

Package Leaflet: Information for the patient

Diabrezide 80mg Tablets

Gliclazide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Diabrezide 80mg Tablets are and what they are used for
2. What you need to know before you take Diabrezide 80mg Tablets
3. How to take Diabrezide 80mg Tablets
4. Possible side effects
5. How to store Diabrezide 80mg Tablets
6. Contents of the pack and other information

1. What Diabrezide 80mg Tablets are and what they are used for

The name of your medicine is Diabrezide 80mg Tablets. Diabrezide 80mg Tablets contain a medicine called gliclazide. This belongs to a group of medicines called 'sulphonylureas'. It works by controlling sugar (glucose) levels in the blood.

Diabrezide 80mg Tablets are used for the sort of diabetes called 'Type 2 diabetes'. This is when insulin is not needed, but diet and exercise alone do not lower sugar levels in the blood. People usually need treatment for diabetes for the rest of their life.

2. What you need to know before you take Diabrezide 80mg Tablets

Do not take Diabrezide 80mg Tablets:

- if you are allergic to gliclazide or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to 'sulphonylureas', 'sulphonamides' or any other similar medicines
- if you have used 'sulphonylureas' before, but they have stopped working for you
- if you have 'Type 1 diabetes' (this is when you need to use insulin to control your diabetes)
- if you have a very high blood sugar which is life threatening ('diabetic ketoacidosis')
- if you are going to have an operation, have recently had a serious accident or been very stressed
- if you have a serious infection
- if you have a severe liver or kidney problem
- if the patient is unconscious or in a coma (diabetic coma)
- if the patient is a child.

Do not take Diabrezide 80mg Tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Diabrezide 80mg Tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Diabrezide Tablets:

- if you are on or are planning to go on a special diet, such as a low calorie diet. See 'Taking Diabrezide 80mg Tablets with food and alcohol' for more information
- if you exercise a lot
- if you have an untreated 'thyroid' problem
- if you have moderate liver or kidney problems. You will need to be monitored more.
- if you are elderly, ill or very thin. You will need to be monitored more.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Diabrezide 80mg Tablets.

Other medicines and Diabrezide Tablets

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you get without a prescription, including herbal medicines. This is because Diabrezide 80mg Tablets can affect the way some other medicines work. Also some other medicines can affect the way Diabrezide 80mg Tablets work.

Some medicines may **increase the effect** of Diabrezide 80mg Tablets. This can cause low blood sugar. These medicines include:

- other medicines for diabetes such as 'insulin', 'acarbose', 'biguanides' or other 'sulphonylureas'
- medicines used to thin the blood such as 'coumarins'
- medicines used to lower uric acid such as 'allopurinol'
- medicines used to lower cholesterol ('fibrates')
- medicines for depression called 'Mono Amine Oxidase Inhibitors' (MAOIs)
- medicines for heart problems such as 'beta blockers'
- some medicines for high blood pressure ('ACE inhibitors')
- some medicines for fungal and bacterial infections such as 'miconazole', 'ketoconazole' or 'chloramphenicol'
- anti-bacterial medicines called 'sulphonamides'
- a medicine for cancer called 'cyclophosphamide'
- caffeine which you get in some medicines for migraine and coffee, tea or some fizzy drinks
- 'theophylline' used for asthma
- anti-inflammatory medicines such as aspirin or 'phenylbutazone'
- anabolic steroids
- male sex hormones.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Diabrezide 80mg Tablets.

Some medicines may **lower the effect** of Diabrezide 80mg Tablets. This can raise your blood sugar. These medicines include:

- medicines that raise blood pressure in serious conditions of low blood pressure such as 'diazoxide'
- some medicines for epilepsy such as 'phenytoin' or 'barbiturates'
- corticosteroids or corticotropin
- female sex hormones
- oral contraceptives
- thyroid hormones
- water tablets ('diuretics')
- 'phenothiazine' used for mental problems
- 'rifampicin' used for tuberculosis (TB).

Cimetidine and ranitidine may **either increase or lower** blood sugar.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Diabrezide 80mg Tablets.

Diabrezide 80mg Tablets with food and alcohol

Do not skip meals or start a special diet while taking Diabrezide 80mg Tablets. This is because if you eat less food than normal, your blood sugar will become too low. Talk to your doctor or dietician if you are not sure.

- Take the medicine 30 minutes before meals (see 'Taking this medicine' in section 3).
- Talk to your doctor about drinking alcohol with this medicine. This is because drinking alcohol can affect how well your diabetes is controlled.

Pregnancy and breast-feeding

- Do not take Diabrezide 80mg Tablets if you are pregnant or breast-feeding.
- Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant or breast-feeding.

Driving and using machines

You may feel less alert while taking Diabrezide 80mg Tablets. If this happens do not drive or use any tools or machines. This is more likely to happen if your diabetes is not controlled properly. Make sure your blood sugar is not low before you drive.

Diabrezide 80mg Tablets contains:

Lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Diabrezide 80mg Tablets

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

Taking this medicine

- Take this medicine by mouth.
- Take the medicine 30 minutes before a meal.
- Swallow the tablets whole with a glass of water.
- Do not crush or chew the tablets.

How much to take

- The doctor will decide how much of this medicine you should take.

- The starting dose is usually half to one tablet each day, taken before breakfast.
- This may be increased every 7 to 14 days until your blood sugar levels are controlled.
- The usual dose is one to two tablets each day. This is usually split into two doses, take it:
 - 30 minutes before breakfast and
 - 30 minutes before your evening meal.
- The maximum dose is 4 tablets each day.

Your doctor will give you advice on when you will need to have blood or urine tests to measure your blood sugar levels.

Elderly patients or patients with liver or kidney problems

Your doctor may prescribe a lower dose.

Use in children

This medicine should not be given to children.

Do not take Diabrezide 80mg Tablets if you have insulin dependent (type 1) diabetes.

If you take more Diabrezide 80mg Tablets than you should

- If you take too much of this medicine, talk to your doctor or go to a hospital straight away.
- The signs of taking too much are the symptoms of low blood sugar (hypo-glycaemia). These include sweating, looking pale, feeling cold, shivering, a fast heart beat, temporary difficulty with seeing or talking.
- These symptoms can be helped by having sugar or sweet drinks.
- You should carry at least 1-2 lumps of sugar all the time. You can also have a sugary drink instead of sugar. This includes lemonade, but not diet lemonade.

If you forget to take Diabrezide 80mg Tablets

- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Diabrezide 80mg Tablets

Do not stop taking Diabrezide 80mg Tablets without talking to your doctor.

4. Possible side effects

Like all medicines, Diabrezide 80mg Tablets cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Common side effects (affects less than 1 in 10 people):

- low blood sugar (hypo-glycaemia). Signs may include sweating, looking pale, feeling cold, shivering, a fast heart beat, temporary difficulty with seeing or talking. If this happens, tell your doctor or go to hospital straight away
- feeling sick, being sick, stomach pain, diarrhoea or constipation. These side effects can be lowered if you take this medicine 30 minutes before meals.

Rare side effects (affects less than 1 in 1,000 people):

- feeling dizzy
- headaches
- skin rashes or reddening of the skin
- changes in the way your liver works, including hepatitis. Signs may include yellow colouring of the skin or eyes
- low number of red blood cells (anaemia). Signs may include feeling tired or dizzy
- low number of white blood cells (leucopenia, agranulocytosis). Signs may include a high temperature (fever) or getting more infections than normal
- low number of platelets in the blood (thrombocytopenia). Signs may include bruising or bleeding more easily.

Other side effects:

- Skin reactions such as rash, redness, itching, hives, angioedema (rapid swelling of tissues such as eyelids, face, lips, mouth, tongue or throat that may result in breathing difficulty) have been reported. The rash may progress to widespread blistering or peeling of the skin.

Reporting of side effects.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRP Pharmacovigilance

Website: <http://www.hpra.ie/>

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diabrezide 80mg Tablets

- Keep out of the reach and sight of children.
- Do not store above 25°C.
- Do not use this medicine after the expiry date which is stated on the package after "Expiry" or "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicines wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Diabrezide Tablets contains

- The active substance is gliclazide. Each tablet contains 80 mg of gliclazide.
- The other ingredients are lactose monohydrate, microcrystalline cellulose PH101, povidone K30, sodium starch glycolate type A, magnesium stearate.

What Diabrezide 80mg Tablets look like and contents of the pack

Diabrezide 80mg Tablets are white, circular compressed tablets with flat levelled edges and breakline scoring on one face.

They come in cartons of 30 and 60 tablets.

Marketing Authorisation Holder and Manufacturer

L. Molteni & C. dei F.lli Alitti Società di Esercizio S.p.A.
Strada Statale 67, Località Granatieri
Scandicci (Firenze), Italy
PA 925/1/1

Distributed in Ireland by:

Fannin Limited,
South County Business Park,
Leopardstown,
Dublin 18

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Diabrezide - Tabletten
Belgium	Gliclazide Mylan
United Kingdom	Diabrezide or Gliclazide 80 mg tablets

This package leaflet was last revised in .