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What Glimicron Tablet is used for

Glimicron tablet is used for Non-Insulin Dependent Diabetes Mellitus (NIDDM).

How Glimicron Tablet works

Glimicron tablet belongs to a group of medicines called sulfonylureas.

These medicines lower blood glucose by promoting the release of insulin from pancreas.

If your blood glucose is not properly controlled, you may experience or hypoglycaemia (low blood glucose) or hyperglycaemia (high blood glucose).

Before you use Glimicron Tablet

- When you must not use it

Do not take Glimicron if you are allergic to:

- medicines containing gliclazide
- sulfonamide ("sulfa") antibiotics or "sulfa" medicines including sulfamethoxazole and acetazolamide
- any of the ingredients of this medicine

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing and shortness of breath.

Do not take Glimicron if you have any of the following medical conditions:

- Type 1 diabetes mellitus, also known as insulin dependent diabetes or juvenile onset diabetes
- unstable diabetes that is not well controlled
- diabetic ketoacidosis, or a history of repeated episodes of ketoacidosis (this a symptom of uncontrolled diabetes, in which substances called ketone bodies build up in the blood)
- diabetic coma or pre-coma, which may follow on from diabetic ketoacidosis mentioned above
- severe kidney disease
- severe liver disease
- acidosis
- burns
- diabetic coma
- infection
- ketosis
- surgery and trauma.

Risk-benefit should be considered when the following medical problems exist:

Adrenal insufficiency, pituitary insufficiency, fever, nausea, vomiting, thyroid function impairment, debilitated physical condition, hepatic function impairment, malnourishment, renal function impairment, sensitivity to oral antidiabetic agents and patients with acute porphyria.

Do not take Glimicron if you are pregnant or plan to become pregnant.

Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will replace Glimicron with insulin while you are pregnant.

Glimicron is not recommended while you are breastfeeding.

Do not give Glimicron to children. There is not enough experience with the use of Glimicron in children.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

- Before you start to use it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you have any medical conditions, especially the following:

- kidney problems
- liver problems
- glucose-6-phosphate dehydrogenase (G6PD) deficiency, a condition in which the body does not have enough of the enzyme G6PD
- a history of diabetic coma
- adrenal, pituitary or thyroid problems
- heart failure.

Tell your doctor if you:

- drink alcohol
- do not eat regular meals
- do a lot of exercise
- are ill or feeling unwell.

Alcohol, diet, exercise and your general health all strongly affect the control of your diabetes. Discuss these with your doctor.

If you have not told your doctor about any of the above, tell them before you start taking Glimicron.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

- Taking other medicines

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

Some medicines may be affected by Gliclazide, or may affect how well it works. These include:

- An odd interaction involves alcohol intolerance which is similar to disulfiram-alcohol interaction. There

is also an increased risk of hypoglycaemia with alcohol.

- Compounds that diminish the hypoglycaemia effect and thus necessitate an increase in the dosage requirement of the sulfonylurea include rifampicin and thiazide diuretics, corticosteroids and estrogens.
- Compounds that may increase the hypoglycaemic effect of sulfonylureas and necessitate a reduction in their dosage requirement include anti-infective agents such as chloramphenicol, guanethidine, monoamine oxidase inhibitors, salicylates, sulfonamides, trimethoprim, phenylbutazone, ketoconazole, miconazole, fluconazole, sulphinpyrazone and azapropazone.
- A reversible decrease in thrombocyte count in patients receiving ketotifen concomitantly with oral antidiabetic agents has been observed in a few cases. Concurrent administration of ketotifen should therefore be avoided.
- Beta-blockers may mask some of the symptoms of hypoglycaemia. Also, beta-blockers may have hypoglycaemic or hypoglycaemic actions of their own.
- The hypoglycaemic effect may be enhanced when administered concurrently with insulin.
- If administered concurrently with anticoagulants, increased plasma concentration of both the anticoagulants and sulfonylurea may occur initially, with continued therapy, decrease anticoagulant plasma concentrations and increased hepatic metabolism of the sulfonylurea may occur, dosage adjustments of the one or both medications may be required.

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

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have more information on medicines to be careful with or avoid while taking Glimicron.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist

How to use Glimicron Tablet

- How much to use

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.

The usual dose of Glimicron tablet 80 mg is half a tablet to one tablet daily.

Your doctor may increase this dose up to four tablets a day, depending on how you respond to Glimicron.

Doses of more than 2 tablets daily should be given in 2 divided doses.

Swallow the tablets with a glass of water.

- When to use it

Use as directed by your doctor or pharmacist.

Do not skip meals while taking Glimicron.

It does not matter if you take Glimicron before, during or after food.

However, it is important that you take it at the same time each day.

If you need to take more than two tablets per day, take them as two divided doses, in the morning and evening.

- How long to use it

Continue using Glimicron Tablet for the duration that the doctor recommends.

Keep taking Glimicron for as long as your doctor recommends.

Glimicron will help control diabetes but will not cure it. Most people will need to take Glimicron for a long period of time

- If you forget to use 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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

- If you use too much (overdose)

If you or someone else has taken too much gliclazide, contact your doctor or pharmacist immediately.

If you take too much gliclazide, you may experience symptoms such as:

- Nausea and vomiting
- Abdominal pain, (rarely) haematemesis and melaena
- Drowsiness, coma, twitching, convulsions
- Depressed limb reflexes with extensor plantar responses
- Hyperapnoea, acute pulmonary oedema
- Sinus tachycardia, hypotension, circulatory failure
- Absence of sweating
- Hypoglycaemia, hyperkalaemia, metabolic (lactic) acidosis, leucocytosis
- Late complication cholestasis jaundice

If not treated quickly, these symptoms may progress to loss of co-ordination, slurred speech, confusion, fits or loss of consciousness. At the first signs of hypoglycaemia, raise your blood glucose quickly by ingestion of a source of sugar.

Treatment includes:

- Emesis or gastric lavage, if appropriate. Administration of repeated doses of oral activated charcoal with appropriate cathartic may also be used.
- Supportive measures.
- 50ml of 50% glucose IV repeated as necessary and/or glucagon 1 – 2 mg IV to correct hypoglycaemia, followed by an IV infusion of 5 – 10% dextrose for 24 to 72 hours as necessary.
- Treat mild hypoglycaemia with immediate ingestion of a source of sugar.

While you are using it

- Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Glimicron.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Glimicron.

If you become pregnant while taking Glimicron, tell your doctor immediately.

Make sure that you, your friends, family and work colleagues can recognize the symptoms of hypoglycaemia and hyperglycaemia and know how to treat them.

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.

Carefully follow your doctor's and dietitian's advice on diet, drinking alcohol and exercise.

If you drink alcohol while taking Glimicron, you may get flushing, headache, breathing difficulties, rapid heart beat, stomach pains or feel sick and vomit.

The combination of alcohol and Glimicron also increases the risk of hypoglycaemia occurring.

Tell your doctor immediately if you notice the return of any symptoms of hyperglycaemia you have experienced before starting Glimicron.

These may include lethargy or tiredness, headache, thirst, passing large amounts of urine and blurred vision. These may be signs that Glimicron is no longer working, even though you may have been taking it successfully for some time.

- Things you must not do

Do not skip meals while taking Glimicron.

Do not stop taking Glimicron, or change the dose, without checking with your doctor.

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

- Things to be careful of

Be careful driving or operating machinery until you know how Glimicron affects you.

Glimicron may cause dizziness in some people. Drinking alcohol can make this worse. If either of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Be careful not to let your blood glucose levels fall too low. Low blood glucose levels may slow your reaction time and affect your ability to drive or operate machinery.

If you become sick with a cold, fever or flu, it is very important to continue taking Glimicron and eating your normal meals.

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 eat on sick days.

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

- wear some form of identification (e.g. bracelet) showing you have diabetes
- carry some form of sugar to treat hypoglycaemia if it occurs, for example, sugar sachets or jelly beans
- bring enough Glimicron with you, so you don't miss any doses

Side effects

All medicines can cause unwanted side effects. These effects can be serious but most of the time, they are mild and temporary.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Glimicron.

Glimicron helps most people with diabetes, but it may have unwanted side effects in some people.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor if you notice any of the following and they worry you:

- signs of hypoglycaemia which may include weakness, trembling or shaking, sweating, lightheadedness, headache, dizziness, irritability and tearfulness
- stomach upset including nausea (feeling sick), heartburn
- constipation or a feeling of fullness in the stomach
- headache
- tiredness, weariness.

Tell your doctor immediately if you notice any of the following:

- Gastro-intestinal disturbances such as nausea, vomiting, heart burn, anorexia, diarrhoea and a metallic taste are usually mild and dose-dependent.
- Skin rashes and pruritus
- Severe, prolonged and sometimes fatal hypoglycaemia
- Other severe effects may be manifestations of a hypersensitivity reaction which includes cholestatic anaemia, erythema multiforme or Stevens-Johnson syndrome, exfoliative dermatitis and erythema nodosum.
- A syndrome of inappropriate secretion of antidiuretic hormone (SIADH) characterized by water retention, hyponatraemia and central nervous effects may infrequently be induced.
- Photosensitivity

Tell your doctor if you notice anything that is making you feel unwell.

Other unwanted side effects not listed may occur. Tell your doctor immediately.

- Warning and Precautions

- Patients sensitive to one of the oral antidiabetic agents may be sensitive to others also.
- Oral antidiabetic agents must not be used during pregnancy. Abnormal blood glucose levels have been associated with a higher incidence of congenital abnormalities during early pregnancy, and with increase perinatal morbidity and mortality later in pregnancy.
- It should not be used in insulin-dependent diabetes mellitus.
- It should not be given in severe impairment of renal or hepatic function because of an increased risk of hypoglycaemia or severe impairment of thyroid function.
- Its antidiuretic effect may cause problems in patients with conditions associated with fluid retention.

- It is not known whether gliclazide is excreted in breast milk. However other sulphonylureas have been found in breast milk and there is no evidence to suggest that gliclazide differs from the group in this respect.
- Geriatric patients and patients with renal insufficiency may be more sensitive to effects of this medication because of reduced metabolism and excretion. Dosage should therefore be initiated at a lower level and adjusted cautiously. In the elderly, hypoglycaemia may be more difficult to recognize and may cause more neurological symptoms. These symptoms include anxiety, confusion, difficulty in concentrating, drowsiness, nervousness or unusual tiredness.
- Dental: The leukopenic and thrombocytopenic effects of sulphonylureas may result in an increase incidence of microbial infection, delayed healing and gingival bleeding. If leukopenia or cytopenia occurs, dental work should be deferred until blood counts have returned to normal. Patients should be instructed in the proper oral hygiene required during this period. This includes cautions use of regular toothbrushes, dental floss and toothpicks.
- Cross-sensitivity to other sulphonylureas or thiazide-type medications may also occur

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npa.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Glimicron Tablet

- Storage

Keep out of reach of children. Store below 30°C. Protect from moisture.

- Disposal

No specific instructions. Please ask your pharmacist how to dispose unused medicines properly.

Product Description

- What it looks like

Round, 8.0mm in diameter, white uncoated tablet, flat faces, bevel-edged, cross score embossed on one face

- Ingredients

- Active ingredient
Gliclazide

- Inactive ingredients
Magnesium Stearate
Microcrystalline Cellulose
Lactose Monohydrate
Polyvinylpyrrolidone K-25
Sodium Starch Glycolate

- MAL number:

MAL19960983AZ

Manufacturer

HOVID Berhad
Lot 56442, 7 ½ Miles
Jalan Chemor, 31200 Chemor, Perak,
Malaysia.

Product Registration Holder

HOVID Berhad
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Date of revision

09 September 2021

Serial Number:

NPRA(R2/1)210906/740