Pfizer Confidential

MINIDIAB® TABLET

Glipizide (5 mg)

PIL Title: Minidiab

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Reason for change: To align as per new PIL template and effective Malaysia LPD.

Update as per BOH request and add NPRA number

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What is in this leaflet

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What Minidiab is used for

Minidiab is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

How Minidiab works

Minidiab stimulates insulin secretion from the pancreas in response to a meal and potentiates insulin action.

Before you use Minidiab

- When you must not use it

Minidiab is contraindicated in patients with:

- 1. Hypersensitivity to glipizide or any excipients in the tablets.
- 2. Type 1 diabetes mellitus, diabetic ketoacidosis, diabetic coma.

Pregnancy and lactation:

Minidiab should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Although it is not known whether Minidiab is excreted in human milk, some sulfonylurea drugs are known to be excreted in human milk.

Do not take Minidiab if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Minidiab if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Be sure to tell your doctor if:

- You have been told you are allergic to glipizide or any of the ingredients in Minidiab.
- You have insulin dependent (Type I) diabetes.
- You suffer from Glucose-6-Phosphate Dehydrogenase deficiency (abnormal destruction of your red blood cells)
- You have ketone bodies and sugar in your urine (this may mean you have ketoacidosis).
- You have liver or kidney problems
- You have thyroid problems
- You are about to have major surgery or you have recently suffered a severe illness or infection. At such times diabetic control may be lost.
- You are pregnant or trying to become pregnant
- You are breast feeding
- You are taking other medicines (See section <u>"Taking other medicines"</u>.)

If any of the above applies to you this medicine may not be suitable for you to use. Your doctor will advise you.

- Taking other medicines

A number of medicines may interact with Minidiab and affect diabetic control. You should tell your doctor if you are taking any of these medicines or any other medicines which you are unsure about:

- Anti-inflammatory agents (used to treat muscle and joint pain)
- Salicylates, such as aspirin (used as a pain killer).
- Sulphonamides (used to treat bacterial infections)
- Chloramphenicol (an antibiotic used to treat bacterial infections)
- Probenecid (used to treat gout, or sometimes given with an antibiotic).
- Quinolones (used to treat bacterial infections)

- Coumarins (used to prevent blood clots).
- Monoamine oxidase inhibitors (used to treat depression)
- Beta-blockers (used to treat high blood pressure and certain heart conditions)
- Diuretics (water tablets)
- Steroids
- Phenothiazines (used to treat psychiatric conditions)
- Thyroid products (used to treat patients with low production of thyroid hormones).
- Oestrogens, progestogens and oral contraceptives
- Phenytoin (used to treat epilepsy)
- Nicotinic acid (used to lower cholesterol and other lipid levels)
- Sympathomimetics, such as nasal decongestants and bronchodilators (used to treat asthma).
- Miconazole products (used to treat fungal infections).
- Fluconazole (used to treat fungal infections)
- Voriconazole (used to treat fungal infections)
- Angiotensin Converting Enzyme Inhibitors (ACEI): used to treat high blood pressure.
- Calcium channel blocking drugs (used to treat angina and high blood pressure).
- Cimetidine (prevents acid production in stomach) used to treat stomach and duodenal ulcers, and other digestive disorders
- Isoniazid (used to treat tuberculosis)
- Alcoholic drinks (wine, beer, spirits) may upset diabetic control.

How to use Minidiab

- How much to use

The dose is decided by your doctor and adjusted individually to you.

The recommended starting dose is 5 mg/day, given before breakfast or the mid-day meal.

Elderly patients and other patients at risk for hypoglycemia may be started on 2.5 mg.

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Some patients may be effectively controlled on a once-a-day regimen. The maximum recommended single dose is 15 mg. If this is not sufficient, splitting the daily dosage may prove effective.

Doses above 15 mg should ordinarily be divided. Total daily dosage above 15 mg should ordinarily be divided.

Total dosage above 30 mg has been safely given on a twice-a-day basis to long-term patients.

Patients can usually be stabilized on a dosage ranging from 2.5 mg to 30 mg daily. The maximum recommended daily dosage is 40 mg.

- When to use it

Use as directed by your doctor or pharmacist.

The tablets should be taken 30 minutes before the meal.

- How long to use it

Do not stop taking the tablets or adjust your dosage without seeing your doctor.

- If you forget to take it

If you miss a tablet take one before your next meal.

- If you use too much (overdose)

If you accidentally take too many tablets seek medical advice immediately. If you suffer faintness, confusion, sweating or shaking these may be symptoms of low blood sugar. You should eat or drink something sugary. If fits or loss of consciousness occur, call urgently for medical assistance.

While you are using it

- Things you must do

It is important that you eat regular meals, follow your doctor's advice about the foods you eat, take regular exercise and test your blood glucose regularly.

Regular carbohydrate intake is important to avoid a hypoglycaemic event.

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

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

- Things you must not do

Do not stop taking the tablets or adjust your dosage without seeing your doctor. Stopping the medicine may make the diabetes worse.

- Things to be careful of

Driving and using machines

All diabetic patients who drive need to be particularly careful to avoid hypoglycaemia (See section "Side effects").

If you are affected do not drive or operate machinery.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Common side effects which may affect more than 1 person in 100 are listed below

- Low blood sugar
- Nausea
- Diarrhoea
- Stomach pain

It is important to tell your doctor or pharmacist if you suffer any other undesirable effects which are not listed above. You may report any side effect or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Consumer -> Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI))).

Storage and Disposal of Minidiab

- Storage
 - Store below 30°C.
 - Keep all medicines out of the reach of children.
 - Please refer to outer carton for shelf-life

- Disposal

For environmental and safety reasons, any remaining or expired medicine from patients should be given to the pharmacy for disposal.

Product Description

- What it looks like

Minidiab is available as 5 mg scored tablets.

- Ingredients

- Active ingredient(s):
 Minidiab contains glipizide as the active ingredient.
- Inactive ingredients:
 Minidiab tablets include the
 following inert ingredients: starch,
 microcrystalline cellulose, stearic
 acid and lactose.

- MAL number(s):

MAL19913361AZ

Manufacturer

Pfizer Italia S.r.l 63046 Marino Del Tronto Ascoli Piceno, Italy

Product Registration older

Pfizer (Malaysia) Sdn. Bhd., Level 9-2, 10 & 11, Wisma Averis,

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Tower 2, Avenue 5, Bangsar South, No.8, Jalan Kerinchi, 59200 Kuala Lumpur, Malaysia

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