

Package leaflet: Information for the user

Gliclazide Sandoz retard 60 mg, tabletten met gereguleerde afgifte

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 Sandoz is and what it is used for
2. What you need to know before you take Gliclazide Sandoz
3. How to take Gliclazide Sandoz
4. Possible side effects
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1. What Gliclazide Sandoz is and what it is used for

Gliclazide Sandoz is a medicine that reduces blood sugar levels (an oral antidiabetic medicine belonging to the sulphonylurea group).

Gliclazide Sandoz is used in a certain form of diabetes (type 2 diabetes mellitus) in adults, when diet, exercise and weight loss alone do not have an adequate effect on keeping blood sugar at the correct level.

2. What you need to know before you take Gliclazide Sandoz

Do not take Gliclazide Sandoz:

- if you are **allergic** to gliclazide or any of the other ingredients of this medicine (listed in section 6), or to other medicines of the same group (sulphonylureas), or to other related medicines (hypoglycaemic sulphonamides),
- if you have **insulin-dependent diabetes (type 1)**,
- if you have **ketone bodies** and **sugar in your urine** (this may mean you have diabetic keto-acidosis), **a 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 Sandoz ”),
- if you are **breast-feeding** (see section “Pregnancy and breast-feeding”).

Warnings and precautions

Talk to your doctor or pharmacist before taking Gliclazide Sandoz.

You should observe the treatment plan prescribed by your doctor to achieve proper blood sugar levels. This means, apart from regular tablet intake, to observe the dietary regimen, have physical exercise and, where necessary, reduce weight.

During gliclazide treatment **regular monitoring of your blood** (and possibly urine) sugar level and also your glycated haemoglobin (HbA1c) is necessary.

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.

If you have **low blood sugar** you may have the **following symptoms**: headache, intense hunger, nausea, vomiting, weariness, sleep disorders, restlessness, aggressiveness, poor concentration, reduced alertness and reaction time, depression, confusion, speech or visual disorders, tremor, sensory disturbances, dizziness, and 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, or 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, if you take St John's Wort (*Hypericum perforatum*) preparations (see section "Other medicines and Gliclazide Sandoz"), 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.

Blood glucose disturbance (low blood sugar and high blood sugar) can occur when gliclazide is prescribed at the same time than medicines belonging to a class of antibiotics called fluoroquinolones, especially in elderly patients. In this case, your doctor will remind you the importance of monitoring your blood glucose.

If you 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. Contact your doctor before taking this medicine.

Children and adolescents

Gliclazide Sandoz is **not recommended** for use **in children and adolescents** due to a lack of data.

Other medicines and Gliclazide Sandoz

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 to treat high blood sugar (**oral antidiabetics, GLP-1 receptor agonists or insulin**)
- antibiotics (*e.g.* **sulphonamides, clarithromycin**)
- 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 (**H₂ receptor antagonists**),
- medicines to treat depression (**monoamine oxidase inhibitors**),
- painkiller or antirheumatics (**phenylbutazone, ibuprofen**),
- **medicines containing alcohol.**

The blood glucose 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 labour (**intravenous salbutamol, ritodrine and terbutaline**),
- medicines to treat breast disorders, heavy menstrual bleeding and endometriosis (**danazol**)
- St John's Wort (*Hypericum perforatum*) preparations.

Blood glucose disturbance (low blood sugar and high blood sugar) can occur when a medicine belonging to a class of antibiotics called fluoroquinolones is taken at the same time than Gliclazide Sandoz, especially in elderly patients.

Gliclazide Sandoz 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 into hospital tell the medical staff you are taking Gliclazide Sandoz.

Gliclazide Sandoz with food, drink and alcohol

Gliclazide Sandoz can be taken **with food** and **non-alcoholic drinks**.

Drinking alcohol is not recommended as it can alter the control of your diabetes in an unpredictable manner.

Pregnancy and breast-feeding

Gliclazide Sandoz is **not recommended** for use 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.

You must **not** take Gliclazide Sandoz 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 (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 low blood sugar (hypoglycaemia),
- have few or no warning signals of low blood sugar (hypoglycaemia).

3. How to take Gliclazide Sandoz

Dose

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

The dose is determined by the doctor, depending on your blood and possibly urine sugar levels. Change in external factors (e.g. weight reduction, change in life style, stress) or improvements in the blood sugar control may require changed gliclazide doses.

The recommended daily dose is half to two tablets (maximum 120 mg) in a single intake at breakfast time. This depends on the response to treatment.

If a combination therapy of Gliclazide Sandoz with metformin, an alpha glucosidase inhibitor, a thiazolidinedione, a dipeptidyl peptidase-4 inhibitor, a GLP-1 receptor agonist or insulin is initiated your doctor will determine the proper dose of each medicine individually for you.

If you notice that your blood sugar levels are high although you are taking the medicine as prescribed, you should contact your doctor or pharmacist.

Routes and method of administration

Oral use.

Swallow your half tablet or whole tablet(s) in one piece. Do not chew or crush.

Take your tablet(s) 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 Sandoz than you should

If you take too many tablets, contact your doctor or the nearest hospital Accident & Emergency department immediately.

The signs of overdose are those of low blood sugar (hypoglycaemia) described in section 2. The symptoms can be helped by taking sugar (4 to 6 lumps) or sugary drinks straight away, followed by a substantial snack or meal. If the patient is unconscious immediately inform a doctor and call the emergency services. The same should be done if somebody else, *e.g.* a child, has taken the product unintentionally. Unconscious patients must not be given food or drink.

It should be ensured that there is always a pre-informed person that can call a doctor in case of emergency.

If you forget to take Gliclazide Sandoz

It is important to take your medicine every day as regular treatment works better.

However, if you forget to take a dose of Gliclazide Sandoz, 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 Sandoz

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

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

4. Possible side effects

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

The most commonly observed side effect is **low blood sugar** (hypoglycaemia). For symptoms and signs see section “**Warnings and precautions**” in section 2 “**What you need to know before you take Gliclazide Sandoz**”.

If left untreated these symptoms could progress to drowsiness, loss of consciousness or possibly coma. If an episode of low blood sugar is severe or prolonged, even if it is temporarily controlled by eating sugar, you should seek immediate medical attention.

Other side effects that may be experienced while taking this medicine are:

Rare: may affect up to 1 in 1,000 people

- Decrease in the number of cells in the blood has been reported (*e.g.* platelets, red and white blood cells). This may cause paleness, prolonged bleeding, bruising, sore throat and fever. These symptoms usually vanish when the treatment is discontinued.

Not known: frequency cannot be estimated from the available data

- Abnormal liver function, which can cause yellow skin and eyes. If you get this, see your doctor immediately. The symptoms generally disappear if the medicine is stopped. Your doctor will decide whether to stop your treatment.
- Skin reactions have been reported such as rash, redness, itching, hives and angioedema (rapid swelling of tissues such as eyelids, face, lips, mouth, tongue or throat that may result in breathing difficulty). The rash may progress to wide spread blistering or peeling of the skin. Exceptionally, signs of severe hypersensitivity reactions (DRESS) have been reported: initially as flu-like symptoms and a rash on the face then an extended rash with a high temperature.
- Stomach pain or discomfort, nausea, vomiting, indigestion, diarrhoea and constipation. These effects are reduced when Gliclazide Sandoz is taken with a meal as recommended (see section 3 “How to take Gliclazide Sandoz”).
- Problems with your eye-sight.
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.

As for other sulphonylureas, the following adverse events have been observed:

- severe changes in the number of blood cells,
- allergic inflammation of the wall of blood vessels,
- reduction in blood sodium (hyponatraemia),
- symptoms of liver impairment (*e.g.* jaundice) which in most cases disappeared after withdrawal of the sulphonylureas, but may lead to life-threatening liver failure in isolated cases.

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 listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store {nationally completed name}

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.

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 Sandoz retard 60 mg, tabletten met gereguleerde afgifte contains

The active substance is gliclazide. Each modified-release tablet contains 60 mg of gliclazide. The other ingredients are: calcium hydrogen phosphate dehydrate, povidone K30, hypromellose K100, hypromellose K4M and magnesium stearate.

What Gliclazide Sandoz retard 60 mg, tabletten met gereguleerde afgifte looks like and contents of the pack

White to off-white oval shape, uncoated tablet, 13.5 mm long, 6.5 mm wide and 4.2 mm thick, with break line on both the surface and debossed '60' on one side of the break line on one surface.

Clear PVC-Al blister
Clear PVC/Aclar-Al blister

Pack sizes of 10, 30, 60, 90, 100 and 180 modified release tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Sandoz B.V.
Veluwezoom 22
1327 AH Almere
Nederland

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

LEK Pharmaceuticals d.d.
Verovškova ulica 57,
1526 Ljubljana
Slovenië
Lek S.A.
ul. Domaniewska 50 C

02-672 Warschau
Polen

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1
39179 Barleben
Germany

**In het register ingeschreven onder:
RVG 116611**

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

NL Gliclazide Sandoz retard 60 mg, tabletten met gereguleerde afgifte
BE Gliclazide Sandoz 60 mg tabletten met gereguleerde afgifte
BG Mellizide
CZ Gliklazid Sandoz 60 mg
EE Dizirel
FR GLICLAZIDE SANDOZ 60 mg, comprimé à libération modifiée
HR Gliklazid Sandoz 60 mg tablete sprilagođenim oslobađanjem
HU Gliclazide Sandoz 60 mg módosított hatóanyagleadású tableta
IT Gliclazide Sandoz BV
LT Dizirel 60 mg modifikuoto atpalaidavimo tabletės
LU Gliclazide Sandoz 60 mg comprimés à libération modifiée
LV Dizirel 60 mg ilgstošās darbības tabletes
PL Salson
PT Gliclazida Sandoz
SI Gliklazid Lek 60 mg tablete sprijejenim sproščanjem
SK Gliklazid Sandoz 60 mg tableta sriadeným uvoľňovaním

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