# GLUCOZIDE 80 MG TABLET

## Gliclazide 80 mg

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#### What Glucozide is used for

Glucozide is indicated in all types of maturity onset, non-insulin dependent diabetes, with or without vascular complications.

#### How Glucozide works

Gliclazide is an orally active sulphonylurea hypoglycemic agent. Gliclazide reduces blood glucose levels by correcting defective insulin secretion. Gliclazide also increases the sensitivity of beta-cells to glucose. Gliclazide also decrease hepatic glucose production, and increasing glucose clearance.

## Before you use Glucozide

# When you must not use it

- if you are allergic to Gliclazide or any of the other ingredients of GLUCOZIDE, to other medicines of the same group (sulphonylureas), to other related medicines (hypoglycemic sulphonamides e.g.
  - (hypoglycemic sulphonamides e.g. Glibenclamide, Glipizide, Tolbutamide);
- If you have insulin-dependent diabetes (type 1);
- if you have ketone bodies and sugar in your urine (this may mean you have keto-acidosis), a diabetic pre-coma and coma;
- if you have severe kidney or liver disease;

# Before you start use it

Follow your doctor's advice about diet and treatment. This is to reduce the chances of very low blood sugar (hypoglycemia). Make sure your doctor knows:

- if you have an operation, a serious injury, fever or infection, difficulty in eating.
- if you plan a pregnancy or become pregnant, tell your doctor about your treatment.

# Taking 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, or insulin),
- antibiotics (e.g. sulphonamides),
- medicines to treat high blood pressure or heart failure (beta blockers),
- medicines to treat fungal infections (miconazole),
- medicines to treat ulcers in the stomach or duodenum (H2 receptor antagonists),
- medicines to treat depression (monoamine oxidase inhibitors),
- painkiller or antirheumatics (phenylbutazone).

The blood glucose lowering effect of Gliclazide may be weakened and raised blood sugar levels may occur when combining with medications used to reduce inflammation.

#### How to use Glucozide

## How much to use

Adult dose: The usual initial dose is ½ tablet (40 mg) to 1 tablet (80 mg) daily, gradually increased, if necessary, up to 4 tablets (320 mg).

A single dose should not exceed 2 tablets (160 mg). Doses of more than 2 tablets (160 mg) daily should be given in two divided doses, usually during breakfast and dinner.

For elderly patients the usual starting dose should be ½ tablet in the morning and ½ tablet in the evening.

#### When to use it

Use as directed by your doctor or pharmacist.

## How long to use it

Continue taking Glucozide for as long as your doctor recommends.

# If you forget to use it

Taking the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

## If you use too much (overdose)

Signs of an overdose include symptoms of low blood sugar (hypoglycemia) such as sweating, trembling, weakness, double vision, palpitation, confusion, headache, hunger, loss of consciousness. 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.

## While you are using it

## Things you must do

While taking Glucozide you should:

- follow a regular diet: it is important to eat regular meals, including breakfast and never to miss or delay a meal;
- take your medicine regularly
- check your blood glucose regularly as recommended by your doctor.

# Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Glucozide to anyone else, even if they have the same symptoms or condition as you.

## Things to be careful of

## Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

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#### Side effects

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

## Low blood sugar (Hypoglycemia)

The most commonly observed side effect is low blood sugar (hypoglycemia).

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

- <u>Digestive disorders</u>: Abdominal pain, nausea, vomiting, indigestion, diarrhea and constipation.
- <u>Skin disorders</u>: Skin reactions such as rash, redness, itching, hives have been reported. The rash may progress to widespread blistering or peeling of the skin.
- <u>Blood disorders</u>: 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. These symptoms usually stop when the treatment is discontinued.
- <u>Liver disorders</u>: 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 drug is stopped. Your doctor will decide whether to stop your treatment.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 (Consumers → Reporting).

# Storage and Disposal of Glucozide

#### Storage

Store at temperature of not more than 30°C.

# **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.

# **Product Description**

#### What it looks like

White, round, flat tablet, beveled on both sides with intersected scored on one side and with engraved 'G' and '80' on the other side.

## **Ingredients**

Active ingredient Gliclazide

Inactive ingredients
Lactose monohydrate
Corn starch
Povidone K-90
Sodium lauryl sulfate
Sodium starch glycolate
Colloidal silicon dioxide
Magnesium stearate
Purified water.

## MAL numbers: MAL20012695A

#### Manufacturer

UNISON LABORATORIES CO., LTD. 39 Moo 4, Klong Udomcholjorn, Muang Chachoengsao, Chachoengsao 24000 Thailand.

# **Product Registration Holder**

PAHANG PHARMACY SDN. BHD (10826K) Lot 5979 Jalan Teratai, 5 ½ Miles Off

Jalan Meru, 41050 Klang, Selangor Darul Ehsan, Malaysia.

## Date of revision

09/01/2014