the other APX-METFORMIN 850 mg tablets are available in blister packs containing 60 tablets
- 1000 mg tablet - oval, white tablet, marked M|O on one side and “ > | > ” on the other. APX-METFORMIN 1000 mg tablets are available in bottles and blister packs containing 90 tablets.

Ingredients

The active ingredient in APX-METFORMIN is metformin hydrochloride:

- each 500 mg tablet contains 500 mg of metformin hydrochloride
- each 850 mg tablet contains 850 mg of metformin hydrochloride
- each 1000 mg tablet contains 1000 mg of metformin hydrochloride.

The tablets also contain:

- povidone
- magnesium stearate
- purified water
- Opadry Clear OY-29020

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

Sponsor

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

Australian registration numbers:

APX-METFORMIN 500 mg tablet bottle –
AUST R 335850

APX-METFORMIN 500 mg tablet blister –
AUST R 335851

APX-METFORMIN 850 mg tablet blister –
AUST R 335853

APX-METFORMIN 1000 mg tablet bottle –
AUST R 335854

APX-METFORMIN 1000 mg tablet blister –
AUST R 335855

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