

# Rolazide Tablet 80mg

Gliclazide (80mg)

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## What Rolazide Tablet 80mg is used for

Rolazide Tablet 80mg is indicated for non-insulin-dependent diabetes (type 2), in adults, when dietary measures, physical exercise and weight loss alone are not sufficient to control blood glucose levels

## How Rolazide Tablet 80mg works

The active ingredient, gliclazide, reduces blood glucose levels by stimulating the release of insulin from beta cells in the pancreas, hence, lowering the amount of sugar in your blood.

## Before you use Rolazide Tablet 80mg

### - When you must not use it

- Hypersensitivity to gliclazide or other sulphonylureas or sulphonamides, or to any of the ingredients used,
- Insulin-dependent diabetes, particularly juvenile diabetes, diabetes complicated by ketosis and acidosis, or diabetic precoma,
- Severe hepatic or renal insufficiency,
- Treatment with miconazole

In general, it is not advisable to combine this drug with phenylbutazone, danazol or alcohol.

### Pregnancy and lactation

- Do not take Rolazide Tablet 80mg if you are pregnant, trying to get pregnant or think you may be pregnant.
- Do not take Rolazide Tablet 80mg if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

### - Before you start to use it

Please tell your doctor if you are suffering or have ever suffered from any of the following conditions or illnesses:

- Carriers of a G6PD (glucose-6-phosphate dehydrogenase) enzyme deficiency

### - Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop because some medicines such as below might interact with Rolazide Tablet 80mg:

Medications that are likely to increase hypoglycaemia (low blood sugar level):

- Miconazole (medicine to treat fungal infection)
- Phenylbutazone (medicine to treat arthritis)
- Alcoholic drinks or medicine containing alcohol
- Beta-blockers (medicine to treat high blood pressure)
- Fluconazole (oral treatment for fungal infection)
- Angiotensin converting enzyme (ACE) inhibitors such as Captopril or Enalapril (medicine to treat high blood pressure and heart failure)

Medications that are likely to increase hyperglycaemia (high blood sugar level):

- Danazol (medicine to treat breast disorders, heavy menstrual bleeding and endometriosis)
- Chlorpromazine (medicine to treat central nervous system disorders)
- Glucocorticoids
- Salbutamol (medicine to treat asthma)
- Terbutaline & ritodrine (used during labor)

## How to use Rolazide Tablet 80mg

### - How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

### - When to use it

Use as directed by your doctor or pharmacist.

Take the medicine 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 medicine.

### - How long to use it

Continue taking Rolazide Tablet 80mg for as long as your doctor recommends.

### - If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

### - If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of the nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause hypoglycaemia (low blood sugar level).

If you experience mild signs of hypoglycaemia: weakness, sweating, intense hunger, trembling, drowsiness, dizziness, headache, visual problems,

eat or drink something containing sugar.

Consult your doctor or pharmacist immediately.

**While you are using it**

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Rolazide Tablet 80mg.

Tell your doctor immediately if you become pregnant while taking this medication.

Follow a regular diet; it is important to eat regular meals, including breakfast and never missed or delay your meals.

Check your blood glucose regularly as recommended by 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 Rolazide Tablet 80mg 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.

**Side effects**

Like all medicines, Rolazide Tablet 80mg can cause side effects, although not everybody gets them.

Treatment with gliclazide tablets might cause the following side effects:

- Hypoglycaemia (decrease in blood sugar level)
- Gastrointestinal disturbances: abdominal pain, nausea, diarrhoea, constipation

- Skin and subcutaneous tissue disorders: rash, pruritus (severe itching of the skin), urticaria (hives), erythema (reddening of the skin)
- Blood and lymphatic system disorders: raised hepatic enzyme levels (AST, ALT, alkaline phosphatase)
- Others: anaemia, leucopenia (reduction in white cells in blood), thrombocytopenia (deficiency of platelets in blood), granulocytopenia (decrease in number of granulocytes), hepatitis (liver inflammation) and eye disorders.

If you notice undesirable effects which have not been mentioned in this package insert, please inform 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).

**Storage and Disposal of Rolazide Tablet 80mg**

- Storage

Keep out of the reach and sight of children.

Store in a dry place (below 30°C). Protect from light.

- 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 to off white, round shaped tablet with cross break line on one side and blank on the other side.

- Ingredients

- Active ingredient  
Gliclazide

- Inactive ingredients

Microcrystalline cellulose, corn starch, croscarmellose sodium, colloidal silicon dioxide & magnesium stearate.

- MAL number:

MAL\*\*\*\*\*

**Manufacturer & Product Registration Holder**

Royce Pharma Manufacturing Sdn.Bhd.  
PT 1663, Nilai Industrial Estate, 71800 Nilai, Negeri Sembilan, Malaysia.

**Date of revision**

16/06/2016

**Serial Number**