GLYADE TABLET

Gliclazide 80mg

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What Glyade is used for

The name of your medicine is Glyade. Glyade contains the active ingredient 'gliclazide'. Gliclazide belongs to a group of medicines called sulfonylureas (sometimes spelled "sulphonylureas"). The medicine releases the active ingredient gliclazide progressively over 24 hours.

Glyade is used to control blood glucose (sugar) in patients with Type II diabetes mellitus. This type of diabetes is also known as noninsulindependent diabetes (NIDDM), or maturity-onset diabetes.

Glyade is used when diet and exercise are not enough to control your blood glucose. Glyade can be used alone or together with insulin or other medicines for treating diabetes.

How Glyade works

Glucose is used by the body as fuel, and all people have glucose circulating in their blood. In diabetes, levels of blood glucose are higher than is needed, which is also known as hyperglycemia.

If your blood glucose is not properly controlled, you may experience hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose). High blood glucose can lead to serious problems with our heart, circulation and/or kidneys.

It is very important to control high blood glucose whether or not you feel unwell. This really helps to avoid serious long-term health problems, which can involve the heart, eyes, circulation, and/or kidneys.

Glyade is used when diet and exercise are not enough to control your blood glucose properly. It lowers blood glucose by increasing the amount of insulin (a hormone that controls blood glucose levels) produced by your pancreas.

As with many medicines used for the treatment of diabetes, there is a possibility that blood glucose levels may become very low during treatment with Glyade. This is known as hypoglycemia.

Glyade is available only with a doctor's prescription. Glyade is not addictive. Ask your doctor if you have any questions about why Glyade has been prescribed for you.

Before you use Glyade

There are some people who should not take Glyade. Please read the lists below. If you think any of these situations apply to you, or you have any questions, please consult your doctor, pharmacist, or diabetes educator.

When you must not use it

Do not take Glyade if you have an allergy to Glyade, sulfonylureas, related medicines such as sulfa antibiotics or to thiazide, diuretics (a type of "fluid" or "water" tablet) or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to these medicines may include:

- skin rash
- itching or hives

If you are not sure if you have an allergy to Glyade, check with your doctor.

Do not take Glyade if you have or have had any of the following conditions:

- Type 1 diabetes mellitus (also known as insulin-dependent diabetes (NIDDM), or juvenile onset diabetes).
- unstable diabetes
- you have diabetic ketoacidosis (a problem which affects the acidity of your blood and can lead to coma which is mainly associated with Type 1 diabetes).
- severe kidney disease
- severe liver disease

If you are not sure if you have any of the above, ask your doctor.

Do not take Glyade if you are pregnant or intend becoming pregnant. Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will usually replace Glyade with insulin while you are pregnant. Do not take Glyade if you are breastfeeding or plan to breastfeed. Glyade is not recommended while you are breastfeeding. It is not known whether Glyade passes into breast milk

Do not take Glyade after the expiry date (EXP) printed on the pack. If you take it after the expiry date has passed, it may not work as well.

Do not take Glyade if the packaging is torn or shows signs of tampering. If it is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should

If you are not sure whether you should start taking Glyade, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to:

- any of the ingredients listed at the end of this leaflet
- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you have had any of the following medical conditions:

• kidney disease

- liver disease
- a history of diabetic coma.
- adrenal, pituitary or thyroid problems

Tell your doctor if you have any medical condition, or do anything, that may increase the risk of hyperglycemia - for example:

- you are ill or feeling unwell (especially with fever or infection)
- you are injured
- you are having surgery.
- you are taking less Glyade than prescribed
- you are taking less exercise than normal
- you are eating more carbohydrate than normal.

Tell your doctor if you have any medical condition, or do anything, that may increase the risk of hypoglycemia - for example:

- drinking alcoholic drinks.
- not eating regular meals.
- taking more exercise than usual.

If you have not told your doctor, pharmacist or diabetes educator about any of the above, tell them before you start taking Glyade.

Taking other medicines

Tell your doctor, pharmacist or diabetes educator if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may lead to low blood glucose (hypoglycemia) by increasing the blood-glucose lowering effect of Glyade.

These include:

- other medicines used to treat diabetes (tablets and insulin)
- some medicines used to treat high blood pressure and other heart conditions
- some medicines for depression and other mental illness
- some medicines for high triglyceride levels
- some medicines used to treat arthritis, pain and inflammation
- some antibiotics

• some medicines used to prevent blood clots (warfarin and similar medicines)

You may need different amounts of your medicine or you may need to take different medicines. Your doctor, pharmacist or diabetes educator can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while taking Glyade.

Ask your doctor or pharmacist if you are not sure if you are taking any of these medicines.

How to take Glyade

Follow all directions given to you by your doctor, pharmacist, and diabetes educator carefully.

They may differ from the information contained in this leaflet.

How much to take it

If you do not understand the instructions on the box, ask your doctor or pharmacist for help. Your doctor will tell you how many tablets to take each day. The recommended starting dose is 40mg daily. Doses up to 160mg daily may be taken in a single dose. Doses more than 160mg should be taken in divided dose. The maximum recommended dose is 320mg daily

When to take it

Swallow the tablets with a glass of water. Glyade tablets can be broken. It is important to take your Glyade at the same time each day – usually with breakfast. For divided dose regimen, Glyade should be taken in the morning and evening. Taking Glyade with food can help to minimise the risk of hypoglycemia.

Do not skip meals while taking Glyade.

How long to take it

Continue taking Glyade for as long as your doctor recommends. Make sure you keep enough Glyade to last over weekends and holidays. Glyade will help control your diabetes but will not cure it. Therefore, you may have to take it for a long time.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as you remember (with food), then go back to taking your tablets as you would normally. Missed doses can cause high blood glucose (hyperglycemia)

If you are not sure whether to skip the dose, talk to your doctor or pharmacist. Do not take a double dose to make up for the dose you have missed. If you double a dose, this may cause low blood glucose (hypoglycemia)

<u>If you take too much (overdose)</u>

Immediately telephone your doctor for advice if you think that you or anyone else may have taken too much Glyade. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. If you take too much Glyade together with other medicines for diabetes or alcohol, you may experience symptoms of low blood glucose (hypoglycemia). If not treated quickly, these symptoms may progress to loss of co-ordination, slurred speech, confusion, loss of consciousness and fitting. At the first signs of hypoglycemia, raise your blood glucose quickly by following the instructions at the end of this leaflet. If you experience any of these symptoms, immediately get medical

While you are using Glyade

Things you must do

If you become pregnant while you are taking Glyade, tell your doctor. Tell all doctors, dentists, pharmacists and diabetes educators who are involved with your treatment that you are taking Glyade. If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking Glyade. Take Glyade exactly as your doctor has prescribed. Otherwise you may not get the full benefits from treatment.

Make sure you check your blood glucose levels regularly. This is the best way to tell if your diabetes is being controlled properly. Your doctor or diabetes educator will show you how and when to do this. Make sure that you, your friends, family and work colleagues can recognize the symptoms of hypoglycemia and hyperglycemia and know how to treat them. Visit your doctor regularly so that they can check on your progress. Carefully follow your doctor's and dietitian's advice on diet, alcohol drinking and exercise.

Tell your doctor immediately if you notice the return of any symptoms of hyperglycemia that you had before starting Glyade. These may include lethargy or tiredness, headache, thirst, passing large amounts of urine and blurred vision. These may be signs that Glyade is no longer working, even though you may have been taking it successfully for some time.

Things you must not do

Do not give Glyade to anyone else, even if they have the same condition as you.

Do not use Glyade to treat other complaints unless your doctor tells you to.

Do not stop taking Glyade, or change the dosage, without checking with your doctor.

Do not skip meals while taking Glyade.

Things to be careful of

If you drink alcohol while taking Glyade, you may get flushing, headache, rapid breathing, rapid heartbeat, chest pains. Protect your skin when you are in the sun, especially between 10am and 3pm. Glyade may cause your skin to be more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness, or severe sunburn. If your skin does appear to be burning, tell your doctor immediately. Be careful driving or operating machinery until you know how Glyade affects you. Also, be especially careful not to let

your blood glucose levels fall too low.

Glyade may cause dizziness and drowsiness in some people. Low blood glucose levels may also slow your reaction time and affect your ability to drive or operate machinery. A section at the end of this leaflet contains advice about recognizing and treating hypoglycemia. Drinking alcohol can make this worse. If either of these occurs, do not drive, operate machinery or do anything else that could be dangerous.

If you are travelling, it is a good idea to:

- wear some form of identification showing you have diabetes
- carry some form of sugar to treat hypoglycemia if it occurs, for example, sugar sachets or jelly heaps
- carry emergency food rations in case of a delay, for example, dried fruit, biscuits or muesli bars
- keep Glyade readily available

If you become sick with a cold, fever or flu, it is very important to continue taking Glyade, even if you fell unable to eat your normal meal. If you have trouble eating solid food, use sugar-sweetened drinks as a carbohydrate substitute or eat small amounts of bland food. Your diabetes educator or dietician can give you a list of foods to use for sick days.

Side effects

If you do not feel well while you are taking Glyade then tell your doctor, pharmacist, or diabetes educator as soon as possible.

All medicines can have side effects. Most of the time they are not serious but sometimes they can be. Glyade helps most people with Type 2 diabetes, but it may sometimes have unwanted side effects. These can include:

- Hypoglycemia
- Stomach upset with symptoms like feeling sick, heartburn, diarrhea or constipation.

Other side effects are usually mild when they occur. Do not be alarmed by this list of possible side effects. You may not experience any of them. However if you do - or if you notice anything else that is making you feel unwell - you should consult your doctor or pharmacist. Other uncommon side effects have been reported and you may wish to discuss this issue with your doctor, pharmacist, or diabetes educator.

If any of the signs below occur then tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital:

• Skin rash, itching and/or hives. These side effects are very rare but can become serious.

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 disposable of Glyade Storage

Keep your tablets in the pack until it is time to take them. Glyade will not keep as well outside its blister packaging.

Keep them in a cool dry place where the temperature stays below 30°C.

Do not store medicines in the bathroom or near a sink. Do not leave them in a car or on a windowsill. Heat and dampness can destroy some medicines.

Keep Glyade tablets where children cannot reach them.

A locked cupboard at least one-and ahalf meters above the ground is a good place to store medicines.

<u>Disposal</u>

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

Glyade tablets are white, flat beveled edged, marked with "GZ80" on one side with a double score on the other. Glyade tablets come in a blister strip. Pack size: Each box contains 100 tablets.

Ingredients

Each tablet of Glyade contains:

Active ingredient

Gliclazide 80mg

Inactive ingredients

Lactose, Microcrystalline cellulose Povidone K30, Sodium starch glycolate, Talc, Magnesium stearate

MAL NO.: MAL19990589AZ

Manufacturer

ALPHAPHARM PTY. LTD. Cnr. Garnet St. and Antimony St. Carole Park, 4300 Brisbane Old., AUSTRALIA

Product Registration Holder

Merck Sdn Bhd (178145-V) Level 3, Menara Sunway Annexe, Jalan Lagoon Timur Bandar Sunway 46150, Petaling Jaya Selangor Darul Ehsan

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