

GLUCOBETE

GLUCOBETE 500, 850 & 1000

Consumer Medicine Information

Metformin hydrochloride

What is in this leaflet

This leaflet answers some common questions about GLUCOBETE. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist or diabetes educator.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking GLUCOBETE against the benefits it is expected for you.

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

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

What GLUCOBETE is used for

GLUCOBETE is used to control blood glucose (the amount of sugar in the blood) in people with diabetes mellitus.

GLUCOBETE can be used in type 2 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, GLUCOBETE 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 GLUCOBETE has been prescribed for you.

Your doctor may have prescribed GLUCOBETE for another reason.

GLUCOBETE is available only with a doctor's prescription.

There is no evidence that GLUCOBETE is addictive.

How GLUCOBETE works

GLUCOBETE belongs to a group of medicines called biguanides. GLUCOBETE lowers high blood glucose (hyperglycaemia) by helping your body make better use of the insulin produced by your pancreas.

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.

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.

Before you take GLUCOBETE

When you must not take it

Do not take GLUCOBETE if you are allergic to:

- Medicines containing metformin or any other biguanide.
- Any of the ingredients listed toward 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 GLUCOBETE if you have any of the following conditions:

- type 1 diabetes mellitus 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.
- kidney failure or severe kidney disease
- 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.

Do not take GLUCOBETE if you plan to have major surgery or an X-ray or a scan requiring an injection of iodinated contrast (dye).

You must stop taking GLUCOBETE 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 GLUCOBETE if you are pregnant or plan to become pregnant.

The safety of GLUCOBETE in pregnant woman has not been established.

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

Do not take GLUCOBETE if you are breast feeding.

GLUCOBETE is not recommended while you are breast feeding. Your doctor will discuss the options available to you.

Do not take GLUCOBETE if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date it may not work as well.

Do not take GLUCOBETE if the packaging shows signs of tampering or the tablets do not look quite right.

If you are not sure whether you should start taking GLUCOBETE, ask your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, food, dyes or preservatives

Tell your doctor if you have any medical conditions, especially the following:

- heart failure
- kidney problems

Your doctor may want to take special care if you have any of these conditions.

Tell to 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 GLUCOBETE may 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 these things, tell him/her before you start taking GLUCOBETE.

Taking other medicines

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

Some medicines may be affected by GLUCOBETE or may affect how well it works. These include:

- other medicines used to treat diabetes
- medicines that contain alcohol, such as cough and cold syrups
- 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
- Repaglinide (Novonorm), another type of medicine used to treat diabetes.
- some medicines used to treat high blood pressure and some heart conditions, including betablockers, calcium channel blockers and ACE inhibitors.
- medicines used to prevent blood clots such as warfarin.
- diuretics, also called fluid tablets.
- chlorpromazine, a medicine used to treat schizophrenia and other mental illness.
- 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 commonly used to treat reflux and ulcers.
- corticosteroids such as prednisone or cortisone.
- some medicines used to treat asthma such as salbutamol or terbutaline

These medicines may be affected by GLUCOBETE 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 have more information on medicines to be careful with or avoid while taking GLUCOBETE.

How to take GLUCOBETE

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

They may differ from the information contained in the leaflet.

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

How much to take GLUCOBETE

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

The usual starting dose for adults is 500 mg 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 1000 mg three times a day.

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

Children and 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 2 g taken as two or three divided doses.

If your child has diabetes that is resistant to insulin and is being treated in hospital, your child's doctor will decide the dose

How to take GLUCOBETE

Swallow the tablet with a glass of water.

When to take GLUCOBETE

Take GLUCOBETE during or immediately after food.

This will reduce the chance of a stomach upset.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effects. It will also help you remember when to take it.

How long to take GLUCOBETE for

Keep taking GLUCOBETE for as long as your doctor recommends.

GLUCOBETE will help control diabetes but will not cure it. Most people will need to take GLUCOBETE on long term basis.

If you forget to take GLUCOBETE

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 the missed dose as soon as you remember (with food), and then go back to taking your tablets 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 GLUCOBETE (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital if you think you or anyone else may have taken too much GLUCOBETE, even if there are no signs of discomfort or poisoning.

If you take too much of GLUCOBETE, you may feel sleepy, very tired, sick, vomit, have trouble breathing and have unusual muscle pain, stomach pain or diarrhoea. These may be the 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 of GLUCOBETE together with other medicines for diabetes or with alcohol.

If you 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 GLUCOBETE

Things you must do

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

HYPOGLYCAEMIA

GLUCOBETE 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, head ache 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 notice the return of any of the 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 GLUCOBETE than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Tell your doctor if you:

- become ill
- become dehydrated
- are injured

- have a fever
- have a serious infection
- are having surgery (including dental surgery).

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 GLUCOBETE with insulin.

Before starting any new medicine, tell your doctor or pharmacist that you are taking GLUCOBETE.

Tell all the doctors, dentists and Pharmacists who are treating you that you are taking GLUCOBETE.

If you become pregnant while taking GLUCOBETE, 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 GLUCOBETE 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 GLUCOBETE.

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 GLUCOBETE, 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 GLUCOBETE.

Do not stop taking GLUCOBETE or change the dose without checking with your doctor.

Do not give GLUCOBETE to anyone else, even if they have the same condition as you.

Do not use GLUCOBETE to treat any other conditions unless your doctor tells you to.

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, GLUCOBETE 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 eating your normal meals.

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

When you are traveling, 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 enough GLUCOBETE with you, so you don't miss any doses.

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 second hand 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 GLUCOBETE.

GLUCOBETE 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 attention 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 .

Do not be alarmed by the following list 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 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 (urticaris).

These are generally mild side effects which disappear after the first few weeks. Taking GLUCOBETE with meals can help reduce nausea and diarrhoea. Skin rash has been reported rarely.

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 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 taking GLUCOBETE

Storage

Keep the medication where children cannot reach it.

A locked cupboard at least one-and-half metres above the ground is a good place to store medicines.

Keep your tablets in the 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 below 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking GLUCOBETE, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product Description

What it looks like

- GLUCOBETE 500 is presented in blister packs of 30 & 100 and bottle pack of 100.
- GLUCOBETE 850 is presented in blister packs of 20 & 60 and bottle packs of 60 & 100.
- GLUCOBETE 1000 is presented in blister packs of 20 & 90 and bottle pack of 100.

GLUCOBETE 500

White, biconvex, circular shaped, film coated tablets with 'A' debossed on one side and '60' debossed on the other side.

GLUCOBETE 850

White, biconvex, circular shaped, film coated tablets with 'A' debossed on one side and '61' debossed on the other side.

GLUCOBETE 1000

White, biconvex, oval shaped, film coated tablets with a score line in between '6' and '2' on one side and 'A' debossed on the other side.

Ingredients

Active ingredients

Metformin hydrochloride
Each tablet contain either 500, 850 or 1000 mg of Metformin hydrochloride.

Inactive ingredients

- Povidone
- Magnesium stearate
- Opadry complete film coating system YS-1R-7006 Clear (PIARTG No. 13068).

Name and Address of the Sponsor

Aurobindo Pharma Australia Pty Ltd

Unit 3, North Rydelink
277-283 Lane Cove Road
Macquarie Park
NSW 2113 Australia

Date of Approval

22 November 2011

Date of most recent amendment

31 May 2012