DIABITOL TABLET

GLIBENCLAMIDE 5 MG

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What Diabitol Tablet is used for

Diabitol tablet is used in treatment and control of maturity onset type II diabetes (Non-insulin-dependent)when diet alone could not control well.

How Diabitol Tablet works

Glibenclamide belongs to group of oral hypoglycemic agents called sulfonylureas.

Is used in conjunction with diet and exercise to control blood sugar. It works by increasing the amount of insulin released by your pancreas.

Before you use Diabitol tablet When you must not use it.

This medication should not be used when the following medical problems exist: -

- Acidosis, significant
 Abnormal increase in blood acidity.
- Burns, severe.
- Diabetic coma (ketoacidotic, nonketotic hyperosmolar, or associated with hypoglycemia).
- Infection, severe.
- Ketoacidosis- is a metabolic state associated with high concentrations of ketone bodies, formed by the breakdown of fatty acids and the deamination of amino acids.
- Surgery, major.
- Trauma, severe.
- Sensitive to glibenclamide.
- Pregnancy.
- Juvenile or unstable diabetes.

Before you start take to it

Tell your physician if you have any allergies to any other medicines or any other substances such as foods, preservatives or dyes, or you are breast feeding or plan to breastfeed.

Always talk to your physician if you have or have had kidney problems, liver problems, a history of diabetic coma adrenal pituitary (or thyroid) problems or heart failure.

Taking other medicines

The hypoglycaemic action of Glibenclamide may be enhanced by sulphonamides, salicylates, phenylbutazone, coumarin derivatives, beta-blocking agents, monoamine oxidase inhibitors, cyclophosphamide, bezafibrate, clofibrate, fenfluramine, tetracyclines, sulphinpyrazone and chloramphenicol.

Conversely, thiazide diuretics, frusemide, ethacrynic acid, oral contraceptives containing oestrogens/gestagens, phenothiazine derivatives, nicotinic acid (high-dosage) sympathomimetics, thyroid hormones and corticosteroids may diminish hypoglycaemic activity.

Tell your physician if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food facility.

How to take Diabitol Tablet *How much to take*

Usual adult dose: Oral, initially 2.5 to 5 mg once a day, the dosage being adjusted in increments of no more than 2.5 mg at weekly intervals until blood sugar control is obtained or until the total daily dose reaches 20 mg.

Note:

If you are more sensitive to glibenclamide, such as elderly, debilitated or malnourished and you have impaired kidney or liver function, the dose would be initiated at 1.25mg once a day.

When taken in divided doses, two times a day, it is usually taken before morning and evening meals ,particularly in patients on a maintenance schedule of 10 mg or more per day, may improve the control of hyperglycaemia in some patients.

Usual adult prescribing limits: Up to 20 mg daily.

Usual paediatric dose: Not effective in insulin-dependent diabetes.

When to take it

If single dose, use once a day, usually before breakfast When taken in divided doses, two times a day, it is usually taken before morning

This is only recommendation, for actual dosage please always refer to your doctor or pharmacists.

How long to take it

and evening meals.

Follow doctor's advice.

If you forget to take it

Take the missed dose as soon as possible as you remember it. However if it is almost time for the next dose, skip the missed dose and continue your regular doing schedule. Do not take a double dose to make up for a missed one.

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If you take too much (overdose)

Overdose may result in hypoglycaemia. If symptoms of mild hypoglycaemia appear, you should eat or drink a source of sugar and obtain medical assistance right away. Adjustment in oral antidiabetic dosage and/ or meal patterns may be required.

Get medical help as soon as possible if above symptoms are observed.

While you are using Diabitol Tablet *Things you must do*

Follow doctor's advice

Things you must not do

Do not stop taking Diabitol Tablet without consulting doctor first.

Do not give your medicine to other people experiencing the same symptoms as you

Things to be careful of

- If you are an elderly, a lower limitation dose may be given.
- Hypoglycaemia.
- Treatment with sulphonylureas has been associated with occasional disturbance of liver function and cholestatic jaundice.
- If hepatitis or cholestatic clinical jaundice occurs, the drug should be discontinued.
- In patients suffering from intercurrent infections or trauma, the dosage may need to be increased or temporary change to insulin.

Side Effects

Like all medicines, Diabitol Tablet can cause side effects, although not everybody gets them.

Some of the reported side effects are:

- hypoglycaemia
- cholestatic jaundice
- skin allergic reaction
- hematologic reaction (blood reaction)
- gastrointestinal disturbances
- headache
- dizziness
- paresthesis (sensation of numbness or tingling on the skin)
- metalic taste

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).

Storage and Disposal of Diabitol Tablet **Storage**

Store below 25°C.Protect from light & moisture and KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

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

A white, uniform capsule shaped uncoated tablet with flat surface and break line.

Ingredients:

Active ingredient used is Glibenclamide5mg

Other ingredients used are Lactose, Purified Talc, Magnesium Stereate, parabean Corn starch

MAL No.: MAL19950084A

Manufacturer and Product Registration Holder:

SM PHARMACEUTICALS SDN.BHD (218628-M)

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Date of Revision: 20.8.2014