

# APO-GLICLAZIDE MR TABLETS

Gliclazide (30mg, 60mg)

## What is in this leaflet

1. What Apo-Gliclazide is used for
2. How Apo-Gliclazide works
3. Before you use Apo-Gliclazide
4. How to use Apo-Gliclazide
5. While you are using it
6. Side effects
7. Storage and Disposal of Apo-Gliclazide
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

## What Apo-Gliclazide is used for

Apo-Gliclazide consist the active ingredient gliclazide, which 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 on keeping blood sugar at the correct level.

## How Apo-Gliclazide works

Gliclazide is a medicine that reduces blood sugar levels (oral antidiabetic medicine belonging to the sulphonylurea group).

## Before you use Apo-Gliclazide

- When you must not use it  
You should not take Apo-Gliclazide:
  - if you have any allergies to gliclazide, or any ingredients in this medication.
  - if you have insulin-dependent diabetes (type 1)
  - if you have ketone bodies and sugar in your urine, a diabetic pre-coma, or coma
  - if you have severe kidney and liver diseases
  - if you are under treatment with miconazole (for fungal).

### *Pregnancy and lactation*

Do not take Apo-Gliclazide if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Apo-Gliclazide if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it  
Before you start to use this medication, make sure that your doctor knows that:

- if you have any other medical conditions, including kidney and liver diseases.

- if you have low blood glucose
- if you have G6PD-deficiency with sulphonylurea agents (medicine used for blood glucose)

### - 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.

Some medication might cause complication when taken together with Apo-Gliclazide, which includes:

- Miconazole (for fungal)
- Phenylbutazone (for relief rheumatic pain)
- Other anti-diabetes agents such as insulins, acarbose, metformin
- Fluconazole (for fungal)
- Danazol (a type of hormone drug)
- Chlorpromazine (for mental problem)
- Glucocorticoids (a type of hormone drug)
- Ritodrine (for uncomplicated premature labour), Salbutamol and terbutaline (for relief asthma)
- Warfarin (for blood thinning)

## How to use Apo-Gliclazide

### - How much to use

The recommended starting dose is 30 mg (one tablet of Apo-Gliclazide MR 30mg or half a tablet of Apo-Gliclazide MR 60mg) daily. If blood glucose is effectively controlled, this dose may be used for maintenance treatment. If blood glucose is not adequately controlled, the dose may be increased to 60, 90 or 120 mg daily, in successive steps.

It is also important to let your doctor know if you have been taking any form of diabetic medication, your dose will be adjusted if you are currently or have taken any medication before this.

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.

### - How long to use it

Continue taking Apo-Gliclazide 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)

Overdose may cause low blood glucose. Moderate low blood glucose may associate with loss of awareness or nerve symptom. Severe low blood glucose may associate with coma.

Contact your doctor immediately or go to the Emergency Department of your 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.

## 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 Apo-Gliclazide.

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

### - 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.	<b>Storage and Disposal of Apo-Gliclazide</b>	Apotex Inc., 150 Signet Drive, Toronto, Ontario, M9L 1T9 Canada.
Do not give Apo-Gliclazide to anyone else, even if they have the same symptoms or condition as you.	- <u>Storage</u> Keep out of the reach and sight of children.	
- <u>Things to be careful of</u> Should any side effects from this medication causes any form of discomfort that will affect you in your work or daily task, let your doctor know.	Apo-Gliclazide MR 30mg tablets: Store below 25°C.  Apo-Gliclazide MR 60mg tablets: Store below 30°C	<b>Product Registration Holder</b> Pharmaforte(M) Sdn Bhd 2, Jalan PJU 3/49, Sunway Damansara, 47810 Petaling Jaya, Selangor
<u>Driving and using machines</u> This medicine has not known if 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.	- <u>Disposal</u> 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.	<b>Date of revision</b> 31/1/2019
<b>Side effects</b> Like all medicines, Apo-Gliclazide can cause side effects, although not everybody gets them.	<b>Product Description</b> - <u>What it looks like</u> Apo-Gliclazide MR 30mg tablets: White, to off-white, flat-faced, radial edge, capsule shaped tablets, engraved “APO 30” on one side and plain on the other side.	<b>Serial Number</b> BPFK (Rx/x)xxxxxx/xxxxx
As for other sulphonylureas, treatment with Apo-Gliclazide tablets can cause low blood glucose , if mealtimes are irregular and, in particular, if meals are skipped. Possible symptoms of low blood glucose, are: headache, intense hunger, nausea, vomiting, fatigue, sleep disorders.	Apo-Gliclazide MR 60mg tablets: White to off-white, oval shaped biconvex tablets. Engraved “GL” bisect “60” on one side, “APO” bisect “APO” on the other side.	
In addition, signs of sweating, sticky skin, anxiety, rapid heart rate, hypertension, palpitations, chest pain and irregular heart beat may be observed. Other common side effects including stomach pain, nausea, vomiting, indigestion, diarrhea and constipation.	- <u>Ingredients</u> - Active ingredient Gliclazide  - Inactive ingredients Apo-Gliclazide MR 30mg tablets: Hydroxypropyl Methylcellulose 2208 K100LV, Hydroxypropyl Methylcellulose 2208 K4M, Stearic Acid, Colloidal Silicon Dioxide	
Visit your doctor or pharmacist immediately if you experience any side effects, even if not mentioned above after taking this medicine.	Apo-Gliclazide MR 60mg tablets: Hydroxypropyl Methylcellulose 2208 K100LV, Anhydrous Lactose, Stearic Acid, Colloidal Silicon Dioxide.	
You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website <a href="http://npra.moh.gov.my">http://npra.moh.gov.my</a> (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).	- <u>MAL number:</u> Apo-Gliclazide MR 30mg tablets: MAL20132289AZ  Apo-Gliclazide MR 60mg tablets: MALXXXXXXXXXX	
<b>Manufacturer</b>		