

Gliclazide Teva is not recommended for use during pregnancy.

You must **not** take Gliclazide Teva 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).

Gliclazide Teva contains lactose.

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

3 How to take Gliclazide Teva

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 starting dose is one tablet once daily. The usual dose can vary from one to four tablets (maximum 120 mg) in a single intake at breakfast time. This depends on the response to treatment.

If a combination therapy of Gliclazide Teva 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

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 Gliclazide Teva.

If you take more Gliclazide Teva 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, 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 Teva

It is important to take your medicine every day as regular treatment works better. If you forget to take a dose, take the next dose at the usual time. **Do not** take a double dose to make up for a forgotten tablet.

If you stop taking Gliclazide Teva

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.

Tell your doctor immediately if you experience any of the following symptoms

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

- Skin reactions such as rash, redness, itching, 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. If you develop this, stop taking Gliclazide Teva, **seek urgent advice from a doctor** and tell him that you are taking this medicine. 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 high temperature.
- Abnormal liver function tests, changes in your liver (which can cause yellow skin and eyes). If you get this, **see your doctor immediately**. These effects generally disappear if the medicine is stopped. Your doctor will decide whether to stop your treatment.

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

- Severe hypoglycaemia (low blood sugar). For symptoms and signs of hypoglycaemia 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**.

As for other sulfonylureas, 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 sulfonylureas, but may lead to life-threatening liver failure in isolated cases.

Other possible side effects

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

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

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

Gastrointestinal disturbances including abdominal pain, nausea, vomiting, indigestion, diarrhoea, constipation. These effects are reduced when Gliclazide Teva 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.
- 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.

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 the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Gliclazide Teva

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.

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 Teva 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 Gliclazide Teva looks like and contents of the pack

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

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer

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

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