

DIABEND

Gliclazide Tablet BP 80mg

What is in this leaflet

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

What DIABEND is used for

DIABEND 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 DIABEND works

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

Before you use DIABEND

- When you must not use it

Do not take DIABEND:

- if you are allergic to gliclazide, to other sulfonylureas or sulfonamides or to one of excipients included,
- if you have diabetes requiring treatment with insulin,
- in case of diabetes complicated by keto-acidosis, diabetic precoma,
- if you suffer from severe liver or kidney disease,
- if you are presently taking a treatment with *miconazole* (Refer to "Taking other medicines"),
- if you are breast-feeding

Pregnancy and breastfeeding

If you are pregnant, your diabetes should be treated with insulin.

If you discover that you are pregnant while taking this medication, you should discontinue your treatment.

Tell your doctor, who will adjust your hypoglycaemic treatment.

This medication is contraindicated when breast-feeding.

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

- Before you start to use it

Warnings

Hypoglycaemia: (decrease in blood sugar levels)

You may suffer from hypoglycaemia in the course of your treatment. If this happens, it may be necessary to hospitalize you to restore your sugar levels. After a hypoglycaemic episode, your doctor will monitor you closely for at least 24 hours.

The following information is necessary to avoid episodes of hypoglycaemia:

- It is important to eat regular meals, including breakfast, due to the increased risk of hypoglycaemia if a meal is missed, or in the case of an inadequate diet or a diet low in sugars,
- Age, renal insufficiency, hepatic insufficiency and certain disorders of the adrenal glands or the pituitary gland may increase the risk of hypoglycaemia,
- The risk of hypoglycaemia is heightened by the following: a diet which is too strict or poorly balanced, considerable or prolonged exertion, consumption of alcohol or combination treatment with other hypoglycaemic medications (refer to "taking other medicines").

Glycaemic imbalance:

In the case of surgery, trauma, fever or infection, your doctor may discontinue this treatment and prescribe insulin for you.

Biological analyses:

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

Due to the presence of lactose, this drug should not be used in the case of congenital galactosemia, the syndrome

of malabsorption of glucose and galactose or a deficit in lactase (rare metabolic diseases).

Precautions

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

Your doctor will also explain the conditions under which you may become resistant to the treatment with gliclazide: other medications may then be prescribed as a replacement.

- Taking other medicines

Please inform your doctor or pharmacist if you are taking or have taken any other medicines even if it is a medicine that can be obtained without a prescription:

1. Medications which risk increasing the hypoglycaemia: *miconazole*, *phenylbutazone*, *beta-blockers*, *fluconazole*, *angiotensin converting enzyme inhibitors*, medications containing alcohol.
2. Medications which risk producing hyperglycaemia by reducing the efficacy of the anti-diabetic agent: *danazol*, *chlorpromazine*, *glucocorticoids*, *salbutamol*, *terbutaline*, *ritodrine*.

How to use DIABEND

Oral use.

Swallow the whole tablet(s). Do not chew or crush.

- How much to use

Always take DIABEND exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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

Please talk to your doctor or pharmacist if you have the impression that DIABEND is acting too strongly or not strongly enough.

- When to use it

Use as directed by your doctor or pharmacists.

DIABEND

Gliclazide Tablet BP 80mg

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 DIABEND for as long as your doctor recommends.

- If you forget to use it

It is important to take your medicine every day as regular treatment works better.

However, if you forget to take a dose of DIABEND, take one tablet with the next meal. Do not take a double dose to compensate the simple dose you have forgotten to take.

- 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 hypoglycaemia: 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 DIABEND.

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.

Do not give DIABEND 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

As with all active substances, this medication may produce distressing effects of varying severity in some people:

- hypoglycaemia (Please refer to “Warnings” and “overdosage”),
- skin reactions: urticaria, itching, skin rash,
- gastrointestinal disorders: nausea, diarrhoea, stomach problems, constipation, jaundice, hepatitis,
- 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 visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF)]

Storage and Disposal of DIABEND

- Storage

Keep out of the reach and sight of children.

Do not use DIABEND 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 DIABEND if you note signs of deterioration on the packaging or on blisters.

Store below 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, flat circular, bevelled edge uncoated tablets with cross scoring on one side and plain on the other side.

- Ingredients

- Active ingredient:

Gliclazide. One tablet containing 80 mg of gliclazide.

- Inactive ingredients:

Lactose Monohydrate, Microcrystalline Cellulose, Povidone K 30, Croscarmellose Sodium, Talc, Magnesium Stearate, Purified Water.

- MAL number:

Xxx

Manufacturer

BAL PHARMA LIMITED, UNIT-IV
Plot No. 1,2,3 and 69, Sector 4,
Integrated Industrial Estate,
Pantnagar, Udham Singh Nagar
Rudrapur, 263153, India

Product Registration Holder

KCK Pharmaceutical Industries Sdn. Bhd
Plot 61, Bayan Lepas Industrial Park
Phase 4,
Lintang Bayan Lepas 1,
11900 Bayan Lepas, Pulau Pinang,
Malaysia.

Date of revision

07/09/2023

Serial Number:

NPRA (R2) 22/146