

# Gliclazide Tablets BP 80mg

Gliclazide

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### 1. What Gliclazide is used for

Gliclazide tablets are used to treat maturity onset diabetes in patients that is not controlled by diet alone.

They are not for use in children or in patients with diabetes requiring insulin.

### 2. How Gliclazide works

Gliclazide is one of a group of medicines called sulphonylureas that are used to lower the blood sugar level.

### 3. Before you use Gliclazide

#### When you must not use it

Do not take Gliclazide tablets **and tell your doctor** if you:

- have ever had **an allergic reaction** to Gliclazide tablets or any of the ingredients in the tablet (Please refer to section 6, further information). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- are **breast feeding**.
- have **severe liver** or **kidney** disease.
- have **porphyria** (a hereditary disease affecting the liver or bone marrow).
- have ever had a severe **diabetic reaction** (such as “acidosis” or diabetic coma).
- have **Type I diabetes**.
- are diabetic and need an **operation**, suffered a **severe trauma** or **infection**,

tell your doctor you are taking Gliclazide tablets.

- take **miconazole** (for fungal infections)

#### Before you start to use it

Check with your doctor or pharmacist before taking Gliclazide tablets if you:

- have **liver** or **kidney** problems.
- have an inherited condition where your red blood cells don't produce enough of the enzyme **G6PD** (glucose 6 phosphate dehydrogenase).
- suffer from particular **hormone-induced disorders** (functional disorders of the thyroid gland, of the pituitary gland or adrenal cortex)
- are at risk of developing **low blood sugar** (hypoglycaemia) - take meals irregularly or skip meals altogether, are fasting, malnourished, change your diet, increase your physical activity and carbohydrate intake does not match this increase, drink alcohol, especially in combination with skipped meals
- take other medicines or **natural remedies** at the same time
- take **too high doses** of gliclazide

#### Taking other medicines

Please **tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Especially:

- medicines to treat high blood pressure such as beta blockers (eg propranolol, atenolol), ACE inhibitors (eg captopril), Angiotensin-II antagonists (eg losartan), nifedipine, diazoxide
- medicines used to treat infections such as co-trimoxazole, fluconazole, rifampicin, chloramphenicol, oral forms of miconazole (see section 2), sulphonamides such as sulphafurazole or tetracycline compounds (eg tetracycline)

- medicines used to prevent blood clotting (eg warfarin)
- medicines used to treat depression such as monoamine oxidase inhibitors (MAOIs eg moclobamide)
- medicines used to treat mental health problems such as lithium, phenothiazine derivatives (eg prochlorperazine)
- corticosteroids used to reduce inflammation in the body (eg prednisolone)
- phenylbutazone, azapropazone and other NSAIDs (non-steroidal anti-inflammatory pain killers)
- diuretics (water tablets) such as bendroflumethiazide, hydrochlorothiazide, furosemide
- oral contraceptives (the “pill”)
- salicylates (used for muscular or skeletal disorders eg aspirin)
- sulfinpyrazone (used for gout)
- aminoglutethimide (used to treat breast or prostate cancer)
- hormones such as testosterone, octreotide or thyroid hormones (eg thyroxine)
- cimetidine (used to treat stomach ulcers)
- clofibrate (used to treat high cholesterol in the blood)
- disopyramide (for irregular heartbeats)
- laxatives
- other medicines used to treat high blood sugar
- medicines containing alcohol
- chlorpromazine to treat disorders of the central nervous system

### 4. How to use Gliclazide

#### How much to use

Always take Gliclazide tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

## Doses:

### Adults and the elderly

The starting dose is usually 40-80mg once daily and may be increased to a total daily dose of 40-320mg.

Do not take more than the maximum of 160mg as single dose, for doses of 320mg this will be split over the day.

### Children

Not recommended.

## When to use it

When higher doses are required, Gliclazide should be taken twice daily and according to the main meals of the day.

## How long to use it

You should continue take Gliclazide for as long as your doctor tells you to. Talk to your doctor before you stop taking the tablets and follow their advice.

## If you forget use it

Take it as soon as you remember, unless it is nearly time for your next dose. Then carry on as before. Do not take a double dose to make up for a missed dose.

## If you use too much (overdose)

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include symptoms of low blood sugar such as sweating, trembling, weakness, double vision, palpitations, confusion.

## 5. While you are using it

### Things you must do

If you are pregnant, planning to become pregnant or are breast-feeding ask your doctor or pharmacist for advice before taking this Gliclazide.

Patients breastfeeding should not take this medicine (see section 2).

### Things you must not do

Low blood sugar may occur at the beginning of the treatment while your doctor is trying to find the dose that best suits you. If you experience the symptoms of low blood sugar, please consult your doctor or pharmacist.

### Things to be careful of

Make sure your blood sugar levels are under control before you drive or operate machinery.

## 6. Side effects

Like all medicines, Gliclazide tablets can cause side-effects although not everybody gets them.

Contact your doctor at once if you experience:

- An allergic reaction: skin rash, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

**Gastrointestinal** - feeling or being sick, abdominal pain or discomfort, indigestion, diarrhoea, constipation.

**Liver** - hepatitis or liver failure causing fatigue, weakness, loss of appetite, weight loss, fever, changes in liver enzymes (seen in tests), jaundice (yellowing of the skin or whites of the eyes).

**Skin** - skin rashes or pale skin, redness, itching and hives, skin reactions to sunlight.

**Blood** - Gliclazide may rarely affect the cells in your blood, which can cause anaemia or mean that you are more likely to catch infections or have a fever or sore throat, or develop bruising or bleeding.

Symptoms of **hypoglycaemia** (low blood sugar level) – sweating, clammy skin, trembling, weakness, double vision, palpitations, confusion, headache, hunger, feeling or being sick, sleep disorders, feeling agitated, unable to concentrate, drowsiness, loss of consciousness, slowed reactions, depression, trouble seeing or speaking, paralysis, numbness, dizziness, loss of self-control, sensing or seeing things that are not there, difficulty breathing, slowed or faster heart beat, chest pains (angina).

**Other** - general feeling of being unwell.

If you have an infection, an operation or a serious injury, tell your doctor that you take Gliclazide.

If you notice any side effects, they get worse, or if you notice any not listed, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting)

## 7. Storage and disposal of Gliclazide

### Storage

Keep out of the reach and sight of children. Store below 25°C in a dry place.

Do not use Gliclazide tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

### Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 8. Product description

### What it looks like

White, circular, flat, bevelled-edge uncoated tablets plain with a central division line on one face and the identifying letters “G” and “Z” on either side of a central division line on the reverse.

### Ingredients

#### Active ingredient

- The active substance (the ingredient that makes the tablets work) is gliclazide. Each tablet contains 80mg of gliclazide.

#### Inactive ingredients

- The other ingredients are maize starch, stearic acid, magnesium stearate, microcrystalline cellulose (E460).

#### MAL number

MAL05090021A

## 9. Manufacturer and Product Registration Holder

### Product Registration Holder

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### Manufacturer

Actavis, Barnstaple, EX 8NS, UK

## 10. Date of Revision

07/10/2013