

DYANIL TABLET

(Glibenclamide 5mg)

Consumer Medication Information Leaflet (RiMUP)

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1. What DYANIL TABLET is used for

The name of your medicine is DYANIL TABLET.

This tablet belongs to a group of medicines called sulphonylureas.

DYANIL TABLET is used to lower blood sugar levels and is used in the treatment of late-onset diabetes (type II diabetes mellitus) in patients whose blood sugar is not controlled by diet alone and who are not suitable for insulin injections.

2. How DYANIL TABLET works

Glibenclamide is a hypoglycaemic agent which is effective when given by mouth. It acts by stimulating the release of insulin from the beta cells of the pancreatic islets. It is not a substitute for insulin as it is effective only in the presence of functioning islet tissue.

3. Before you take DYANIL TABLET

When you must not use it:

You must not use it if you

- are allergic (hypersensitive) to glibenclamide, other sulphonylureas or any of the other ingredients in DYANIL TABLET (see Product information section)
- suffer from early onset or type I diabetes (requiring insulin)
- suffer from severe kidney disease
- are suffering from ketoacidosis (caused by excessively high blood sugars in diabetics)
- are suffering from a severe infection
- are suffering from stress
- are suffering from any condition likely to make controlling your blood sugar difficult
- are due to undergo surgery
- have reduced consciousness or coma resulting from your diabetes

This medicine can cause low blood sugar (hypoglycaemia). Symptoms include sweating, hunger, increased heart rate, reduced consciousness, coma or seizures.

Low blood sugar may occur particularly in the following situations, so patients should use caution:

- in patients whose diabetes is controlled by diet alone
- if you take too high doses of glibenclamide tablet
- if you are malnourished
- if you take meals irregularly or skip meals altogether
- if you increase your physical activity and carbohydrate intake does not match this increase
- if you are unwell
- if your kidney function is decreased
- if you suffer from particular hormone-induced disorders (functional disorders of the pituitary or adrenal glands)
- if you drink alcohol, especially in combination with skipped meals.

Low blood sugar may occur if you are in stress situations (e.g. accidents, surgical operations, fever etc.). During such times you should inform your doctor you are taking DYANIL TABLET, as your doctor may adjust your dose of medicine or may temporarily switch you to insulin therapy.

Before you start to take it

Before taking glibenclamide make sure your doctor or pharmacist knows:

- If you are pregnant, trying for a baby or breast-feeding.
- If you suffer from kidney or liver problems.
- If you suffer from porphyria (a blood disorder).
- If you are elderly.
- If you are taking other medicines, including those available to buy without a prescription, herbal or complementary medicines.
- If you have ever had an allergic reaction to this or any other medicine.

Pregnancy and breast-feeding

You should not take this medicine if you are pregnant.

Talk to your doctor or pharmacist before taking them if you are breastfeeding a baby.

This medicine contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. The following medicines can affect or be affected by DYANIL TABLET:

- medicines used to reduce pain and inflammation (e.g. aspirin, other non-steroidal anti-inflammatory drugs and phenylbutazone)
- medicines used to treat bacterial infections (e.g. chloramphenicol, sulphonamides and tetracyclines)
- medicines used to treat depression (e.g. monoamine oxidase inhibitors [MAOIs])
- medicines used to treat fungal infections (e.g. miconazole)
- medicines used to treat gout (e.g. sulfinpyrazone)
- medicines used to thin the blood and prevent clotting (e.g. warfarin)
- medicines used to reduce cholesterol (e.g. clofibrate)
- hormone treatments and contraceptives (e.g. oestrogens, oral contraceptives, anabolic steroids and corticosteroids)
- thyroid hormone (used to treat an underactive thyroid gland)

4. How to use DYANIL TABLET

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.

How much to use

This medicine should be swallowed whole with some liquid.

Stabilisation should be instituted by a doctor only. Treatment is started with a daily dose of half a tablet (2.5 mg), taken immediately before breakfast. If necessary, raise the dose in increments of 2.5 mg until the blood glucose levels have been normalised. As a rule, the maximum effect is obtained with 3 tablets daily, in exceptional cases 4 tablets daily. A maximum single dose of 2 tablets (10 mg) should not be exceeded.

When to use it

It is to be taken before breakfast, any remaining portion before the evening meal, or as directed by your doctor or pharmacist.

How long to use it

Continue taking DYANIL TABLET for as long as your doctor recommends.

If you forget to use it

If you forget a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. NEVER take a double dose to make up for the one missed.

Consult your doctor or pharmacist if you are in doubt.

If you use too much (overdose)

If you (or anybody else, including a child) take more DYANIL TABLET than you should, contact your nearest hospital casualty department or your doctor immediately. Always take the container and this leaflet with you. Signs that could indicate you have taken too many are symptoms of low blood sugar which include sweating, hunger, increased heart rate, reduced consciousness, coma or seizures.

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.

5. While you are using it

Things you must do

You may have been warned about hypoglycaemia. Hypoglycaemia is the medical term for low blood sugar. It is important for you to recognise the symptoms of hypoglycaemia and correct the low blood sugar level. If you don't, you may faint.

How do I know if I am experiencing hypoglycaemia?

Some of the symptoms of hypoglycaemia include dizziness, headache, shaky hands, feeling hungry, weak or confused, problems speaking. These symptoms are your body's way of warning you that your blood sugar is dangerously low.

What should I do if I am experiencing hypoglycaemia?

You should take a drink or food containing sugar (for example, fruit juice, soft drinks, sweets) at the first sign of hypoglycaemia. If your symptoms do not improve, get medical help. Keep some glucose tablets (also known as dextrose tablets) with you at all times.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking DYANIL TABLET.

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

Things you must not do

Never take more than the prescribed dose. Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give DYANIL TABLET to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving and using machinery

If your blood sugar is not well controlled then this can affect your vision and/or concentration. If you are affected in any way do not drive or operate machinery.

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.

6. Side effects

Like all medicines, DYANIL TABLET can cause side effects, although not everybody gets them.

Side effects that have been reported with DYANIL TABLET are:

- rash
- itching
- sensitivity to light
- skin inflammation
- changes in blood cells
- liver problems
- low blood sugar
- feeling and being sick (nausea/vomiting)
- anorexia

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

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 (Consumers → Reporting).

7. Storage and Disposal

Storage

- Keep out of the reach and sight of children.
- Store below 25°C.
- Store in the original package in order to protect from light and moisture.
- DYANIL TABLET should not be taken after the expiry date. The expiry date refers to the last day of the month.

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.

8. Product Description

What it looks like

DYANIL TABLETS are oblong & flat in shape. The white coloured tablets are scored in the middle. DYANIL TABLETS are packed in plastic container of 1000's and blister packs of 10 x 10's and 100 x 10's per box.

Ingredients

Each tablet contains the active ingredient glibenclamine, and also contains the following inactive ingredients: Magnesium stearate, starch, gelatin (bovine), lactose & starch .

Registration number:

MAL19910070A

9. Manufacturer and Product Registration Holder

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10. Date of revision

10 January 2014