GLUCOVANCE®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using GLUCOVANCE?

GLUCOVANCE contains the active ingredients metformin hydrochloride and glibenclamide. GLUCOVANCE is used to control blood glucose levels (the amount of sugar in the blood) in adults with type II diabetes mellitus.

For more information, see Section 1. Why am I using GLUCOVANCE? in the full CMI.

2. What should I know before I use GLUCOVANCE?

Do not use if you have ever had an allergic reaction to GLUCOVANCE or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section 2. What should I know before I use GLUCOVANCE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with GLUCOVANCE and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use GLUCOVANCE?

- The dose varies from person to person.
- Your doctor will decide the right dose for you, depending on your blood glucose levels and other tests. More instructions can be found in Section 4. How do I use GLUCOVANCE? in the full CMI.

5. What should I know while using GLUCOVANCE?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using GLUCOVANCE. • Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia and know how to treat them. • Visit your doctor regularly for check ups.
Things you should not do	• Do not take any other medicines containing metformin or glibenclamide while taking GLUCOVANCE. • Do not skip meals while taking GLUCOVANCE. • Do not stop using this medicine or change the dose, without checking with your doctor.
Driving or using machines	• If you have to be alert, for example driving, be 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	• Avoid alcohol as it can strongly affect the control of your diabetes and may lead to serious side effects.
Looking after your medicine	• Keep your tablets in a cool dry place where temperature stays below 25°C. • Keep your tablets in the pack until it is time to take them. • Keep GLUCOVANCE where children cannot reach it.

For more information, see Section 5. What should I know while using GLUCOVANCE? in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist if you notice any of the following and they worry you: weakness, trembling or shaking, sweating, light headedness, headache, dizziness, irritability and tearfulness, stomach upset, nausea (feeling sick), vomiting, indigestion, diarrhoea, loss of appetite, taste disturbance, skin rash. **Tell your doctor immediately or go to accident and emergency at the nearest hospital if you notice any of the following symptoms:** nausea, vomiting, stomach pain, trouble breathing, feeling weak, tired or generally unwell, unusual muscle pain, sleepiness, dizziness or light headedness, shivering, feeling extremely cold or slow heartbeat.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

WARNING: Life threatening lactic acidosis (build-up of lactic acid in the blood), can occur due to accumulation of metformin. The main risk factor is renal impairment, other risk factors include old age associated with reduced renal function and high doses of metformin above 2 g per day.

GLUCOVANCE®

Active ingredient(s): *metformin hydrochloride and glibenclamide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using GLUCOVANCE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using GLUCOVANCE.**

Where to find information in this leaflet:

1. Why am I using GLUCOVANCE?
2. What should I know before I use GLUCOVANCE?
3. What if I am taking other medicines?
4. How do I use GLUCOVANCE?
5. What should I know while using GLUCOVANCE?
6. Are there any side effects?
7. Product details

1. Why am I using GLUCOVANCE?

GLUCOVANCE contains the active ingredients metformin hydrochloride and glibenclamide. Metformin belongs to a group of medicines called biguanides. Metformin lowers blood glucose by helping your body make better use of insulin. Glibenclamide belongs to a group of medicines called sulfonylureas. Glibenclamide lowers blood glucose by increasing the amount of insulin produced by your pancreas.

GLUCOVANCE is used to control blood glucose levels (the amount of sugar in the blood) in adults with type II diabetes mellitus. This type of diabetes is also known as non-insulin dependent diabetes mellitus (NIDDM) or maturity onset diabetes.

GLUCOVANCE is used:

- when diet, exercise and treatment with either metformin or a sulfonylurea medicine are not enough to control your blood glucose
- in people whose blood sugar levels are already well controlled by the combination of metformin and a sulfonylurea medicine. GLUCOVANCE is to replace these two medicines.

If your blood glucose is not properly controlled, you may experience hypoglycaemia (low blood glucose) or hyperglycaemia (high blood glucose).

Hypoglycaemia

Hypoglycaemia (low blood glucose) can occur suddenly. 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 quickly, these may progress to:

- loss of co-ordination
- slurred speech
- confusion
- fits or loss of consciousness.

Hyperglycaemia

Hyperglycaemia (high blood glucose) usually occurs more slowly than hypoglycaemia. Signs of hyperglycaemia may include:

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

Long-term hyperglycaemia can lead to serious problems such as heart disease, blindness, poor blood circulation, gangrene or kidney damage.

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

There is no evidence that GLUCOVANCE is addictive.

This medicine has been prescribed for you personally and you should not pass it onto others even if their symptoms are the same as yours.

2. What should I know before I use GLUCOVANCE?

Warnings

Do not take GLUCOVANCE if:

- you are allergic to metformin hydrochloride, glibenclamide, any other sulfonylurea medicine such as gliclazide, glipizide, glimepiride, any other sulfonamides or 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.
- Always check the ingredients to make sure you can use this medicine.
- **you have the following conditions:**

- type I diabetes mellitus also known as insulin dependent diabetes
- type II 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)
- known or suspected of having a genetic problem causing a mitochondrial disorder such as Mitochondrial Encephalopathy with Lactic Acidosis, and Stroke-like episodes (MELAS) syndrome and Maternal inherited diabetes and deafness (MIDD).
- severe liver disease
- kidney failure or severe kidney disease
- dehydration (for instance due to persistent or severe diarrhoea or recurrent vomiting), severe blood loss or shock
- severe infection or gangrene
- certain heart or blood vessel problems, including a recent heart attack or heart failure (when the heart fails to pump blood effectively)
- severe breathing difficulties
- blood clots in the lung (symptoms include coughing, shortness of breath, chest pain and a fast heart rate)
- pancreatitis (symptoms include severe upper stomach pain, often with nausea and vomiting) if associated with severe infection or hypoxia (lack of oxygen)
- alcohol dependence or binge drinking
- porphyria, an inherited disorder
- glucose and galactose malabsorption syndrome or lactase deficiency.

- **you are currently taking miconazole, either orally or as a mouth gel.** Taking GLUCOVANCE with miconazole may cause an excessive drop in your blood glucose level.
- **you need to have major surgery or an examination such as an X-ray or a scan involving the injection of contrast medicines that contain iodine into your bloodstream.** You must stop taking GLUCOVANCE 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 pregnant.**
- **you are breastfeeding.**
- the expiry date printed on the pack has passed. If you take this medicine after the expiry date, it may not work as well.
- the packaging shows signs of tampering or the tablets do not look quite right.

Check with your doctor if you:

- have any, or have had, other medical conditions:
  - kidney problems
  - liver problems
  - hormone problems with the thyroid (e.g., hypothyroidism), pituitary or adrenal gland
  - heart or blood vessel problems including heart failure.

  Your doctor may want to take special care if you have any of these conditions.
- take any medicines for any other condition.
- have allergies to any other medicines, any other substances, such as foods, preservatives or dyes.
- **drink alcohol**
- do not eat regular meals, are fasting or have changed your diet
- do a lot of exercise
- are ill or feeling unwell.

Alcohol, diet, exercise and your general health all strongly affect the control of your diabetes.

If you have not told your doctor about any of the above, tell him/her before you start taking GLUCOVANCE.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Do not take GLUCOVANCE if you are pregnant.

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

Do not take GLUCOVANCE if you are breastfeeding.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Since it is not known whether GLUCOVANCE passes into breast milk, GLUCOVANCE is not recommended while you are breast-feeding.

Children or adolescents

- **Do not give GLUCOVANCE to children or adolescents.** The safety and effectiveness of GLUCOVANCE have not been established in children or adolescents.

3. What if I am taking other medicines?

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

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

- other medicines containing metformin or glibenclamide
- other medicines used to treat diabetes
- iodinated contrast agents (dyes)
- medicines that contain alcohol, such as cough and cold syrups
- diuretics, also called fluid tablets

- certain antifungal medicines, such as miconazole and fluconazole
- certain antibiotics including medicines used to treat tuberculosis
- medicines used to treat high blood pressure and heart conditions (clonidine, reserpine, guanethidine, sympathicomimetics, beta-blockers, calcium channel blockers and ACE inhibitors)
- disopyramide, a medicine used to treat an irregular heart beat
- non-steroidal anti-inflammatory drugs (NSAIDS), medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis, such as aspirin and phenylbutazone
- desmopressin, a medicine used to treat diabetes insipidus, a condition causing large amounts of urine to be produced
- danazol, a medicine used to treat endometriosis
- bosentan, a medicine used to treat pulmonary hypertension
- phenytoin, a medicine used to treat epilepsy (fits or seizures)
- medicines used to treat depression such as fluoxetine and monoamine oxidase inhibitors (MAOIs)
- medicines used to treat schizophrenia and mental illnesses, such as chlorpromazine and phenothiazines
- corticosteroids, such as prednisone and cortisone
- medicine used to stimulate the adrenocortical hormones, such as tetracosactide
- anabolic steroids
- estrogens and progestogens in hormone replacement therapy and oral contraceptives
- thyroid hormones, such as levothyroxine
- some medicines used for asthma
- medicines used to treat for ulcers and reflux, such as cimetidine and ranitidine
- medicines used to prevent or to treat blood clots such as warfarin, heparin or sulfinpyrazone
- medicines used to lower lipids, such as bezafibrate, clofibrate, gemfibrozil and nicotinic acid
- pentoxifylline injection, a medicine used to treat blood vessel problems
- certain medicines used to treat cancer
- certain medicines used to treat gout such as probenecid
- acetazolamide, a medicine used to treat glaucoma
- certain weight reducing medicines
- large doses of laxatives
- 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, such as zonisamide, acetazolamide or dichlorphenamide.

These medicines may be affected by GLUCOVANCE 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 can tell you what to do if you are taking any of these medicines.

Check with your doctor or pharmacist if you are not sure whether you are taking any of these medicines, whether you should start taking this medicine, or if you are not sure what medicines, vitamins or supplements you are taking, and if these affect GLUCOVANCE.

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

4. How do I use GLUCOVANCE?

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

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

People who do not respond to either metformin or a sulfonylurea medicine alone:

- The usual starting dose is one GLUCOVANCE 500 mg/2.5 mg tablet once a day.

Replacing combined use of metformin and a sulfonylurea or glibenclamide medicine:

- The usual starting dose is one to two tablets of GLUCOVANCE 500 mg/2.5 mg daily.

Follow the instructions provided and use GLUCOVANCE until your doctor tells you to stop.

Elderly people

The dose depends on the renal function. The usual starting dose for elderly patients is one daily dose of metformin 250 mg and glibenclamide 1.25 mg.

Age 65 years and older has been identified as a risk factor for hypoglycaemia in patients treated with sulfonylureas. Hypoglycaemia can be difficult to recognize in the elderly. Starting and maintenance doses of glibenclamide must be carefully adjusted to reduce the risk of hypoglycaemia.

It is recommended that these patients are not titrated to the maximum dose of GLUCOVANCE to avoid the risk of hypoglycaemia.

Smaller doses may be prescribed by your doctor if you have kidney problems or generally poor health.

Your doctor may increase the dose slowly over one or two weeks, depending on your blood glucose levels and other tests.

The usual maximum recommended dose is one GLUCOVANCE 500mg/5mg tablet three times a day.

When to take GLUCOVANCE

- **GLUCOVANCE should be taken immediately before your meal.** This will reduce the chances of you having an upset stomach or a hypoglycaemic episode.
- **Take your medicine at about the same time each day.** Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How to take GLUCOVANCE

- Swallow the tablets with a glass of water.

How long to take GLUCOVANCE

- **Keep taking GLUCOVANCE for as long as your doctor tells you to.**
- GLUCOVANCE will help control diabetes but will not cure it. Most people will need to take GLUCOVANCE for long periods of time.

If you forget to use GLUCOVANCE

If you miss your dose at the usual time, take the next dose at the usual time.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you are not sure what to do or have any questions, ask your doctor or pharmacist.

If you use too much GLUCOVANCE

If you think that you or anyone else may have taken too much GLUCOVANCE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you take too much GLUCOVANCE, 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). If not treated quickly, these symptoms may progress to loss of co-ordination, slurred speech, confusion, fits or loss of consciousness.

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.

5. What should I know while using GLUCOVANCE?

Things you should 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

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.

Make sure that you have a full breakfast immediately after your first dose. If you usually have a light breakfast, hold off the first dose until lunch.

Due to the hypoglycaemic effect of GLUCOVANCE, it is recommended that you have a full meal immediately after a dose, to avoid a drop in your blood glucose level.

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.

The risk of hypoglycaemia is increased in the following situations:

- irregular meals or changes to diet
- intensive or prolonged exercise
- after alcohol intake, especially combined with fasting
- taking more GLUCOVANCE than prescribed
- taking certain other medicines
- in patients with kidney or liver problems
- in patients with hormone problems with the thyroid, pituitary or adrenal gland
- in patients from 65 years of age. Hypoglycaemia may be more severe and more prolonged than in younger adults.

Discuss with your doctor whether GLUCOVANCE is the appropriate treatment for your diabetes if you often experience severe symptoms of low blood sugar or if you find it hard to recognise them.

Hyperglycaemia

Call your doctor straight away if you:

- **notice the return of any symptoms of hyperglycaemia.** Your doctor may need to consider additional or other treatments for your diabetes.

The risk of hyperglycaemia is increased in the following situations:

- taking less GLUCOVANCE than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Tell your doctor if you:

- become ill
- become dehydrated (for instance due to persistent or severe diarrhoea or recurrent vomiting)
- are injured
- have a fever
- have a serious infection such as influenza, respiratory tract infection or urinary tract infection
- are having surgery with general anaesthesia (including dental surgery)
- are having any X-ray or scan that requires the injection of contrast medicines that contain iodine into your bloodstream.

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 GLUCOVANCE with insulin.

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

Remind any doctor, dentist or pharmacist who are treating you that you are using GLUCOVANCE.

If you become pregnant while taking GLUCOVANCE, tell your doctor.

Visit your doctor regularly for check ups.

Your doctor may want to perform blood tests to check your kidneys, liver, heart, and vitamin B12 levels while you are taking GLUCOVANCE. Make sure that you return to your doctor at least once a year (more often if you are elderly or if your kidney function is at the limit of normal).

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 from your doctor and dietician on diet, drinking alcohol and exercise.

If you drink alcohol while taking GLUCOVANCE, you may get flushing, headache, breathing difficulties, rapid heartbeat, stomach pains or feel sick and vomit.

Your doctor may suggest avoiding alcohol.

Things you should not do

- **Do not use any other medicines containing metformin or glibenclamide, in the form of either a single or a combination product, while you are being treated with GLUCOVANCE.** Taking additional metformin or glibenclamide-containing products may increase the risk of you getting unwanted side effects.
- **Do not skip meals while taking GLUCOVANCE.** You are more at risk of developing hypoglycaemia if you skip meals.
- **Do not stop taking this medicine suddenly, or change the dose, without checking with your doctor.**
- Do not use GLUCOVANCE to treat any other conditions unless your doctor tells you to.
- Do not give GLUCOVANCE to anyone else, even if they have the same condition as you.

Things to be careful of

If you become sick with a cold, fever or flu, it is very important to continue eating your normal meals. If you have trouble eating solid food, use sugar-sweetened drinks as a carbohydrate substitute or eat small amounts of bland food.

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

When 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 enough GLUCOVANCE tablets with you, so you don't miss any doses.

Protect your skin when you are in the sun, especially between 10 am and 3 pm. If outdoors, wear protective clothing and use a 15+ sunscreen. If your skin does appear to be burning, tell your doctor immediately.

GLUCOVANCE may cause your skin to be more sensitive to sunlight than it is normally. Exposure to sunlight may cause skin rash, itching, redness or severe sunburn.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how GLUCOVANCE affects you.

If you have to be alert, for example driving, be 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

Tell your doctor or pharmacist if you drink alcohol.

Alcohol can strongly affect the control of your diabetes and if you drink alcohol while taking GLUCOVANCE it may lead to serious side effects.

Your doctor may suggest avoiding alcohol.

Looking after your medicine

- Store below 25°C.
- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine, if your doctor tells you to stop taking GLUCOVANCE or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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

GLUCOVANCE helps most people with type II diabetes but it may have unwanted side effects in some people.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

If you are an elderly person over 65 years of age, report any side effects promptly to your doctor. You may have an increased chance of getting side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• signs of hypoglycaemia which may include weakness, trembling or shaking, sweating, light headedness, headache, dizziness, irritability and tearfulness • stomach upset including nausea (feeling sick), vomiting and indigestion • pressure on the stomach or feeling of fullness • diarrhoea • loss of appetite • taste disturbance • mild skin rash • transient visual disturbances due to a decrease of blood glucose levels • flushing, headache, breathing difficulties, rapid heart beat, stomach pains or feel sick and vomit if you drink alcohol while taking GLUCOVANCE.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• skin reactions including severe skin rash, itching or hives • symptoms of sunburn such as redness, itching or blistering, which may occur more quickly than normal • bleeding or bruising more easily than normal, reddish or purplish blotches under the skin • symptoms of liver disease such as yellowing of the eyes or skin (jaundice) and dark coloured urine • frequent signs of infection, such as fever, chills, sore throat or mouth ulcers. **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 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 heartbeat.** **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.**	**Emergency Department at your nearest hospital if you notice any of these serious side effects.** **These side effects are serious and require urgent medical attention or hospitalization.**

Tell your doctor or pharmacist if you notice anything else that may be 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 here may occur in some people.

Other side effects not listed above may also occur in some patients. Some side effects from e.g., reduced vitamin B12 level may occur. Your doctor may arrange some tests from time to time to check your progress and to find out the cause of any symptoms.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What GLUCOVANCE contains

Active ingredient (main ingredient)	Each GLUCOVANCE 500/2.5 tablet contains metformin hydrochloride 500 mg and glibenclamide 2.5 mg. Each GLUCOVANCE 500/5 tablet contains metformin hydrochloride 500 mg and glibenclamide 5 mg.
Other ingredients (inactive ingredients)	GLUCOVANCE 500/2.5 and GLUCOVANCE 500/5 tablets contain croscarmellose sodium, povidone, magnesium stearate, microcrystalline cellulose. GLUCOVANCE 500/2.5 tablet also contains Opadry II complete film coating system OY-L-24808 Pink (ID 4390). GLUCOVANCE 500/5 tablet also contains Opadry II complete film coating system 31F22700 Yellow (ID 4391).
Potential allergens	Contains lactose and trace quantities of sulfites.

Do not take this medicine if you are allergic to any of these ingredients.

What GLUCOVANCE looks like

GLUCOVANCE 500/2.5 is pale orange film-coated, capsule-shaped, biconvex tablet, engraved with "2.5" on one side (AUST R 96728).

GLUCOVANCE 500/5 is yellow film-coated, capsule-shaped, engraved with "5" on one side (AUST R 96729).

Each pack contains 90 tablets.

Some strengths or pack sizes may not be marketed.

Who distributes GLUCOVANCE

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in August 2026.

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