

GLUCODEX TABLET

Gliclazide (80mg)

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What GLUCODEX is used for

GLUCODEX is a medicine used to lower blood glucose level in adult patients with type 2 diabetes mellitus when proper diet, physical exercise, and weight loss are not sufficient to control blood glucose.

How GLUCODEX works

GLUCODEX is an antidiabetic agent belongs to a subfamily of medicines called sulfonylureas. It stimulates insulin secretion by the pancreas in the body.

Insulin is made by special cells in the pancreas known as beta cells. In type 2 diabetes you either do not make enough insulin for your body's needs, and/or the cells in your body are not able to use the insulin properly.

By stimulating the beta cells in the pancreas, GLUCODEX causing more insulin to be produced and this helps to decrease the amount of sugar in your blood.

Before you use GLUCODEX

- When you must not use it

Do not take GLUCODEX if:

- You have insulin-dependent diabetes or experienced of diabetes coma.
- You are diabetic patients with acidosis (an accumulation of acid in the body) and ketosis (where the body converts fat into energy) complications.
- You are about to undergo surgery, or if you have severe trauma or infection.
- You have diabetes mellitus which occurred during childhood or growing period.

- You have ever had an allergic or hypersensitivity reaction to gliclazide or to other sulfonylureas.

Pregnancy and lactation

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

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

- Before you start use it

Talk to your doctor or pharmacist if:

- You have liver or kidney problems.
- You take other medicines (anticoagulants) at the same time with GLUCODEX.
- You suffer from acute complications such as trauma, fever or surgery, hypoglycemia, dietary restriction.

- 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.

The blood sugar lowering effect of GLUCODEX may be strengthened and signs of low blood sugar level (hypoglycemia) may occur when one of the following medicines is taken:

- Antibiotics: sulphonamides (such as sulphafurazole or sulfisoxazole, sulfafenazole), tetracycline and its derivatives, chloramphenicol.
- Miconazole.
- Cimetidine.
- Monoamine oxidase inhibitor.
- Pain killer: phenylbutazone, oxyphenbutazone, aspirin.
- Clofibrate.
- Disopyramide.

The symptoms of hypoglycemia may be masked when you take medicines which inhibit β -adrenoreceptor such as

propranolol at the same time with GLUCODEX.

The blood sugar lowering effect of GLUCODEX may be weakened and raised blood sugar level (hyperglycemia) may occur when one of the following medicines is taken:

- Phenothiazine and its derivatives.
- Corticosteroids.
- Oral contraceptives.
- Thiazide diuretics.
- Thyroid hormone medicines.
- Coumarin anticoagulants.

How to use GLUCODEX

- How much to use

Adults and elderly:

The initial dose is 40 to 80 mg ($\frac{1}{2}$ or 1 tablet) a day. Dosage can be increased until daily dose reached 240 mg, especially in severe diabetic patients.

Do not take more than 160 mg as a single dose. In certain cases, daily dosage can be increased up to 320 mg, given in divided doses (2 times a day).

Children:

Not recommended for use in children.

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.

- When to use it

You should take GLUCODEX orally each day before breakfast.

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking GLUCODEX for as long as your doctor recommends.

- 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.

Signs of an overdose include symptoms of low blood sugar such as sweating, trembling, weakness, double vision, palpitations, confusion.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

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

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

It is important for you to eat regular meals. Avoid sugary foods and reduce the amount of fat and salt in your food. Eat more fruit and vegetables, fibre-rich starchy foods, and oily fish. Consult your doctor or pharmacist or dietitian's to get some advice about eating a well-balanced, healthy diet.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

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

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

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

Mild side effects: nausea, vomiting, gastric pain, headache.

Skin reactions: rash, pruritus, urticaria, erythema, flushing.

Hypoglycemic symptoms: sweating, dizziness, tremor, visual disturbances, intense hunger, slurred speech, weakness, poor concentration, confusion. These may occur in the presence of overdose in irregular diet.

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

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 Disposal of GLUCODEX

- Storage

Keep out of the reach and sight of children.

Store in a dry place below 30 °C. Protect from light.

- 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

GLUCODEX is round, white tablet, with beveled edge surfaces. It is odorless, tasteless, and printed a breakline on side I and "DEXA" on side II.

- Ingredients

- Active ingredient
Gliclazide

- Inactive ingredients
Calcium hydrogen phosphate (CaHPO₄), lactose, corn starch, primojel, sodium lauryl sulfate, starch 1500, magnesium stearate, talc, purified water.

- MAL number:

MAL 19991352A

Manufacturer

PT Dexa Medica
Jl. Jenderal Bambang Utoyo 138
Palembang-Indonesia

Product Registration Holder

Pharmaforte (Malaysia) Sdn. Bhd.
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Date of revision

11/9/2014

Serial Number

BPFK(R4/1)110914/00014