

APO-Metformin 500/850/1000

Contains the active ingredient metformin (met-FOR-min) 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 or diabetes educator.

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 using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Metformin 500, 850 or 1000 tablets.

It contains the active ingredient metformin (as metformin hydrochloride).

It is used to treat type 2 diabetes (also called non-insulin dependent diabetes mellitus or maturity onset diabetes) 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 high 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 2 diabetes.

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.

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

How it works

Metformin belongs to a group of medicines called biguanides.

Metformin lowers high blood glucose 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).

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, which can lead to serious medical problems with your heart, eyes, circulation or kidneys.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children under 10 years of age.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have or have had any of the following:**
 - **type 1 diabetes that is well controlled by insulin alone**
 - **type 2 diabetes that is already well controlled by diet alone**
 - **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
- severe kidney disease or kidney failure
- dehydration, severe blood loss, shock
- a 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.
- **You need to have major surgery or an examination such as an X-ray or 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.

- **You are breast-feeding.**
Metformin may pass into human breast milk.
- **You are hypersensitive to, or have had an allergic reaction to, metformin, other biguanides or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty

breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

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.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - kidney problems
 - heart failure.
3. 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.
4. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
5. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding.
6. You are planning to have surgery or an anaesthetic.

7. You are currently receiving or are planning to receive dental treatment.
8. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with metformin. These include:

- other medicines used to treat diabetes, such as sulfonylureas or repaglinide
- some medicines used to treat high blood pressure and some heart conditions, including beta-blockers, calcium channel blockers and ACE inhibitors; some examples include metoprolol, nifedipine and enalapril
- medicines used to prevent blood clots such as warfarin
- diuretics, also called fluid tablets
- thyroid preparations such as thyroxine
- cimetidine, a medicine commonly used to treat reflux and ulcers
- glucocorticoids such as prednisone and cortisone
- some medicines used to treat asthma such as salbutamol or terbutaline.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with metformin.

How to take this medicine

Follow carefully all directions given to you by your doctor.

Their instructions may be different to the information in this leaflet.

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.

Adults

The usual starting dose for adults is 500mg one to two times a day. Your doctor may increase or decrease the dose, depending on your blood glucose levels. The maximum recommended dose is 1000mg three times a day.

People over 65 years of age or those with kidney problems may need smaller doses.

Children & Adolescents

The usual starting dose for children from 10 years of age and adolescents is one tablet of 500 mg or 850 mg once daily. Your doctor may increase or decrease the dose, depending on your blood glucose levels.

The maximum recommended dose is 2000 mg daily, taken as two or three divided doses.

How to take it

Swallow the tablets with a glass of water.

When to take it

Take your medicine during or immediately after a meal, at about the same time each day.

This will reduce the chance of a stomach upset.

Taking your medicine 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

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

Metformin will help control your diabetes but will not cure it. Most people will need to take metformin on a long-term basis.

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 missed dose and take your next dose at the usual time.

Otherwise take it as soon as you remember (with or immediately after a meal) and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you getting low blood sugar levels (hypoglycaemia).

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

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 (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your 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 sleepy, 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.

While you are taking this medicine

Things you must do

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

HYPOGLYCAEMIA

Metformin does not normally cause hypoglycaemia, although you may experience it if you also 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
- 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.

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

Hyperglycemia is often asymptomatic (doesn't cause any immediate symptoms) in many people. However some people will develop symptoms. Those people who develop symptoms may experience the following:

- high levels of sugar in the urine
- frequent urination
- increased thirst.

If you develop any signs of hyperglycaemia, contact your doctor immediately.

Your doctor may need to consider additional or other treatments for your diabetes.

The risk of hyperglycaemia is increased in the following situations:

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

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests

You must also tell your doctor if:

- 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) or are going into hospital

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.

Go to your doctor regularly for a check-up. Your doctor may want to perform blood tests to check your kidneys, liver, heart and vitamin B12 level while you are taking this medicine.

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, 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 skip meals while taking this medicine.**
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to.
- 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, metformin by itself is unlikely to affect how you drive or operate machinery.

If you become sick with a cold, fever or flu, it is very important to continue taking metformin even if you feel unable to eat your normal meal.

Your diabetes educator or dietician can give you a list of foods to use for sick days.

If you are travelling, it is a good idea to:

- wear some form of identification (e.g. 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 your medicine with you, so you don't miss any doses.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking metformin.

Metformin helps most people with diabetes, but it may have unwanted side effects in a few people.

If you are over 65 years of age, report any side effects to your doctor immediately.

People over his age may have an increased chance of getting side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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

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

These are generally mild side effects. Stomach upset and diarrhoea are common but usually short-lived. Taking your medicine with meals can help reduce nausea and diarrhoea. Skin rash has been reported rarely.

Tell your doctor immediately or go to Accident or 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 light-headedness
- 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 and liver problems.

Other side effects not listed above may occur in some patients.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Allergic reactions

If you think you are having an allergic reaction to metformin, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

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 will stay below 25°C.

Do not store your medicine, or any other 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 this medicine 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Metformin 500, 850 or 1000 looks like

500 mg tablets:

White coloured, film-coated biconvex capsule shaped tablet with central break-line on one side and '500' embossed on the other side.

They are packaged in a blister pack of 100 tablets.

850 mg tablets:

White coloured, film-coated, round biconvex tablets plain on one side and '850' embossed on the other side.

They are packaged in a blister pack of 60 tablets.

1000 mg tablets:

White, film-coated, capsule-shaped, biconvex tablet, plain on one side and a breakline on the other.

They are packed in a blister pack of 10, 30, 60 and 90 tablets.

* Not all strengths and/or pack sizes may be available.

Ingredients

Each tablet 500 mg, 850 mg or 1000 mg of metformin hydrochloride as the active ingredient.

It also contains the following inactive ingredients:

- hypromellose
- macrogol 6000
- magnesium stearate
- povidone
- propylene glycol
- silica - colloidal anhydrous
- sodium starch glycollate
- starch - maize
- talc- purified
- colloidal anhydrous silica
- titanium dioxide.

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

Australian Registration Numbers

APO-Metformin 500 tablets (blister pack): AUST R 174815.

APO-Metformin 850 tablets (blister pack): AUST R 174816.

APO-Metformin 1000 tablets (blister pack): AUST R 176509.

Sponsor

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