

IDAMAN PHARMA GLICLAZIDE TABLET 80MG

Gliclazide (80mg)

What is in this leaflet

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

What Idaman Pharma Gliclazide Tablet is used for

This medicine used for adults with type 2 diabetes, when diet, exercise and weight loss alone do not have an adequate effect on keeping blood sugar at the correct level.

How Idaman Pharma Gliclazide Tablet works

Gliclazide is an oral antidiabetic medicine belonging to the sulfonylurea group, which reduces blood glucose levels by stimulating the secretion of insulin.

Before you use Idaman Pharma Gliclazide Tablet

- When you must not use it

Do not take:

- If you are allergic to Gliclazide or other sulfonylureas or sulfonamides or to any of excipients as listed at the end of this leaflet
- If you have diabetes requiring treatment with insulin,
- In case of diabetes complicated by keto- acidosis, diabetic pre-coma,
- If you suffer from severe liver or kidney disease,
- If you are in a treatment with miconazole, phenylbutazone, danazol or medicine containing alcohol
- If you are breast-feeding

Pregnancy and breast-feeding

There is no data concerning the use of Gliclazide in pregnant woman; even though there are few data with other sulfonylurea.

Studies in animals have shown reproductive toxicity. As a precautionary

measure, it is preferable to avoid the use of Gliclazide during pregnancy.

Control of diabetes should be obtained before the time of conception to reduce the risk of congenital abnormalities due to uncontrolled diabetes.

During pregnancy, oral hypoglycemic agents are not suitable, so insulin is the first choice for the treatment of diabetes. It is recommended that oral hypoglycaemic therapy is changed to insulin before a pregnancy is attempted, or as soon as pregnancy is discovered.

Breast-feeding

It is unknown whether gliclazide or its metabolites are excreted in human milk. Given the risk of low blood sugar level, the product is therefore should not be used in breast-feeding mothers. The risk is included to the newborns/infants.

Fertility

No effect on fertility or reproductive performance was noted in male and female rats

- Before you start use it

You may suffer from hypoglycemic (excessive reduce of blood sugar level) in the course of your treatment. If this happens, it may be necessary to hospitalization might be required to restore your sugar levels. After a hypoglycemic episode, your doctor will monitor you closely for 24 hours.

The following information is necessary to avoid episodes of hypoglycemia:

- It is important to eat regular meals, including breakfast, due to the increased risk of hypoglycemia if a meal is missed, or in the case of an inadequate diet or a diet low in sugars.
- Age, poor kidney function, liver failure and certain disorders of the adrenal glands or the pituitary gland may increase the risk of hypoglycemia.

Your doctor will explain to you and your family how to avoid hypoglycemia, how to recognize the first symptoms and how to treat them.

The risk of hypoglycemia could be increased by unbalance diet, considerable or prolonged exertion, consumption of alcohol or combination treatment with other hypoglycemic medications (Refer to "Taking other medicines")

In the case of surgery, trauma, fever or infection, your doctor may discontinue this treatment and prescribe insulin for you since it might cause imbalance glycaemia

The levels of glucose in your blood and urine also should be monitored regularly.

Your doctor will also explain the conditions under which you may become resistant to the treatment with Idaman Pharma Gliclazide Tablet, other medications may then be prescribed a replacement.

Please get advice from your doctor or pharmacists if you have G6PD deficiency as this medicine might lead to abnormal lysis of red blood cell to you.

- Taking other medicines

Tell your doctor or pharmacists if you are taking other medicine, including that you buy without a prescription from pharmacy, supermarket or health food shops.

Some medicines might have interaction if taken together with Idaman Pharma Gliclazide Tablet. These include:

1. Medications which risk increasing the hypoglycaemia: miconazole, sulfonamides, phenylbutazone, anti-inflammatory agents, and medications containing alcohol.
2. Medications which risk producing hyperglycaemia by reducing the efficacy of the anti-diabetic agent: danazol, chlorpromazine, glucocorticoids, salbutamol, terbutaline, ritodrine and St. John's Wort.

How to use Idaman Pharma Gliclazide Tablet

Route of administration: Oral

For adult use only and to be taken orally. Swallow the whole tablet(s). Do not chew or crush a tablet.

IDAMAN PHARMA GLICLAZIDE TABLET 80MG

Gliclazide (80mg)

- How much to use

The standard dosage is 2 tablets per day, in 2 daily doses. This depends on the response to treatment.

Follow all directions instructed by your doctor or pharmacists 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.

You might need consultation from your doctor or pharmacists if you are above 65 years, have kidney or liver failure or taking hypoglycemic medicines.

- When to use it

Use as directed by your doctor or pharmacists.

Take your tablet(s) 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 tablet(s).

- How long to use it

Continue taking Gliclazide for as long as your doctor recommends.

- If you forget to use it

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

Take missed dose as soon as you remember. If it 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 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.

If you experience mild signs of hypoglycemia, weakness, sweating, intense hunger, trembling, drowsiness, dizziness, headache, visual problems, eat or drink something containing sugar.

Consult your doctor or your 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 Idaman Pharma Gliclazide Tablet.

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 or combine with any other medicine without consulting your doctor or pharmacist.

Do not give Idaman Pharma Gliclazide Tablet 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 medicine, Idaman Pharma Gliclazide Tablet may produce distressing effects of varying severity in some people:

- Hypoglycaemia (low blood sugar level)
- Skin reactions: urticarial, itching, skin rash,
- Gastrointestinal disorders: nausea, diarrhea, stomach problems, constipation.
- Blood and lymphatic system disorders: lack of healthy red blood cells and white blood cell
- Hepatobiliary disorder: jaundice, hepatitis.
- Eye disorders: visual disturbances
- Abnormal laboratory results affecting the blood, liver and kidney functions.

If you notice undesirable effects which have not been mentioned in this package insert, please inform your doctor or your pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Idaman Pharma Gliclazide Tablet

- Storage

Store below 30°C. Protect from light and moisture.

Keep out of the reach and sight of children. Do not use Idaman Pharma Gliclazide Tablet after the expiry date which is stated on the carton and the blister strip. The expiry date refers to the last day of that month.

Do not use Idaman Pharma Gliclazide Tablet if you note signs of deterioration on the packaging or on blisters.

- Disposal

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

Product Description

- What it looks like

White to off white, round, flat, beveled-edge tablet and scored on one side.

- Ingredients

- Active ingredient:

Gliclazide 80 mg

- Inactive ingredients:

- Microcrystalline cellulose
- Corn starch
- Croscarmellose sodium Colloidal silicone dioxide
- Stearic acid.

- Pack Sizes

Blister Pack (PVC/Aluminium) of 10's tablets:-

- 6 x 10's tablets
- 10 x 10's tablets
- 50 x 10's tablets

IDAMAN PHARMA GLICLAZIDE TABLET 80MG

Gliclazide (80mg)

- *MAL number*

MAL20086005AZ

Product Registration Holder & Manufacturer

Idaman Pharma Manufacturing Sdn Bhd
Lot 24 & 25, Jalan Perusahaan Lapan,
Bakar Arang Industrial Estate,
08000 Sungai Petani,
Kedah Darul Aman, Malaysia.

Date of revision

24/09/2024

Serial number

NPRA (R2)19/126