**Package leaflet: Information for the patient**

**Gliclazide Sandoz® retard 30 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 [Nationally completed name] is and what it is used for

[Nationally completed name] is a medicine that reduces blood sugar levels (an oral antidiabetic medicine belonging to the sulphonylurea group).
[Nationally completed name] 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 [Nationally completed name]

**Do not take [Nationally completed name]:**
- 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 [Nationally completed name]"),
- if you are **breast-feeding** (see section "Pregnancy and breast-feeding").

**Warnings and precautions**

Talk to your doctor before taking [Nationally completed name]. 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 [Nationally completed name]"), 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**), reduced haemoglobin levels and breakdown of red blood cells (haemolytic anaemia) can occur. Contact your doctor before taking this medicine.

**Children and adolescents**
[Nationally completed name] is **not recommended** for use **in children and adolescents** due to a lack of data.

**Other medicines and [Nationally completed name]**
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, 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 **($H_2$ 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 [Nationally completed name], especially in elderly patients.

[Nationally completed name] 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 [Nationally completed name].

**[Nationally completed name] with food, drink and alcohol**
[Nationally completed name] 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**
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.

[Nationally completed name] is **not recommended** for use during **pregnancy**.

You must **not** take [Nationally completed name] 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).

**[Nationally completed name] contains lactose and sodium**
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 1 mmol (23 mg) sodium per modified release tablet, that is to say essentially ‘sodium-free’.

## 3. How to take [Nationally completed name]

**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.

Only adults may take this medicine.
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 dose** is 1 to 4 tablets (maximum 120 mg) in a single intake at breakfast time. This depends on the response to treatment.

If a combination therapy of [Nationally completed name] 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 tablets whole. Do not chew them.
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).

**If you take more [Nationally completed name] 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 [Nationally completed name]**
It is important to take your medicine every day as regular treatment works better.
However, if you forget to take a dose of [Nationally completed name], 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 [Nationally completed name]**
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 [Nationally completed name]”.
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.

**Blood disorders**

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.

**Eye disorders**
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.

**Digestive disorders**
Stomach pain or discomfort, feeling or being sick nausea, indigestion, diarrhoea and constipation.

These effects are reduced when [Nationally completed name] is taken with a meal as recommended (see section 3 "How to take [Nationally completed name]").

**Liver disorders**
There have been isolated reports of 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 disorders**
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.

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 (*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.

[*For the printed material, please refer to the guidance of the annotated QRD template.]

## 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 blister, bottle label or carton after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 [Nationally completed name] contains**
- The active substance is gliclazide. Each modified release tablet contains 30 mg of gliclazide.

- The other ingredients are hypromellose, calcium hydrogen phosphate dihydrate, lactose monohydrate *(see end of section 2 for further information about lactose)*, colloidal anhydrous silica, sodium stearyl fumarate.

**What [Nationally completed name] looks like and contents of the pack**

White, oval, biconvex tablet, imprinted with “GLI 30” on one side.

The modified release tablets are packed in Alu/PVC blisters and inserted in a carton, or packed in HDPE-bottles with screw cap with a tamper evident ring and mounted desiccant capsule.

Pack sizes:
Blister: 10, 20, 30, 60, 90, 100, 120, 180 modified release tablets
Bottles: 10, 20, 30, 60, 90, 100 modified release tablets

Not all pack sizes may be marketed.

**Houder van de vergunning voor het in de handel brengen**
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

**Fabrikanten**
Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

Lek Pharmaceuticals d.d.
Trimlini 2D
9220 Lendava
Slovenië

LEK S.A.
ul. Domaniewska 50 C
02-672 Warschau
Polen

LEK S.A.
Ul. Podlipie 16
95-010 Stryków

Polen

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

**In het register ingeschreven onder:**
Gliclazide Sandoz retard 30 mg - RVG 105042

**Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:**

| | |
|---|---|
| Oostenrijk | Gliclazid Sandoz 30 mg - Tabletten mit veränderter Wirkstofffreisetzung |
| België | Glecloz 30 mg tabletten met gereguleerde afgifte |
| Spanje | Gliclazida Placasod 30 mg comprimidos de liberación modificada EFG |
| Nederland | Gliclazide Sandoz retard 30 mg, tabletten met gereguleerde afgifte |
| Portugal | Gliclazida Sandoz |

**Deze bijsluiter is voor het laatst goedgekeurd in februari 2024.**