DIATICA TABLET

Gliclazide 80mg

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What DIATICA is used for

DIATICA is used for the treatment of Type 2 (non-insulin dependent) diabetes mellitus particularly where diet and exercise changes alone have not been sufficient to control it.

How DIATICA works

DIATICA is an oral anti-diabetic drug belonging to a group of medicines called sulphonylureas. It acts by reducing the blood sugar levels in the body.

Before you use DIATICA

- *When you must not use it*

Do not take DIATICA if:

- You are allergic (hypersensitive) to gliclazide or any of the other ingredients of DIATICA, to other medicines of the same group (Sulphonylureas), or to other related medicines (Hypoglycaemic Sulphonamides).
- If you have insulin-dependent diabetes (type 1).
- If you have ketone bodies and sugar in your urine (this means you have diabetic ketoacidosis), a diabetic pre-coma or coma.
- You are under the age of 14 and suffer from juvenile onset diabetes (diabetes which start in childhood).
- You are diabetic and undergoing surgery, after trauma or during serious infections
- You have severe kidney or liver disease/failure
- You experience symptoms of hypoglycemia (low blood sugar) such as sweating, pallor, hunger, irregular heartbeats.
- You take Miconazole (for fungal infections). (see section "Taking other medicines").
- If you are pregnant or breast – feeding (see section "Pregnancy and breast-feeding).

If you think any of these situations applies to you, or if you have any questions or doubts about taking DIATICA Tablets, then you should consult your doctor or pharmacist.

- *Before you start to use it*

- You may have hypoglycaemia: All sulphonylureas are capable of causing this especially in the following conditions: in patients controlled with diet alone, overdose, low calorie/glucose intake, in patients with kidney/liver impairment.

You should observe the treatment plan prescribed by your doctor to achieve proper blood sugar levels. This means, apart from regular tablet intake, you observe the dietary regimen, have physical exercise and, where necessary, reduce weight.

During DIATICA treatment regular monitoring of your blood (and possibly urine) sugar level and also your glycated haemoglobin (HbA1c) is necessary.

Pregnancy and breast-feeding

DIATICA Tablets is not recommended for use in pregnancy. if you are pregnant, or planning to become pregnant, inform your doctor so that he may prescribe a more suitable treatment for you.

You must not take DIATICA tablets while you are breast feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Your ability to concentrate or react may be impaired if your blood sugar is too low (hypoglycaemia), or too high (hyperglycaemia) or if you develop visual problems as a result of such conditions. Bear in mind that you could endanger yourself or others (e.g. when driving a car or using machines).

Please ask your doctor for further advise if you wish to drive a car or use the machinery.

- *Taking other medicines*

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor if you are taking any of the following:

The following medicines may enhance the blood sugar lowering effect of this medicine and therefore increase the chance of low blood sugar (hypoglycaemia). If you start treatment with any of these your dose of DIATICA Tablets may therefore need to be decreased:

- Medicines to treat high blood pressure or heart failure or irregular heartbeats (Beta-blockers, Antiarrhythmics e.g. captopril, enalapril, propranolol, disopyramide)
- Medicines to treat ulcers in the stomach or duodenum (Antiulcer e.g. cimetidine).
- Medicines used to reduce high blood fat levels (Lipid lowering agents e.g. clofibrate).
- Medicines to treat depression (MAOI antidepressants, e.g. phenelzine).
- Medicines to treat fungal infections (Antifungals e.g. miconazole, fluconazole).
- Other medicines used to treat high blood sugar (Oral antidiabetics or insulin).
- Painkiller or antirheumatics (e.g. phenylbutazone, azapropazone, ibuprofen, aspirin).
- Sulphonamide antibiotics, e.g. sulfamethoxazole, co-trimoxazole.
- Antibacterials including tetracycline compounds, sulphonamides and chloramphenicol

The following medicines may increase blood glucose levels. If you start treatment with any of these your dose of DIATICA Tablets may therefore need to be increased:

- Medicines to treat disorders of the central nervous system (Antipsychotics e.g. Chlorpromazine, Olanzapine).
- Medicines reducing inflammation (Corticosteroids, e.g. Hydrocortisone, Prednisolone).
- Medicines which increase urine flow (Diuretics, especially thiazide diuretics, e.g. Bendroflumethiazide).
- Oral contraceptives e.g. Oestrogens and Progesterones.

How to use DIATICA

- *How much to use*

Always take DIATICA Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is as mentioned below:

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

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Adults:

The total daily dose may vary to four tablets daily taken orally. The dose may be increased by your doctor if your blood sugar level does not come down enough.

You should not take more than two tablets at a time. When higher dose is required, you will be given DIATICA tablets in divided doses twice a day.

Elderly:

The total daily dose may vary to four tablets daily taken orally. The dose may be increased by your doctor if your blood sugar level does not come down enough.

You should not take more than two tablets at a time. When higher dose is required, you will be given DIATICA tablets in divided doses twice a day. Extra care is required due to a possible age-related increased risk of hypoglycaemia.

Obese: Additional therapy may also be required.

Children

DIATICA tablets should not be used in children.

- *When to use it*

These tablets should be taken as instructed, followed by a glass of water.

- *How long to use it*

You should continue to take these tablets for as long as your doctor tells you to.

Treatment for diabetes is usually life-long.

- *If you forget to use it*

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose and just carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking DIATICA Tablets

You should continue to take these tablets for as long as your doctor tells you to as your diabetes will not be controlled if you stop your medication.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

- *If you use too much (overdose)*

If you or someone else swallows several of these tablets all together, or you think a child has swallowed any of these tablets, contact your doctor or pharmacist or hospital emergency department immediately. Always take any tablets left over with you, also the box and leaflet as this will allow easier identification of the tablets.

The symptoms to be expected of overdose are those of low sugar in the blood (hypoglycaemia) Symptoms include sweating, pale colour of the skin (pallor), hunger pangs, Increased heart beats(tachycardia) and malaise. These symptoms can be helped by taking glucose or sweet drinks.

While you are using it

- *Things you must do*

Take DIATICA Tablets exactly as your doctor has told you.

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

- *Things you must not do*

Do not stop taking this medicine until advised by your doctor.

Do not give DIATICA to others although they might have the same symptoms or condition as you.

- *Things to be careful of*

Additional information for the patient on DIATICA Therapy

In the first few weeks of treatment the risk of having reduced blood sugar levels (hypoglycaemia) may be increased. So particularly close medical monitoring is necessary.

Low blood sugar (Hypoglycaemia) may occur for the following reasons:

- if you take meals irregularly or skip meals altogether,
- if you are fasting,
- if you are malnourished,
- if you change your diet,
- if you increase your physical activity and carbohydrate intake does not match this increase,
- if you take too high doses of DIATICA,
- if your kidney function or liver function is severely decreased.

If you have low blood sugar you may have the following symptoms: headache, intense hunger, nausea, vomiting, weariness, sleep, disorders, restlessness, aggressiveness, poor 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 heart beat, high blood pressure and sudden strong pain in the chest that may radiate into nearby areas (angina pectoris).

If blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop convulsions, lose self-control, your breathing may be shallow and your heart beat slowed down, you may become unconscious.

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 symptom reoccurs.

Symptoms of low blood sugar may be absent, less obvious or develop very slowly or you are not aware in time that your blood sugar level has dropped.

Symptoms of high blood sugar (hyperglycaemia) may occur when DIATICA has not yet sufficiently reduced the blood sugar, when you have not complied with the treatment plan prescribed by your doctor or in special stress situations). These may include thirst, frequent urination, dry mouth, dry itchy skin, skin infections and reduced performance.

If these symptoms occur, you must contact your doctor or pharmacist.

Side effects

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

The most commonly observed side effect is low blood sugar (hypoglycaemia). For symptoms and signs see *Before you start to take it* and *Things to be careful of.*

If left untreated these symptoms could progress to drowsiness, loss of consciousness or possibly coma. If an episode of low blood sugar is severe or prolonged, even if it is temporarily

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controlled by eating sugar, you should seek immediate medical attention

If you experience any of below mentioned side effects, stop taking the tablets and contact your doctor immediately. The symptoms generally disappear if the medicine is stopped. Your doctor will decide whether to stop your treatment.

- Abnormal liver function which causes yellowing of the skin and eyes (jaundice).
- Inflammation of the liver (hepatitis).

The other possible side effects are as below.

Skin disorders

Allergic skin reactions such as

- Rash
- Redness
- Itching
- Hives
- pruritis

Severe reactions may also appear.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 DIATICA

- Storage

Keep out of the reach and sight of children.

Do not store above 30ºC. Store in the original package.

Do not use your tablets after the expiry date stated on the label or carton.

- 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*

White to yellowish uncoated tablets, with a break line on one side.

Ingredients

- *Active ingredient (s)*
  Gliclazide
- *Inactive ingredients*

  Colloidal anhydrous silica, magnesium stearate, purified talc, crosscarmellose sodium, lactose, maize starch and purified water.

MAL number:

MAL20033485A

Manufacturer
Unique Pharmaceutical Labs.

218/219, GIDC, Panoli
394 116, India.

Product Registration Holder

Unimed Sdn Bhd

No 53, Jalan Tembaga SD 5/2B,
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52200 Kuala Lumpur.

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July 2024

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