GLICLAZIDE LUPIN MR

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 Gliclazide Lupin MR?

Gliclazide Lupin MR contains the active ingredient gliclazide. Gliclazide Lupin MR is used to control blood glucose (sugar) in patients with type II diabetes mellitus when diet and exercise are not enough to control your blood glucose.

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

2. What should I know before I use Gliclazide Lupin MR?

Do not use if you have ever had an allergic reaction to gliclazide 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 Gliclazide Lupin MR? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Gliclazide Lupin MR 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 Gliclazide Lupin MR?

Swallow the tablet(s) as prescribed by your physician with a glass of water at the same time-usually with breakfast.

More instructions can be found in Section 4. How do I use Gliclazide Lupin MR? in the full CMI.

5. What should I know while using Gliclazide Lupin MR?

Things you should do	 Remind any doctor, dentist, pharmacist, or diabetes educator you visit that you are using gliclazide. Check your blood glucose levels regularly to know if your diabetes is being controlled properly.
Things you should not do	 Do not stop using this medicine or change the dosage, without checking with your doctor. Do not skip meals while taking Gliclazide Lupin MR.
Driving or using machines	 Gliclazide Lupin MR may cause dizziness and drowsiness in some people. Drinking alcohol can make this worse. If either of these occurs, do not drive or operate machinery. Be careful driving or operating machinery until you know how Gliclazide Lupin MR affects you.
Drinking alcohol	Drinking alcohol while taking Gliclazide Lupin MR, may cause flushing, headache, breathing difficulties, rapid heartbeat, stomach pains or feel sick, and vomit.
Looking after your medicine	 Store it in a cool, dry place where the temperature stays below 25°C. Do not store it in the bathroom or near a sink or leave it in the car or on windowsills.

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

6. Are there any side effects?

Hypoglycaemia, hyperglycaemia (for more information, see section on recognising and treating hypoglycaemia and hyperglycaemia), runny or blocked nose, sneezing, facial pressure or pain, bronchitis, sore throat and discomfort when swallowing, upper respiratory infection, coughing, back pain, arthralgia, arthrosis, high blood pressure, chest pain, headache, unusual weakness, viral infection, urinary tract infection, dizziness, stomach upset with symptoms like feeling sick, stomach pain, vomiting, diarrhoea, or constipation are common side effects.

Skin rash, redness itching and/or hives, blisters, angioedema (rapid swelling of tissues such as eyelids, face, lips, mouth, tongue or throat that may result in breathing difficulty), and rash progressing to widespread blistering or peeling of the skin and may be the first sign of rare life-threatening conditions (eg. Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and severe hypersensitivity reactions (DRESS) are serious side effects).

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.

GLICLAZIDE LUPIN MR

Active ingredient: *gliclazide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Gliclazide Lupin MR. 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 Gliclazide Lupin MR.

Where to find information in this leaflet:

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

1. Why am I using Gliclazide Lupin MR?

Gliclazide Lupin MR contains the active ingredient gliclazide. Gliclazide Lupin MR belongs to a group of medicines called sulphonylureas. The medicine releases the active ingredient gliclazide progressively over 24 hours.

Glucose is used by the body as fuel, and all people have glucose circulating in their blood. In diabetes, levels of blood glucose are higher than is needed, which is also known as hyperglycaemia.

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 our heart, circulation and/or kidneys.

It is very important to control high blood glucose whether or not you feel unwell. This really helps to avoid serious long-term health problems, which can involve the heart, eyes, circulation, and/or kidneys.

GLICLAZIDE LUPIN MR is used to control blood glucose (sugar) in patients with type II diabetes mellitus. This type of diabetes is also known as non-insulin-dependent diabetes (NIDDM), or maturity-onset diabetes.

GLICLAZIDE LUPIN MR is used when diet and exercise are not enough to control your blood glucose properly. It lowers blood glucose by increasing the amount of insulin (a hormone that controls blood glucose levels) produced by your pancreas. As with many medicines used for the treatment of diabetes, there is a possibility that blood glucose levels may become very low during treatment with GLICLAZIDE LUPIN MR. This is known as hypoglycaemia.

For more information, see "Recognising and treating hyPOglyacemia", Section <u>5. What should I know while using GLICLAZIDE LUPIN MR?</u>

Gliclazide Lupin MR can be used alone or together with insulin or other medicines for treating diabetes.

Gliclazide Lupin MR is not addictive.

Ask your doctor if you have any questions about why Gliclazide Lupin MR has been prescribed for you.

2. What should I know before I use Gliclazide Lupin MR?

Warnings

Do not use Gliclazide Lupin MR if:

- you are allergic to gliclazide, or any of the ingredients listed at the end of this leaflet.
 Always check the ingredients to make sure you can use this medicine.
- you have had an allergic reaction to any other sulphonylureas, or related medicines such as sulfa antibiotics or to thiazide diuretics (a type of "fluid" or "water" tablet).
 - Symptoms of an allergic reaction to Gliclazide Lupin MR, or to these medicines, may include skin rash, itchiness or hives, shortness of breath, swelling of the face, lips or tongue, muscle pain or tenderness or joint pain. If you are not sure if you have an allergy to Gliclazide Lupin MR, check with your doctor.
- you are pregnant or trying to become pregnant.
- you are breastfeeding or plan to breastfeed.
- you have type 1 diabetes mellitus (also known as insulin-dependent diabetes (IDDM), or juvenile-onset diabetes).
- you have unstable diabetes.
- you have diabetic ketoacidosis (a problem which affects the acidity of your blood and can lead to coma-which is mainly associated with type 1 diabetes).
- you have severe kidney disease.
- you have severe liver disease.
- you are taking an antibiotic medicine containing the active ingredient miconazole.
- the expiry date (EXP) printed on the pack. If you take it after the expiry date has passed, it may not work as well.
- the packaging is torn or shows signs of tampering. If it is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking Gliclazide Lupin MR, talk to your doctor.

For children

Do not give Gliclazide Lupin MR to a child.

There is no experience with the use of gliclazide in children.

For older people

Elderly people can generally use Gliclazide Lupin MR safely.

There are no special instructions for older people taking Gliclazide Lupin MR.

Check with your doctor if you:

- have any other medical conditions like:
 - kidney disease;
 - liver disease;
 - o a history of diabetic coma;
 - o adrenal, pituitary, or thyroid problems;
 - heart failure.
- are allergic to any of the ingredients listed at the end of this leaflet; to any other medicines, or to any other substances, such as foods, preservatives or dyes.
- have a family history of or know you have the hereditary condition glucose-6-phosphate dehydrogenase (G6PD) deficiency (abnormality of red blood cells), lowering of the haemoglobin level and breakdown of red blood cells (haemolytic anaemia) can occur.
- have any medical condition, or do anything that may increase the risk of hyperglycaemia, for example:
 - you are ill or feeling unwell (especially with fever or infection).
 - o you are injured.
 - o you are having surgery.
 - o you are taking less exercise than normal.
 - o you are eating more carbohydrate than normal.
 - o drinking alcoholic drinks.
 - o not eating regular meals.
 - taking more exercise than usual.
- take any medicines for any other condition.

If you have not told your doctor, pharmacist or diabetes educator about any of the above, tell them before you start taking Gliclazide Lupin MR.

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 <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

Your doctor can discuss with you the risks and benefits involved.

Gliclazide Lupin MR may affect your developing baby if you take it during pregnancy. Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will usually replace Gliclazide Lupin MR with insulin while you are pregnant.

Gliclazide Lupin MR is not recommended while you are breastfeeding. It is not known whether Gliclazide Lupin MR passes into breast milk.

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.

Taking Gliclazide Lupin MR may change the effect of some medicines, and some medicines may affect how well Gliclazide Lupin MR works.

Some medicines may lead to low blood glucose (hypoglycaemia) by increasing the blood glucose lowering effect of Gliclazide Lupin MR.

These include:

- some medicines used to treat fungal or yeast infections (miconazole which is contraindicated).
- alcohol.
- other medicines used to treat diabetes, such as biguanides and insulin.
- some medicines used to treat high blood pressure and other heart conditions (including angiotensin receptor blocker, beta-blockers).
- some medicines used to treat depression and other mental illness (MAOIs).
- some cholesterol-lowering medicines, such as clofibrate.
- some medicines used to treat arthritis, pain and inflammation (including high dose aspirin, ibuprofen, phenylbutazone).
- some antibiotics, such as chloramphenicol, tetracyclines, or long-acting sulphonamides.
- some medicines used to treat acid reflux and stomach ulcers.

Some medicines may lead to high blood glucose levels (hyperglycaemia) by weakening the blood glucose lowering effect of Gliclazide Lupin MR.

These include:

- alcohol.
- some medicines for epilepsy(danazol).
- some medicines used to treat depression and other mental illness, such as chlorpromazine and St John's Wort (Hypericum perforatum) - preparations used to treat depression.
- some hormones used in hormone replacement therapy and oral contraceptives, such as estrogen and progesterone.
- some medicines for asthma, such as salbutamol and intravenous terbutaline.
- barbiturates, medicines used for sedation.
- glucocorticoids.

Some medicines may lead to unstable blood glucose (low blood sugar and high blood sugar) when taken at the same time as Gliclazide Lupin MR, especially in elderly patients.

These include:

• a class of antibiotics called fluoroguinolones.

Gliclazide Lupin MR may change the effects of some other medicines.

These include:

some medicines used to prevent blood clots, such as warfarin

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 Gliclazide Lupin MR.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Gliclazide Lupin MR.

4. How do I use Gliclazide Lupin MR?

How much to take

Your doctor will tell you how many tablets to take each day. They may increase or decrease the dose, depending on your blood glucose levels.

Follow the instructions provided and use Gliclazide Lupin MR until your doctor tells you to stop. 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.

When to take Gliclazide Lupin MR

Gliclazide Lupin MR tablets should be swallowed with a glass of water. Gliclazide Lupin MR tablets can be broken in half. However, they should not be crushed or chewed.

Crushing or chewing the tablets may change the effectiveness of the tablet.

It is important to take your Gliclazide Lupin MR at the same time each day, usually with breakfast.

Taking Gliclazide Lupin MR with food can help to minimise the risk of hypoglycaemia.

If you forget to use Gliclazide Lupin MR

Gliclazide Lupin MR should be used regularly at the same time each day, usually with breakfast. If you miss your dose at the usual time, take another as soon as possible. Then go on as before.

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 you remember (with food), then go back to taking your tablets as you would normally.

Missed doses can cause high blood glucose (hyperglycaemia).

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

If you double a dose, this may cause low blood glucose (hypoglycaemia).

If you use too much GLICLAZIDE LUPIN MR

If you think that you have used too much GLICLAZIDE LUPIN MR, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26); 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 Gliclazide Lupin MR together with other medicines for diabetes or alcohol, you may experience symptoms of low blood glucose (hypoglycaemia).

If not treated quickly, these symptoms may progress to loss of co-ordination, slurred speech, confusion, loss of consciousness and fitting.

At the first signs of hypoglycaemia, raise your blood glucose quickly by following the instructions at "Recognising and treating hyPOglycaemia", Section <u>5.</u> What should I know while using GLICLAZIDE LUPIN MR?

If you experience any of these symptoms, immediately get medical help.

5. What should I know while using Gliclazide Lupin MR?

Things you should do

Tell all doctors, dentists, pharmacists and diabetes educators who are involved with your treatment that you are taking Gliclazide Lupin MR.

If you are about to start taking any new medicines, tell you doctor and pharmacist that you are taking Gliclazide Lupin MR.

Take Gliclazide Lupin MR exactly as your doctor has prescribed. Otherwise you may not get the full benefits from treatment.

Continue taking Gliclazide Lupin MR for as long as your doctor recommends. Make sure you keep enough Gliclazide Lupin MR to last over weekends and holidays. Gliclazide Lupin MR will help control your diabetes but will not (cure) it. Therefore, you may have to take it for a long time

Make sure you check your blood glucose levels regularly. This is the best way to tell if your diabetes is being controlled properly. Your doctor or diabetes educator will show you how and when to do this.

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

Instructions for recognising and treating hypoglycaemia

and hyperglycaemia in this this section can help you with

Visit your doctor regularly so that they can check on your progress. Carefully follow your doctor's and dietician's advice on diet, drinking alcohol and exercise.

Protect your skin when you are in the sun, especially between 10am and 3pm.

Sulphonylureas (the group of medicines that Gliclazide Lupin MR belongs to) may cause your skin to be more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness, or a severe sunburn.

If outdoors, wear protective clothing and use a 30+ sunscreen. Also, be especially careful not to let your blood glucose levels fall too low.

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 Gliclazide Lupin MR readily available.

If you become sick with a cold, fever or flu, it is very important to continue taking Gliclazide Lupin MR, even if you feel unable to eat your normal meal. 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 use for sick days.

Call your doctor straight away if you:

- notice the return of any symptoms of hyperglycaemia that you had before starting Gliclazide Lupin MR.
 These may include lethargy or tiredness, headache, thirst, passing large amounts of urine and blurred vision. These may be signs that Gliclazide Lupin MR is no longer working, even though you.
- are pregnant or planning to become pregnant, or are breastfeeding.
- notice your skin does appear to be burning despite wearing protective clothing and using a 30+ sunscreen outdoors.
- Develop/get any new medical condition, or do anything unusual, that may increase the risk of hyperglycaemia-for example:
 - you are ill or feeling unwell (especially with fever or infection);
 - you are injured;
 - you are having surgery;
 - o taking less Gliclazide Lupin MR than prescribed;
 - you are taking less exercise than normal;
 - you are eating more carbohydrate than normal;
 - drinking alcoholic drinks;
 - not eating regular meals;
 - taking more exercise than usual.

Remind any doctor, dentist, pharmacist, or diabetes educators you visit that you are using GLICLAZIDE LUPIN MR.

Things you should not do

- Do not stop using this medicine or change the dosage, without checking with your doctor.
- Do not give Gliclazide Lupin MR to anyone else, even if they have the same condition as you.
- Do not use Gliclazide Lupin MR to treat other complaints unless your doctor tells you to.
- Do not skip meals while taking Gliclazide Lupin MR.

Recognising and treating hyPOglycaemia (very LOW blood sugar levels

Hypoglycaemia may occur during Gliclazide Lupin MR treatment.

The first signs of hypoglycaemia are usually weakness, trembling or shaking, sweating, light headedness, dizziness, headache or lack of concentration, irritability, tearfulness, hunger, and/or numbness around the lips and tongue.

At the first signs of hypoglycaemia take some sugar to raise your blood sugar level quickly.

Do this by eating 5 to 7 jellybeans, 3 teaspoons of sugar or honey, drinking half a can of non-diet soft drink, taking 2-3 glucose tablets or a tube of glucose gel.

Then take some extra carbohydrates, such as plain biscuits, fruit or milk - unless you are within 10-15 minutes of your next meal. Taking this extra carbohydrate will help to prevent a second drop in your blood glucose level.

If not treated quickly, hypoglycaemia symptoms may progress to loss of co-ordination, slurred speech, confusion, fits or loss of consciousness.

If hypoglycaemia symptoms do not get better straight away after taking sugar, then go to the Accident and Emergency department at your nearest hospital - if necessary, by calling an ambulance.

Contact your doctor or diabetes educator for advice if you are concerned about hypoglycaemia.

Recognising and treating hyPERglycaemia (HIGH blood sugar levels)

Some people may feel fine when their glucose levels are high. Others notice symptoms of hyperglycaemia like tiredness, lack of energy, thirst, passing large amounts of urine, headache, and/or blurred vision.

If you notice symptoms of hyperglycaemia, or your blood sugar levels are high, tell your doctor immediately. You may need adjustments of the dose or type of medicines you are taking.

It is very important to control high blood glucose whether or not you feel unwell. This really helps to avoid serious long-term health problems, which can involve the heart, eyes, circulation, and/or kidneys.

If you experience any of the signs of hyperglycaemia (high blood glucose) contact your doctor or diabetes educator for advice immediately.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Gliclazide Lupin MR affects you.

Gliclazide Lupin MR may cause dizziness and drowsiness in some people. Low blood glucose levels may also slow your reaction time and affect your ability to drive or operate machinery. Instructions above contains advice about recognising and treating hypoglycaemia.

Drinking alcohol can make this worse. If either of these occurs, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may cause flushing, headache, breathing difficulties, rapid heartbeat, stomach pains or feel sick and vomit while taking Gliclazide Lupin MR.

Gliclazide Lupin MR may cause dizziness and drowsiness in some people. Drinking alcohol can make this worse.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them.
- Gliclazide Lupin MR will not keep as well outside its blister packaging.

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

Store it in a cool dry place away from moisture, heat, or direct sunlight where the temperature stays below 30°C. For example, do not store it:

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

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine 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?

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.

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 • HyPOglycaemia and hyPERglycaemia. Section 5 of this leaflet contains advice about recognising and treating hyPOglycaemia and hyPERglycaemia. • Runny or blocked nose, sneezing, facial pressure or pain, bronchitis, sore throat and discomfort when swallowing, upper respiratory infection, coughing. • Back pain, arthralgia, arthrosis. • High blood pressure, chest pain. • Headache, unusual weakness. • Viral infection, urinary tract infection. • Dizziness. • Stomach upset with symptoms like feeling sick, stomach pain, vomiting, diarrhoea, or constipation. • Decrease in the number of cells in

- the blood (eg. platelets, red and white blood cells) which may cause paleness, prolonged bleeding, bruising, sore throat and fever have been reported. These symptoms usually vanish when the treatment is discontinued.
- Increase of some hepatic enzyme levels, and exceptionally a liver disease.
- Your vision may be affected for a short time especially at the start of treatment. This effect is due to changes in blood sugar levels.

What to do

Speak to your doctor if you have any of these less serious side effects and they worry you.

Other uncommon side effects have been reported and you may wish to discuss these with your doctor, pharmacist, or diabetes educator.

Serious side effects

Serious side effects What to do Skin rash, redness itching and/or Stop taking **Gliclazide Lupin** hives, blisters, angioedema (rapid MR and call swelling of tissues such as eyelids, face, lips, mouth, tongue, or throat your doctor that may result in breathing straight away, difficulty) have been reported. or go straight Rash may progress to widespread to the blistering or peeling of the skin and **Emergency** may be the first sign of rare Department at life-threatening conditions (eg. your nearest Stevens-Johnson syndrome (SJS), hospital if you toxic epidermal necrolysis (TEN) notice any of and severe hypersensitivity these serious reactions (DRESS)). Exceptionally, side effects. DRESS have been reported initially

as flu-like symptoms and a rash on the face then an extended rash with a high temperature.

• As for other sulphonylureas, the following adverse events have been observed: cases of severe changes in the number of blood cells and allergic inflammation of the wall of blood vessels, reduction in blood sodium (hyponatraemia), symptoms of liver impairment (eg. jaundice) which in most cases disappeared after withdrawal of the sulfonylurea, but may lead to life-threatening liver failure in isolated cases.

Who distributes Gliclazide Lupin MR

Generic Health Pty Ltd Suite 2, Level 2 19-23 Prospect Street Box Hill, VIC, 3128 Australia

***** +61 3 9809 7900

www.generichealth.com.au

This leaflet was prepared in November 2022.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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 Gliclazide Lupin MR contains

Active ingredient (main ingredient)	Gliclazide
Other ingredients (inactive ingredients)	Calcium hydrogen phosphate dihydrate
	Povidone
	Hypromellose
	 Magnesium stearate

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

What Gliclazide Lupin MR looks like

Gliclazide Lupin MR tablets are white to off white, oval shaped, biconvex, uncoated tablet with a breakline on both sides and debossed with '60' on one side of the breakline on one surface and plain on the other side. (AUSTR 370851)