

DIAMITEX TABLET

Gliclazide (80mg)

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What DIAMITEX TABLET is used for

DIAMITEX TABLET is used to control blood glucose in patients with Type II diabetes mellitus.

This type of diabetes is also known as non-insulin-dependent diabetes mellitus (NIDDM) or maturity onset diabetes.

DIAMITEX is used when diet and exercise are not enough to control your blood glucose.

DIAMITEX can be used alone, or together with other medicines for treating diabetes.

How DIAMITEX TABLET works

DIAMITEX TABLET contains gliclazide and belongs to a group of medicines called the sulfonylureas.

DIAMITEX lowers high blood glucose by increasing the amount of insulin produced by your pancreas. 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. This is called hyperglycaemia.

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.

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 DIAMITEX. This is known as hypoglycaemia.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you use DIAMITEX TABLET

- When you must not use it

Do not use DIAMITEX TABLET if you are allergic to gliclazide or any of the other ingredients listed at the end of the leaflet.

Do not take this medicine if you have had an allergic reaction to:

- gliclazide or other sulfonylureas
- antibiotics called sulfonamides
- thiazide diuretics (a type of "fluid" or "water" tablet).
- any of the ingredients listed at the end of this leaflet

Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint pain; or rash, itching or hives on the skin.

If you are not sure if you have an allergy to any of the above, check with your doctor.

Do not take DIAMITEX if you are using miconazole to treat fungal infections.

You should not take DIAMITEX in combination with medicines called phenylbutazone or danazol.

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

- Type I diabetes mellitus (insulin dependent diabetes mellitus, also known as IDDM, or juvenile or growth onset diabetes)
- unstable or brittle diabetes
- diabetic acidosis
- diabetic coma or pre-coma
- a history of repeated ketoacidosis or coma
- severe kidney disease
- severe liver disease.
- If you are not sure if you have any of the above, ask your doctor.

- Before you start to use it

Before taking DIAMITEX TABLET, you must tell your doctor or pharmacist if you have, or have had, any of the following conditions:

- Allergies to any other medicines and other substances such as foods, preservatives or dyes.
- Kidney problems
- Liver problems
- A growth in your pancreas, called an insulinoma
- A history of diabetic coma
- Adrenal, pituitary or thyroid problems.
- Heart failure

If you are not sure if you have, or have had, any of these conditions, you should raise

those concerns with your doctor or pharmacist.

Pregnancy

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication.

Do not take DIAMITEX if you are pregnant or planning to become pregnant.

DIAMITEX may affect your developing baby if you take it during pregnancy. Your doctor will usually replace DIAMITEX with insulin while you are pregnant.

Breastfeeding

Ask for your doctor's advice if you are breastfeeding, or likely to breastfeed during your course of medication.

Do not take DIAMITEX if you are breast-feeding or plan to breast-feed.

It is not known whether DIAMITEX passes into human breast milk.

- Taking other medicines

Inform your doctor or pharmacist before taking DIAMITEX TABLET.

Before using DIAMITEX TABLET, it is important to tell your doctor or pharmacist if you are taking any other medicines, obtained with or without a doctor's prescription.

Some medicines and gliclazide may interfere with each other. These include:

- Other medicines used to treat diabetes (tablets and insulin)
- Some medicines used to treat high blood pressure and other heart conditions such as beta-blockers, ACE inhibitors
- Some hormones used in hormone replacement therapy and oral contraceptives (oestrogens and progestogens)

- Monoamine oxidase inhibitors (MAOIs), used for treating depression, Parkinsons Disease or infections
- Some medicines used for mental illness (e.g. chlorpromazine) some medicines for epilepsy such as phenobarbitone
- clofibrate, a medicine for lowering cholesterol
- some medicines used to treat arthritis, pain and inflammation (oxyphenbutazone, phenylbutazone, high dose salicylates)
- antibiotics called sulfonamides, or chloramphenicol
- miconazole, or fluconazole, used to treat fungal infections
- some medicines used to prevent blood clots (warfarin and similar medicines)
- cimetidine, used to treat acid reflux and stomach ulcers
- steroid medicines called glucocorticoids (e.g. prednisolone, cortisone)
- some medicines for hormonal disturbances (such as danazol)
- salbutamol and terbutaline, medicines for asthma
- diuretics, also known as fluid

Remember to keep checking your blood glucose levels.

You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor, pharmacist or diabetes educator can tell you if you are taking any of these medicines. They may also have more information on medicines to be careful with or avoid while taking DIAMITEX.

Drinking alcohol can also affect your blood sugar levels and how well DIAMITEX works. If taken with DIAMITEX, it can also cause flushing of the face, throbbing headache, giddiness, fast breathing, fast heart rate, angina, stomach pains or feeling sick or vomiting.

Other interactions not listed above may also occur.

How to use DIAMITEX TABLET

- How much to use

Follow the instructions carefully. If you do not understand the instructions on the label, ask your doctor, or pharmacist for help.

Dosage should be initiated at 40 mg (½ tablet) daily and may be increased if necessary, to 320 mg (4 tablets daily). Doses up to 160 mg daily may be taken in a single daily dose but preferably at the same time each morning.

Doses in excess of 160mg should be taken in divided doses in the morning and evening. The dosage will depend on the severity of the glycaemia with ongoing adjustments made in order to obtain the optimal response at the lowest dosage.

Transferring to Gliclazide: Patients who have been previously treated with sulphonylureas or biguanides alone or in combination may be transferred to Gliclazide. When Gliclazide is administered as sole therapy (e.g. biguanides and sulphonylureas), careful observation is essential during the transitional phase. It is not generally recommended that insulin treated patients be transferred to Gliclazide.

The dose may need to be titrated if a patient has been switched from a different brand of product containing Gliclazide.

- When to use it

Use as directed by your doctor or pharmacist. Dose should be taken twice daily, one in the morning and one in the evening during meals.

- How long to use it

Continue taking DIAMITEX TABLET as your doctor recommended. If symptoms persist, consult your doctor.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

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.

If you take too much DIAMITEX you may experience symptoms of hypoglycaemia (low blood glucose).

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 hypoglycaemia (low blood glucose), raise your blood glucose quickly by taking jelly beans, sugar or honey, (non-diet) soft drink or glucose tablets.

While you are using DIAMITEX TABLET

- Things you must do

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

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

- Things you must not do

Do not take more than the recommended dose unless your pharmacist or doctor tells you.

Do not take any new medicines without consulting your doctor or pharmacist.

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

Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to.

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

Do not skip meals while taking DIAMITEX.

- Things to be careful of

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

DIAMITEX may cause dizziness and drowsiness in some people.

Drinking alcohol can make this worse. If either of these occurs, 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.

Side effects

Like all medicines, DIAMITEX TABLET can cause side effects, although not everybody gets them. If side effects persist, do not take the medicine and refer to the doctor.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- stomach upset including nausea and vomiting (feeling or being sick), heartburn, diarrhoea, constipation or a feeling of fullness in the stomach
- weariness
- dizziness or giddiness
- headache
- mild rash.
- Hypoglycaemia or
- Hyperglycaemia
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- signs of anaemia such as tiredness, being short of breath and looking pale
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin.

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

- Severe rash or itching of the skin (this could mean that you are allergic to gliclazide)
- yellowing of the skin or eyes, also called jaundice
- Vomiting blood or passing bloody or black, tarry stools
- Angina

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines

(ConSERF) or Vaccines
(AEFI)]

Storage and disposal of DIAMITEX TABLET

- Storage

Store below 30°C. Protect from light. Keep 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. These measures will help to protect the environment.

Product description

- What it looks like

A 8 mm round tablet, white in colour with double scored at one side and plain at another side.

- Active Ingredients

Active ingredient:

- Gliclazide

Other Ingredients:

- Aerosil
- Lactose
- Cornstarch
- Magnesium Stearate
- Polyvinylpyrrolidone
- Promigel

- MAL number

MAL19950414AZ

Manufacturer and Product Registration Holder

Duopharma (M) Sdn. Bhd.
Lot. 2599, Jalan Seruling 59,
Kawasan 3, Taman Klang Jaya,
41200 Klang, Selangor Darul
Ehsan, Malaysia

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