

## Package Leaflet: Information for the user

### Gliclazide-Lupin 60mg prolonged-release tablets Gliclazide

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What Gliclazide-Lupin is and what it is used for
2. What you need to know before you take Gliclazide-Lupin
3. How to take Gliclazide-Lupin
4. Possible side effects
5. How to store Gliclazide-Lupin
6. Contents of the pack and other information

#### **1. What Gliclazide-Lupin is and what it is used for**

Gliclazide-Lupin is a medicine that **reduces blood sugar levels** (oral diabetic medicine belonging to the sulphonylurea group) and contains 60mg of the active substance Gliclazide per tablet.

Gliclazide-Lupin is used to keep blood sugar at the correct level in adults with a certain form of diabetes (type 2 diabetes mellitus) when it is not controlled by diet, exercise and weight loss alone.

#### **2. What you need to know before you take Gliclazide-Lupin**

##### **Do not take Gliclazide-Lupin:**

- If you are **allergic to gliclazide** or any of the other ingredients in this medicine (listed in section 6).
- If you are allergic to any other medicine of the same group (sulphonylurea), or to other related medicines (hypoglycaemic sulphonamides);
- If you have insulin-dependent (type 1) diabetes;
- If you have ketone bodies and sugar in your urine (this may mean you have diabetic keto-acidosis), diabetic pre-coma or coma;
- If you have severe kidney or liver disease;
- If you are taking medicines to treat fungal infections (miconazole – see Section “Other medicines and Gliclazide-Lupin”)
- If you are breast-feeding (see Section “Pregnancy and breastfeeding”)

## Warnings and precautions

Talk to your doctor or pharmacist before taking Gliclazide-Lupin.

Take this medicine only if you have regular food intake. Otherwise you may develop a low blood sugar (also known as “hypoglycaemia”).

During Gliclazide treatment, you need regular monitoring of your blood (and possibly urine) sugar levels and also your glycated haemoglobin (hbA1c).

In the first few weeks of treatment the risk of having reduced blood sugar levels (hypoglycaemia) may be increased. So particularly close medical monitoring is necessary.

Low blood sugar (hypoglycaemia) may occur:

- if you take meals irregularly or skip meals altogether,
- if you are fasting,
- if you are malnourished,
- if you change your diet,
- if you increase your physical activity and carbohydrate intake does not match this increase,
- if you drink alcohol, especially in combination with skipped meals,
- if you take other medicines or natural remedies at the same time,
- if you take too high doses of gliclazide,
- if you suffer from particular hormone-induced disorders (functional disorders of the thyroid gland, of the pituitary gland or adrenal cortex),
- if your kidney function or liver function is severely decreased.

The symptoms of low blood sugar are:

- headache
- intense hunger,
- nausea and vomiting,
- weariness,
- sleep disorders,
- restlessness or aggressiveness,
- poor concentration with reduced alertness and reaction time,
- depression or confusion,
- speech or visual disorders,
- tremor,
- sensory disturbances,
- dizziness,
- helplessness.

The following signs and symptoms may also occur: sweating, clammy skin, anxiety, fast or irregular heart beat, high blood pressure, sudden strong pain in the chest that may radiate into nearby areas (angina pectoris).

If blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop convulsions, lose self control, your breathing may be shallow and your heart beat

slowed down, you may become unconscious.

In most cases the symptoms of low blood sugar vanish very quickly when you consume some form of sugar, e.g. glucose tablets, sugar cubes, sweet juice, sweetened tea. You should therefore always carry some form of sugar with you (glucose tablets, sugar cubes). Remember that artificial sweeteners are not effective. Please contact your doctor or the nearest hospital if taking sugar does not help or if the symptoms recur.

Symptoms of low blood sugar may be absent, less obvious or develop very slowly or you are not aware in time that your blood sugar level has dropped. This may happen if you are an elderly patient taking certain medicines (e.g. those acting on the central nervous system and beta blockers). If you are in stress-situations (e.g. accidents, surgical operations, fever etc.) your doctor may temporarily switch you to insulin therapy.

Symptoms of high blood sugar (hyperglycaemia) may occur when gliclazide has not yet sufficiently reduced the blood sugar, when you have not complied with the treatment plan prescribed by your doctor or in special stress situations. These may include thirst, frequent urination, dry mouth, dry itchy skin, skin infections and reduced performance. If these symptoms occur, you must contact your doctor or pharmacist.

Talk to your doctor before taking Gliclazide-Lupin if you know you have a family history of glucose-6-phosphate dehydrogenase deficiency or if you know you suffer from this condition, because lowering of the haemoglobin level and breakdown of red blood cells (haemolytic anaemia) can occur.

### **Children**

Gliclazide-Lupin 60mg tablets is not recommended for use in children due to a lack of data.

### **Other medicines and Gliclazide-Lupin**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The blood sugar lowering effect of gliclazide may be strengthened and signs of low blood sugar levels may occur when one of the following medicines is taken:

- Other medicines used to treat high blood sugar (oral antidiabetics or insulin),
- Antibiotics (e.g. sulphonamides),
- Medicines to treat high blood pressure or heart failure (beta blockers, ACE-inhibitors such as captopril or enalapril),
- Medicines to treat fungal infections (miconazole, fluconazole),
- Medicines to treat ulcers in the stomach or duodenum (H<sub>2</sub> receptor antagonists),
- Medicines to treat depression (monoamine oxidase inhibitors),
- Painkillers or anti-rheumatics (phenylbutazone, ibuprofen),
- Medicines containing alcohol.

The blood sugar lowering effect of gliclazide may be weakened and raised blood sugar levels may occur when one of the following medicines is taken:

- Medicines to treat disorders of the central nervous system (chlorpromazine)

- Medicines reducing inflammation (corticosteroids)
- Medicines to treat asthma or used during labor (intravenous salbutamol, ritodrine and terbutaline),
- Medicines to treat breast disorders, heavy menstrual bleeding and endometriosis (danazol)

Gliclazide-Lupin may increase the effects of medicines which reduce blood clotting (e.g. warfarin).

Consult your doctor before you start taking another medicine. If you go to the hospital tell the medical staff you are taking Gliclazide-Lupin.

#### **Gliclazide-Lupin with food, drink and alcohol:**

Gliclazide-Lupin can be taken with food and drink. Drinking alcohol is not recommended as it can alter the control of your diabetes in an unpredictable manner.

#### **Pregnancy and breast-feeding:**

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 this medicine.

Gliclazide-Lupin are not recommended for use during pregnancy.

Do not take Gliclazide-Lupin while you are breast-feeding.

#### **Driving and using machines:**

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

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

- Have frequent episodes of low blood sugar (hypoglycaemia)
- Have few or no warning signals of low blood sugar (hypoglycaemia)

### **3. How to take Gliclazide-Lupin**

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

Your dose will be determined by the doctor, depending on your blood and possibly urine sugar levels. Changes in external factors (ie. weight loss, change in life style or stress) or improvements in your blood sugar control may require changed gliclazide doses.

#### **Adults:**

The usual daily dose can vary from half to two tablets per day (30mg – 120mg). This depends on your response to treatment.

Swallow your tablets whole with a glass of water at breakfast time (and preferably at the same time each day). You must always eat a meal after taking your tablet(s).

The tablet can be divided into equal doses.

**If you take more Gliclazide than you should:**

If you take too many tablets, contact your doctor or the nearest hospital immediately. The signs of overdose are those of low blood sugar (hypoglycaemia), as described in Section 2. Symptoms of low blood sugar can be helped by taking sugar or sugary drinks straight away, followed by a substantial snack or meal. The same should be done if somebody, *e.g.* a child, has taken the product unintentionally.

Be aware that the state of hypoglycaemia may persist for some time. Severe cases of hypoglycaemia accompanied by altered behaviour or loss of consciousness requires immediate treatment and admission to hospital. Never put anything in the mouth of an unconscious person, seek immediate medical help. Ensure that you have a friend or colleague who knows about your condition and can call a doctor in case of emergency.

**If you forget to take Gliclazide-Lupin:**

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Gliclazide 60mg Tablets, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Gliclazide-Lupin:**

As the treatment for diabetes is usually life long, you should discuss with your doctor before stopping your medicine. Stopping could cause high blood sugar (hyperglycaemia).

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

**4. Possible side effects**

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

Hypoglycaemia is an important and common side effect and will require immediate action if you experience it (take a sugary drink or sugary food). For symptoms and signs see section "Warnings and Precautions".

If the hypoglycaemia is severe or prolonged even after intake of sugar, you should stop taking Gliclazide-Lupin and should seek immediate medical attention. If not treated it could lead to drowsiness, loss of consciousness or possible coma.

Other side effects have been reported at the frequencies shown below:

**Common (may affect up to 1 in 10 people)**

- Hypoglycaemia (see above)

**Uncommon (may affect up to 1 in 100 people)**

- Abdominal pain, nausea, vomiting, indigestion, diarrhoea and constipation.

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

- Skin rashes and itching, hives, blistering
- Changes in your blood (such as decrease in the number of certain cells in the blood which may cause paleness, prolonged bleeding, bruising, sore throat and fever)
- Changes in your liver (which can cause yellow skin and eyes). These tend to disappear when the medicine is stopped.
- Your vision may be affected for a short time especially when treatment starts. This is due to changes in the blood sugar level.

With other medicines of the same class (sulphonylureas), the following side effects were reported:

- cases of severe changes in the number of blood cells (erythrocytopenia, agranulocytosis),
- changes in your red blood cells (haemolytic anemia, pancytopenia),
- allergic inflammation of the wall of blood vessels (allergic vasculitis),
- low sodium levels in your blood (hyponatremia),
- changes in liver enzyme levels and even life-threatening liver failure have been described.

**Reporting of side effects**

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

You can also report side effects directly via the [national reporting system](#). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Gliclazide-Lupin**

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.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information****What Gliclazide-Lupin contains**

The active substance is Gliclazide. Each tablet contains 60mg gliclazide.

The other ingredients are calcium hydrogen phosphate dihydrate, povidone K30, hypromellose K100, hypromellose K4M, magnesium stearate.

**What Gliclazide-Lupin look like and contents of the pack:**

- Gliclazide 60mg tablets are white to off-white, oval shaped, uncoated tablet with a break line on both sides and debossed “60” on one side of the breakline on one side. Each tablet is approximately 13.5 mm x 6.5 mm in size.

The tablet can be divided into equal doses.

Gliclazide 60mg tablets are available in blister packs containing 10, 28, 30, 60, 90 and 120 tablets.

\* Not all pack sizes may be marketed

#### **Marketing Authorisation Holder and manufacturer**

Lupin (Europe) Ltd.  
Victoria Court  
Bexton Road  
Knutsford  
Cheshire, WA16 0PF  
UK

**This medicinal product is authorised in the Member States of the EEA under the following names:**

<b>Portugal</b>	Gliclazida-Lupin
<b>Belgium</b>	Gliclazide Lupin 60mg, comprimé à libération prolongée
<b>Bulgaria</b>	Gliclazide Lupin 60mg, Таблетка с удължено освобождаване
<b>Latvia</b>	Gliclazide Lupin 60mg ilgstošās darbības tabletes
<b>Lithuania</b>	Gliklazido Lupin 60mg pailginto atpalaidavimo tabletės
<b>Poland</b>	Gliklazid Lupin
<b>Slovenia</b>	Gliklazida Lupin 60mg tablete s podaljšanim sproščanjem
<b>Slovakia</b>	Gliklazid Lupin 60mg tableta s predĺženým uvoľňovaním
<b>Romania</b>	Gliclazidă Lupin 60mg comprimate cu eliberare prelungită
<b>Hungary</b>	Gliklazid Lupin 60mg retard tableta

**The leaflet was last revised in 06/2015**