

"Gliclazide 80 mg"

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What GLYGARD is used for

GLYGARD (gliclazide) is used to keep blood sugar at the correct level in adults with type 2 diabetes mellitus when it is not controlled by diet, physical exercise and weight loss alone.

How GLYGARD works

Glygard (gliclazide) is one of a group of medicines called sulphonylureas. It is an oral hypoglycaemic agent (blood sugar lowering drug). Gliclazide lowers blood glucose by stimulating the release of insulin from functioning pancreatic beta cells.

Before you use GLYGARD

When you must not take it

- If you are allergic (hypersensitive) to gliclazide or any of the other ingredients of GLYGARD, to other medicines of the same group (same group(sulphonylureas) or other medicine that reduces the blood sugar and certain group of antibiotic such as sulphonamides)
- If you have type 1 diabetes mellitus
- If you have ketone bodies and sugar in your urine (this may mean you have ketoacidosis) or if you have diabetic pre-coma and coma
- •If you have severe kidney or liver disease
- •If you are taking miconazole (a treatment for fungal infections)
- •If you are breastfeeding

Before you start to take it

Follow your doctor's advice about diet and treatment. This is to reduce the chances of very low blood sugar (hypoglycaemia).

Make sure your doctor knows:

- •If you are going to have an operation, a serious injury, fever or infection, difficulty in eating.
- •If you plan a pregnancy or become pregnant
- •If you are taking medicines listed below

Taking other medicines

The effect of GLYGARD on your blood sugar levels may be changed by a number of other medicines.

Make sure to tell your doctor if you are taking any of the following medicines, as special care may be required

- You should not take GLYGARD with miconazole (a treatment for fungal infections)
- •Phenylbutazone (used to treat arthritis)
- •Other medicines used to treat high blood sugar (e.g. insulin)
- •Beta blockers (used to treat high blood pressure
- •H2 receptor antagonists for ulcers or dyspepsia
- •Chlorpromazine (used to treat disorders of the central nervous system)
- •Steroids (for treating a number of conditions including severe asthma and rheumatoid arthritis)
- •Anticoagulants to control blood clotting (e.g. warfarin)

Inform the medical staff in hospital that you are taking GLYGARD. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

How to take GLYGARD

How much to take

Always take GLYGARD exactly as your doctor has told you. You should check with you doctor or pharmacist if you are not sure. The usual dose is from one half to four tablets daily. This depend on the response to treatment. Your doctor will tell you how much to take.

When to take it

GLYGARD is usually supposed to be taken with the first main meal of the day. When the total daily dose exceeds two tablets, it should be divided into two equal doses taken morning and evening.

How long to take it

All treatment for diabetes is life-long

If you forget to take it

It is important to take your medicines every day as regular treatment works better. However, if you forget to take a dose of GLYGARD, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you take too much (overdose)

If you take too many tablets, contact your doctor immediately. The signs of overdose are those of low blood sugar (hypoglycaemia) described in **Side Effects.** The symptoms can be helped by taking sugar (4 to 6 lumps) or sugary drinks straight away, followed by a substantial snack or meal.

While you are using GLYGARD

Things you must do

- •Follow a regular diet: it is important to eat regular meals, including breakfast and never to miss or delay a meal
- •Take your medicine regularly
- •Check your blood glucose regularly as recommended by your doctor
- •Tell your dentist, other doctors and pharmacist that you are on this medicine

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Things you must not do

- •Drinking alcohol is not recommended as it can alter the control of your diabetes
- •GLYGARD is not recommended for use during pregnancy. If you are planning a pregnancy, or become pregnant, inform your doctor so that he/she may prescribe a more suitable treatment for you. You must not take GLYGARD while your are breastfeeding.

Things to be careful of

This medicine may cause episodes of low blood sugar (hypoglycaemia). This is more likely if:

- •you are on a strict diet
- •your diet is poorly balanced
- •you are taking prolonged or strenuosus exercise
- •you drink alcohol
- •if you are taking several medicines for high blood sugar (see Taking Other Medicines)

Side effects

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

Low blood sugar (Hypoglycaemia)

The most commonly observed side effect is low blood sugar (hypoglycaemia). If you have low blood sugar you may have the following symptoms: headache, intense hunger, nausea, vomiting, weariness, disorders, sleep restlessness, aggressiveness, concentration, reduced alertness and reaction time, depression, confusion, speech or visual disorders, tremor, sensory disturbances, dizziness, and helplessness.

The following signs and symptoms may also occur: sweating, clammy skin, anxiety, fast or irregular heartbeat, high blood pressure, sudden strong pain in the chest that may radiate

into nearby areas (angina pectoris). In most cases the symptoms of low blood sugar vanish very quickly when you consume some form of sugar, e.g. glucose tablets, sugar cubes, sweet juice, sweetened tea. You should therefore always carry some form of sugar with you (glucose tablets, sugar cubes). Remember that artificial sweeteners are not effective. Please contact your doctor or the nearest hospital if taking sugar does not help or if the symptoms recur.

Other side effects

- •Digestive disorders: Abdominal pain, nausea, vomiting, indigestion, diarrhea and constipation. These effects are reduced when GLYGARD is taken with a meal as recommended
- •Skin disorders: Skin reactions such as rash, redness, itching and hives have been reported.
- •Liver disorders: There have been isolated reports of abnormal liver function which can cause yellow skin and eyes. If you get this see you doctor immediately. The symptoms generally disappear if the drug is stopped. Your doctor will decide whether to stop your treatment.
- Symptoms of liver impairment (e.g. jaundice) have been observed which in most cases disappeared after withdrawal of the sulphonylurea, but may lead to life threating liver failure in isolated cases. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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 GLYGARD<u>Storage</u>

Store below 25°C

Disposal

Please ask you pharmacist on how to dispose unused / left medicines

Product Description

What it looks like?

White, circular, flat, beveled tablets with a break line on one side and other side plain.

Ingredients

Active ingredients Gliclazide

Inactive ingredients

Lactose, Povidone, Magnesium, Stearate, Talc, Microcrystalline Cellulose, Croscarmellose Sodium

MAL No. MAL20033670A

Manufacturer

Cipla Ltd, Maharastra, MIDC Patalganga, 410 220, District Raigad, Mahashrasra, India

Product Registration Holder

Cipla Malaysia Sdn Bhd Suite 1101, Amcorp Tower, Amcorp Trade Centre, 18 Persiaran Barat, 46050 Petaling Jaya Selangor

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