

Package leaflet: Information for the user

Diaglyc 30 mg Modified-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 Diaglyc is and what it is used for
2. What you need to know before you take Diaglyc
3. How to take Diaglyc
4. Possible side effects
5. How to store Diaglyc
6. Contents of the pack and other information

1. What Diaglyc is and what it is used for

Diaglyc is a medicine to reduce blood sugar levels (antidiabetic medicine taken orally).
Diaglyc 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.

2. What you need to know before you take Diaglyc

Do not take Diaglyc

- if you are allergic to gliclazide, to other sulphonylureas, to sulphonamides or any of the other ingredients of this medicine (listed in section 6),
- if you have insulin-dependent (type 1) diabetes,
- if you have ketone bodies and sugar in the 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 Diaglyc'),
- if you are breast-feeding.

If you think any of the above situations applies to you, tell your doctor, nurse or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Diaglyc.

This medicine should be used only if you are likely to have regular food intake (including breakfast).

It is important to have a regular carbohydrate intake due to the increased risk of low blood sugar level (hypoglycaemia) if a meal is delayed or skipped, if an inadequate amount of food is consumed or if the food is low in carbohydrate.

During gliclazide treatment regular monitoring of your blood (and possibly urine) sugar level is necessary. Your doctor may also take blood tests to monitor your glycated haemoglobin (HbA_{1c}).

You should observe the treatment plan prescribed by your doctor in order to achieve the recommended blood sugar levels. This means regular tablet intake in addition to a dietary regimen and physical exercise.

In the first few weeks of treatment the risk of having reduced blood sugar levels (hypoglycaemia) may be increased. Therefore it is vital that you are carefully monitored by your doctor.

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 without an appropriate increase in carbohydrate intake,
- 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 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 renal function or liver function is severely decreased.

If you suffer from low blood sugar you may have the following symptoms: headache, intense hunger, paleness, weakness, exhaustion, nausea, vomiting, weariness, sleepiness, sleep disorders, restlessness, aggressiveness, impaired 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, and sudden strong pain in the breast that may radiate into neighbouring areas (angina pectoris).

If your blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop cerebral convulsions, lose self control, breathing may be shallow and your heart beat slowed down, you may fall into unconsciousness possibly resulting in coma. The clinical picture of a severe reduced blood sugar level may resemble that of a stroke.

In most cases the symptoms of lower 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 (sugar cubes). Remember that sweeteners are not effective. Please contact your doctor or the nearest hospital if taking sugar does not help or if the symptoms recur.

It is possible that symptoms of lower blood sugar may be absent, that they develop slowly or that you do not realise 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). It may also happen when you suffer from certain disorders of the endocrine system (e.g. certain disorders of thyroid function and anterior pituitary or adrenocortical insufficiency).

If you are in stress-situations (e.g. accidents, acute operations, infections with 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. Symptoms may include thirst, frequent urination, dry mouth, dry itchy skin, skin infections and diminished performance.

If these symptoms occur, you must contact your doctor or pharmacist.

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 hemoglobin level and breakdown of red blood cells (hemolytic anemia) can occur. Contact your doctor before taking this medicinal product.

Children and adolescents

Diaglyc is not to be used for the treatment of diabetes in children and adolescents under 18 years of age.

Other medicines and Diaglyc

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines, including medicines obtained without a prescription.

The effectiveness and safety of Diaglyc may be affected if this medicine is taken at the same time as certain other medicines. Conversely, other medicines may be affected if they are taken at the same time as Diaglyc.

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),
- antibacterial medicines (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 (miconazol, fluconazole),
- medicines to treat indigestion and ulcers in the stomach or duodenum (H₂ receptor antagonists such as ranitidine),
- medicines to treat depression (monoamine oxidase inhibitors),
- painkillers or antirheumatics (ibuprofen, phenylbutazone),
- 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:

- medicine to treat disorders of the central nervous system (chlorpromazine),
- medicines reducing inflammation (glucocorticoids),
- medicine to treat asthma (salbutamol when given by injection),
- medicines used during labour (ritodrine and terbutaline given by injection),
- medicine to treat breast disorders, heavy menstrual bleeding and endometriosis (danazol),

Gliclazide may potentiate anticoagulation during concurrent treatment with warfarin (a medicine that inhibits blood clotting).

Consult your doctor before you start taking another medicinal product. If you go into hospital tell the medical staff you are taking Diaglyc.

Diaglyc with food, drink and alcohol

Diaglyc can be taken with food and non-alcoholic drinks.

Avoid alcohol as it can alter the control of your diabetes in an unpredictable manner and can even lead to coma.

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.

Diaglyc is not recommended for use during pregnancy.

You must not take Diaglyc 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 hypoglycaemia,
- have fewer or no warning symptoms of hypoglycaemia.

Diaglyc contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Diaglyc

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 of Diaglyc 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 starting dose is one tablet once daily.

The usual dose can vary from one to a maximum of four tablets in a single intake at breakfast. This depends on the response to treatment.

If blood glucose is not adequately controlled, your doctor may increase it in successive steps usually not less than 1 month apart.

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

Please talk to your doctor or pharmacist if you have the impression that Diaglyc is acting too strongly or not strongly enough.

Routes and method of administration

Swallow your tablets whole with a glass of water whilst having your breakfast, preferably at the same time each day. Do not chew the tablets. You must always eat a meal after taking your tablet(s). It is important not to skip a meal when you are on Diaglyc.

If you take more Diaglyc than you should

If you happen to have taken too much gliclazide 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, 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 Diaglyc

Do not take a double dose to make up for a forgotten tablet.

If you forget to take a dose, take the next dose at the usual time.

If you stop taking Diaglyc

If you interrupt or stop the treatment you should be aware that your blood sugar control will deteriorate. If any change is necessary it is absolutely important to contact your doctor first.

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 assessment of side effects is based on their frequency.

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

Hypoglycaemia (low blood sugar). For symptoms and signs see section 2 'Warnings and precautions'. 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.

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

- Abdominal pain
- Nausea
- Vomiting
- Indigestion
- Diarrhoea
- Constipation.

These effects are reduced when Diaglyc is taken with a meal as recommended.

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

- Decrease in the number of cells in the blood (e.g. 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.
- Skin reactions such as rash, redness, itching and hives. angioedema (rapid swelling of the tissue such as eyelids, face lips, mouth, tongue or throat that may result in breathing difficulty have been reported. The rash may progress to widespread blistering or peeling of the skin.
- Abnormal liver function tests, changes in your liver (which can cause yellow skin and eyes). If you get this, see your doctor immediately.
- 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.

These effects generally disappear if the medicine is stopped.

Severe changes in the number of blood cells and allergic inflammation of the wall of blood vessels have been described very rarely for other sulphonylureas. With other sulphonylureas signs and symptoms of liver impairment (e.g. jaundice) have been observed rarely which in most cases disappeared after withdrawal of the sulphonylureas, but may led to life-threatening liver failure in isolated cases.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diaglyc

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, the tablet container and the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product 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 Diaglyc contains

- The active substance is gliclazide. Each modified-release tablet contains 30 mg gliclazide.
- The other ingredients are lactose monohydrate, hypromellose, calcium carbonate, colloidal anhydrous silica, magnesium stearate.

What Diaglyc looks like and contents of the pack

The modified-release tablets are white, oval, biconvex tablets.

Diaglyc is available in blisters in boxes of 10, 14, 20, 28, 30, 56, 60, 84, 90, 100, 120 or 180 tablets and in tablet containers of 90, 120 or 180 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva Pharma B.V.,
Swensweg 5,
2031GA Haarlem,
The Netherlands

Manufacturer

Teva Operations Poland Sp. z.o.o,
80, Mogilska
Str., 31-546 Kraków,
Poland.

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

Denmark:	Gliclazid Teva
France:	Gliclazide Teva 30 mg, comprimé à libération modifiée
Germany:	Gliclazid-TEVA 30 mg Tabletten mit veränderter Wirkstofffreisetzung
Ireland:	Diaglyc 30 mg Modified-release Tablets
Italy:	Gliclazide Teva Italia 30 mg compressa a rilascio modificato
Netherlands:	Gliclazide 30 mg PCH, tabletten met gereguleerde afgifte
Portugal:	Gliclazida Teva 30 mg comprimido de libertação modificada

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