

LIMERAL 2MG TABLET

Consumer Medication Information Leaflet (RiMUP)

Glimepiride

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What Limeral is used for

Limeral is used to treat a certain form of diabetes (type 2 diabetes mellitus) when diet, physical exercise and weight loss alone have not been able to control your blood sugar levels.

How Limeral works

Limeral is a medicine taken by mouth to help lower blood sugar. It belongs to a group of medicines called sulfonylureas.

Limeral works by increasing the amount of insulin released from your pancreas. The insulin then lowers your blood sugar levels.

Before you use Limeral

- When you must not use it
- if you are allergic to glimepiride, to other sulfonylureas (medicines used to lower your blood sugar such as glibenclamide) or sulfonamides (medicines for bacterial infections such as sulfamethoxazole) or to any of the other ingredients of this medicine (listed in "Ingredients")
- if you have insulin-dependent diabetes (type 1 diabetes mellitus)
- if you have diabetic ketoacidosis (a complication of diabetes when your acid level is raised in your body and you may have some of the following symptoms: tiredness, feeling sick (nausea), frequent urination and muscular stiffness)
- if you have a severe kidney or liver disease
- in the case of sleepiness and loss of consciousness due to a strongly

increased blood sugar level (diabetic coma)

- Before you start use it

Check with your doctor or pharmacist before taking Limeral if:

- You are recovering from an injury, operation, infections with fever, or from other forms of stress, inform your doctor as temporary change of treatment may be necessary
- You have a severe liver or kidney disorder.

If you are not sure, talk to your doctor or pharmacist before taking Limeral.

Lowering of the haemoglobin level and breakdown of red blood cells (haemolytic anaemia) can occur in patients missing the enzyme 'glucose-6-phosphate dehydrogenase' (G6PD-deficiency).

The information available on the use of Limeral in people below 18 years of age is limited. Therefore, its use in these patients is not recommended.

Important information about hypoglycaemia (low blood sugar):

When you take Limeral, you may get hypoglycaemia (low blood sugar). Please see below for additional information about hypoglycaemia, its signs and treatment.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor may wish to change your dose or Limeral if you are taking other medicines, which may weaken or strengthen the effect of Limeral on the level of sugar in your blood.

The following medicines can increase the blood sugar lowering effect of Limeral. This can lead to a risk of hypoglycaemia (low blood sugar):

- Other medicines to treat diabetes mellitus (such as insulin or metformin)

- Medicines to treat pain and inflammation (phenylbutazone, azopropazone, oxyphenbutazone, aspirin-like medicines)
- Medicines to treat urinary infections (such as some long acting sulfonamides)
- Medicines to treat bacterial and fungal infections (tetracyclines, chloramphenicol, fluconazole, miconazole, quinolones, clarithromycin)
- Medicines to inhibit blood clotting (coumarin derivatives such as warfarin)
- Medicines supporting muscle build up (anabolics)
- Medicines used for male sex hormone replacement therapy
- Medicines to treat depression (fluoxetine, MAO-inhibitors)
- Medicines lowering high cholesterol level (fibrates)
- Medicines lowering high blood pressure (ACE inhibitors)
- Medicines to treat gout (allopurinol, probenecid, sulfapyrazone)
- Medicines to treat cancer (cyclophosphamide, ifosfamide, trofosfamide)
- Medicines used to reduce weight (fenfluramine)
- Medicines to increase circulation when given in a high dose intravenous infusion (pentoxifylline)
- Medicines to treat nasal allergies such as hay fever (tritoqualine)
- Medicines called sympatholytics to treat high blood pressure, heart failure, or prostate symptoms.

The following medicines may decrease the blood sugar lowering effect of Limeral. This can lead to a risk of hyperglycaemia (high blood sugar level):

- Medicines containing female sex hormones (oestrogens, progestogens)
- Medicines to treat high blood pressure called thiazide diuretics (water tablets)
- Medicines used to stimulate the thyroid gland (such as levothyroxine)
- Medicines to treat allergies and inflammation (glucocorticoids)
- Medicines to treat severe mental disorders (chlorpromazine and other phenothiazine derivatives)

- Medicines used to raise heartbeat, to treat asthma or nasal congestion, coughs and colds, used to reduce weight, or used in life-threatening emergencies (adrenaline and sympathomimetics)
- Medicines to treat high cholesterol level (nicotinic acid)
- Medicines to treat constipation when they are used long term (laxatives)
- Medicines to treat seizures (phenytoin)
- Medicines to treat nervousness and sleep problems (barbiturates)
- Medicines to treat increased pressure in the eye (acetazolamide)
- Medicines to treat high blood pressure or lowering blood sugar (diazoxide)
- Medicines to treat infections, tuberculosis (rifampicine)
- Medicines to treat severe low blood sugar levels (glucagon).

The following medicines can increase or decrease the blood sugar lowering effect of Limeral:

- Medicines to treat stomach ulcers (called H2 antagonists)
- Medicines to treat high blood pressure or heart failure such as beta-blockers, clonidine, guanethidine and reserpine.

Limeral may either increase or weaken the effects of the following medicines:

- Medicines inhibiting blood clotting (coumarin derivatives such as warfarin)

How to use Limeral

- How much to use

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The dose depends on your needs, condition and results of blood and urine sugar tests and is determined by your doctor. Do not take more tablets than your doctor has prescribed.

- The usual starting dose is 1 mg of glimepiride once a day.
- If necessary, your doctor may increase the dose after each 1-2 weeks of treatment.
- The maximum recommended dose is 6 mg glimepiride per day.
- A combination therapy of glimepiride plus metformin or of glimepiride plus

insulin may be started. In such a case your doctor will determine the proper doses of glimepiride, metformin or insulin individually for you.

- Your dose of Limeral may need to be adjusted if you change weight, change your lifestyle, or if you are under a lot of stress. Please speak to your doctor if any of these situations apply to you.
- If you feel the effect of your medicine is too weak or too strong do not change the dose yourself, but ask your doctor.

- When to use it

- Take this medicine by mouth, just before or with the first main meal of the day (usually breakfast). If you do not have breakfast you should take the product on schedule as prescribed by your doctor. It is important not to leave out any meal when you are on Limeral.
- Swallow the tablets whole with at least half glass of water. Do not crush or chew the tablets

- How long to use it

Continue taking Limeral for as long as your doctor recommends.

- If you forget to use it

If you forget to take a dose, do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

If you happen to have taken too much glimepiride or an additional dose there is a danger of hypoglycaemia and therefore you should instantly consume enough sugar (e.g. a small bar of sugar cubes, sweet juice, sweetened tea) and inform a doctor immediately.

When treating hypoglycaemia due to accidental intake in children, the quantity of sugar given must be carefully controlled to avoid the possibility of producing dangerous hyperglycaemia. Persons in a state of unconsciousness must not be given food or drink.

Since the state of hypoglycaemia may last for some time it is very important that the patient is carefully monitored until there is no more danger. Admission

into hospital may be necessary, also as a measure of precaution. Show the doctor the package or remaining tablets, so the doctor knows what has been taken.

Severe cases of hypoglycaemia accompanied by loss of consciousness and coma are cases of medical emergency requiring immediate medical treatment and admission into hospital. It may be helpful to tell your family and friends to call a doctor immediately if this happens to you.

- If you stop taking Limeral

If you interrupt or stop the treatment, you should be aware that the desired blood sugar lowering effect is not achieved or that the disease will get worse again. If any change is necessary, it is absolutely important for you to contact your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

While you are using it

- Things you must do

Treating hypoglycaemia

In most cases the signs of reduced blood sugar vanish very quickly when you consume some form of sugar, e.g. sugar cubes, sweet juice, sweetened tea.

You should therefore always take some form of sugar with you (e.g. sugar cubes). Remember that artificial sweeteners are not effective. Please contact your doctor or go to the next hospital if taking sugar does not help or if the symptoms recur.

Following factors could increase the risk of you getting hypoglycaemia:

- Undernourishment, irregular meal time, missed or delayed meal or period of fasting
- Changes to your diet
- Taking more Limeral than needed
- Having kidneys that do not work properly
- Having severe liver disease
- If you suffer from particular hormone-induced disorders (disorders of the thyroid glands, of the pituitary gland or adrenal cortex)

- Drinking alcohol (especially when you skip a meal)
- Taking certain other medicines
- If you increase the amount of exercise you do and you don't eat enough food or eat food containing less carbohydrate than usual.

Signs of hypoglycaemia include:

Hunger pangs, headache, nausea, vomiting, sluggishness, sleepiness, problems sleeping, restlessness, aggression, problems with concentration, reduced alertness and reaction time, depression, confusion, problems with your speech and sight, slurred speech, shakiness, partial paralysis, dizziness, helplessness

The following signs may also occur: sweating, clammy skin, anxiety, fast or uneven heartbeat, high blood pressure, awareness of your heart beat (palpitations), sudden strong pain in the breast that may radiate into neighbouring areas (angina pectoris).

If blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop fits, lose self-control, breathing may be shallow and your heart beat slowed down and you may fall into unconsciousness.

The clinical picture of a severe reduced blood sugar level may resemble that of a stroke.

Laboratory tests

The level of sugar in your blood or urine should be checked regularly. Your doctor may also take blood tests to monitor your blood cell levels and liver function.

Things you must not do

Pregnancy and breast-feeding

Limeral should not be taken during pregnancy.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Limeral may pass into breast milk. Limeral should not be taken during breast feeding.

Things to be careful of

Limeral with food, drink and alcohol

Alcohol intake may increase or decrease the blood sugar lowering action of Limeral in an unpredictable way.

Driving and using machines

Your ability to concentrate and react may be impaired if your blood sugar is lowered (hypoglycaemia) or raised (hyperglycaemia) or if you develop visual problems as a result of such conditions. Bear in mind that you could endanger yourself or others (e.g. when driving a car or using machines).

Please ask your doctor whether you can drive a car if you

- have frequent episodes of hypoglycaemia
- have fewer or no warning signals of hypoglycaemia

Medicines to treat high blood pressure or heart failure such as beta-blockers, clonidine, guanethidine and reserpine can hide the signs of hypoglycaemia, so special care is needed when taking these medicines.

Limeral contains lactose and colouring agents

This medicinal product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Limeral. Some colouring agents (Iron oxide yellow E172 and Indigo carmine E132) in the tablets may cause hypersensitivity reactions.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following occurs, contact a doctor or go to the nearest hospital straight away, as you may need urgent medical attention:

- Rare** (may affect up to 1 in 1,000 people)
- Severe hypoglycaemia including loss of consciousness, seizures or coma.

Very rare (may affect up to 1 in 10,000 people)

- Allergic reactions (including inflammation of blood vessels, often with skin rash) which may develop into serious reactions with difficulty in breathing, fall in blood pressure and sometimes progressing to shock.
- Abnormal liver function including yellowing of the skin and eyes (jaundice), problems with the bile flow (cholestasis), inflammation of the liver (hepatitis) or liver failure.

Not known (frequency cannot be estimated from the available data)

- Allergy (hypersensitivity) of the skin such as itching, rash, hives and increased sensitivity to sun. Some mild allergic reactions may develop into serious reactions with swallowing or breathing problems, swelling of your lips, throat or tongue.

Other possible side effects:

Rare (may affect up to 1 in 1,000 people)

- Lower blood sugar than normal (hypoglycaemia)
- Decrease in the number of blood cells:
- Blood platelets (which increases risk of bleeding or bruising)
- White blood cells (which makes infections more likely)
- Red blood cells (which can make the skin pale and cause weakness or breathlessness)

These problems generally get better after you stop taking Limeral

Very rare (may affect up to 1 in 10,000 people)

- Feeling or being sick, diarrhoea, feeling full or bloated, and abdominal pain
- Decrease in the amount of sodium level in your blood (shown by blood tests)

Not known (frequency cannot be estimated from the available data)

- Allergic reactions with sulfonylureas, sulphonamides, or related drugs may occur
- Problems with your sight may occur when beginning treatment with Limeral. This is due to changes in

blood sugar levels and should soon improve

- Increased liver enzymes

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of Limeral

- Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.

Store below 25°C, in the original package.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Green oblong shaped tablets, with dimensions approximate 11x5.5mm, bearing a break line on both sides.

- Ingredients

- Active ingredient
Each tablet contains 2mg
glimepiride.

- Inactive ingredients
lactose monohydrate,
microcrystalline cellulose, sodium
starch glycolate, povidone and
magnesium stearate. 2 mg tablets
(green): yellow iron oxide (E172),
indigo carmine (E132)

- MAL number
MAL10100141AC

Manufacturer

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Product Registration Holder

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