

AXCEL GLIMEPIRIDE-2MG TABLET

Glimepiride (2mg)

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What Axcel Glimepiride-2mg Tablet is used for

Axcel Glimepiride-2mg Tablet is used as an adjunct to diet and exercise in Non-Insulin-Dependent (Type II) diabetes, whenever blood sugar levels cannot be controlled adequately by diet, physical exercise and weight reduction alone.

How Axcel Glimepiride-2mg Tablet work

Glimepiride is an orally active hypoglycaemic substance (blood sugar lowering drug) belonging to the sulfonylurea group (medication that control blood sugar level). Glimepiride acts mainly by stimulating insulin release from the pancreas.

Before you use Axcel Glimepiride-2mg Tablet

– When you must not use it

Do not take Axcel Glimepiride-2mg Tablet if:

- If you are having allergy to any component of this medication.
- If you are allergic to other sulfonylureas or sulfonamides.
- If you have heart, liver or kidney disease, an enzyme deficiency (G6PD), adrenal or pituitary gland problems, or if you are under-nourished.
- If it is not prescribed by a qualified doctor or pharmacist.
- If you are pregnant, trying to get pregnant or think you may be pregnant.

- If you are breast-feeding.

– Before you start to use it

You need to tell your doctor:

- If you are allergic to any medicines, food and dyes.
- If you are taking any other medicines (including those not prescribed by your doctor).
- If you are having renal failure.
- If you are pregnant and nursing babies.

– Taking other medicines

You should tell your doctor if you are taking any medicine as it may interact with your Axcel Glimepiride-2mg Tablet including:

- Phenylbutazone, azapropazone and oxyfenbutazone.
- Insulin and oral antidiabetic products, such as metformin
- Salicylates and p-amino-salicylic acid
- Anabolic steroids and male sex hormones
- Chloramphenicol, certain long acting sulfonamides, tetracyclines, quinolone antibiotics and clarithromycin
- Coumarin anticoagulants
- Fenfluramine
- Fibrates
- ACE inhibitors
- Fluoxetine, MAO-inhibitors
- Allopurinol, probenecid, sulfinpyrazone
- Sympatholytics
- Cyclophosphamide, trophosphamide and iphosphamides
- Miconazole, fluconazole
- Pentoxifylline (high dose parenteral)
- Tritoqualine
- Oestrogens and progestogens
- Saluretics, thiazide diuretics
- Thyroid stimulating agents, glucocorticoids
- Phenothiazine derivatives, chlorpromazine
- Adrenaline and sympathicomimetics

- Nicotinic acid (high dosages) and nicotinic acid derivatives
- Laxatives (long term use)
- Phenytoin, diazoxide
- Glucagon, barbiturates and rifampicin
- Acetazolamide

How to use Axcel Glimepiride-2mg Tablet

– How much to use

For oral administration only.

Adults

The starting dose is 1 mg glimepiride per day. The dosage can be increased in a stepwise manner with an interval of about 1 to 2 weeks between each step, to 2, 3 or 4 mg glimepiride per day. The maximum recommended dose is 6 mg glimepiride per day.

Children and adolescents

The use of Axcel Glimepiride-2mg Tablet is not recommended for children and adolescents.

– When to use it

Your doctor will decide when it is appropriate for you to use Axcel Glimepiride-2mg Tablet according to the type of condition you have.

– How long to use it

Continue taking Axcel Glimepiride-2mg Tablet for as long as 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)

- Hypoglycaemia (low blood sugar).
- Nausea
- Vomiting
- Epigastric pain.
- Restlessness

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- Tremor
- Visual disturbances
- Co-ordination problems
- Sleepiness
- Coma
- Convulsion

It is advisable for you to contact your doctor immediately or go to the Emergency Department of your nearest hospital if you did take Axcel Glimepiride-2mg Tablet too much.

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 Axcel Glimepiride-2mg Tablet.
- Tell your doctor immediately if you become pregnant while taking this medication.

– 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 Axcel Glimepiride-2mg Tablet to anyone else, even if they have the same symptoms or condition as you.

– Things to be careful of

- Avoid prolonged usage in high dosage.
- Pregnancy and lactation.

Side effects

Like all medicines, Axcel Glimepiride-2mg Tablet can cause side effects although not everybody gets them. You are advised to consult doctor/ pharmacist for further information. The following common side effects have been reported:

Common side effects:

- Visual Disturbances
- Pruritus (itching)
- Skin rash
- Urticaria (a raised, itchy rash)
- Photosensitivity

Rare side effects:

- Blood and lymphatic system disorders (general reversible upon discontinuation of medication)
- Hypoglycaemia (low blood sugar, mostly occur immediately)

Very rare side effects:

- Immune system disorders (leukocytoclastic vasculitis).
- Gastrointestinal disorders (nausea, vomiting, diarrhea, abdominal distension, abdominal discomfort and abdominal pain).
- Abnormal hepatic function.
- Blood sodium decrease.

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 npra.moh.gov.my (Public -> Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and disposal of Axcel Glimepiride-2mg Tablet

– Storage

Keep Axcel Glimepiride-2mg Tablet out of reach of children.

Store below 30°C. Keep container well closed and protect from light.

– Disposal

Do not use Axcel Glimepiride-2mg Tablet after the expiry date which is stated on the carton.

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

Green tablet, capsule shaped, flat marked with kotra logo on one side and score line on the other side.

– Ingredients

Active Ingredient:
Glimepiride

Inactive Ingredients:

Lactose, Microcrystalline Cellulose PH101, Povidone K-25, Spectracol CU Chlorophyllin Lake, Sodium Starch Glycolate, Magnesium Stearate, and Isopropyl Alcohol.

– MAL Number

MAL

Manufacturer and product registration holder

KOTRA PHARMA (M) SDN BHD
No. 1, 2 & 3, Jalan TTC 12,
Cheng Industrial Estate,
75250 Melaka, Malaysia.

Date of revision

05/03/2018