

AZUKON MR TABLET

Gliclazide (30mg)

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What Azukon MR is used for

AZUKON MR is indicated in Therapy of maturity onset Diabetes Mellitus (noninsulin-dependent or Type II), where dietary management alone has been insufficient.

How Azukon MR works

Gliclazide stimulates the secretion of insulin from functioning pancreatic islet β -cells. Gliclazide reduces blood glucose levels by stimulating insulin secretion from the β -cells of the islets of Langerhans.

Before you use Azukon MR

- When you must not use it
 - Hypersensitivity to sulphonylureas and related substances;
 - Not to be used for: type 1 diabetes, juvenile onset diabetes;
 - Diabetes complicated by ketosis or acidosis;
 - Diabetics undergoing surgery, after severe trauma or during infections;
 - Diabetic precoma and coma;
 - Severe renal or liver insufficiency;
 - Porphyria (a type of hereditary metabolism disease), hyperthyroidism (excessive functional activity of the thyroid gland).

Pregnancy and lactation

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

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

- Before you start to use it
AZUKON MR is susceptible to cause episodes of hypoglycemia.

Inform the doctor in the case of sweating, intense hunger, trembling, pallor, visual disturbances, feeling of malaise, abnormal behavior, immediately eat sugar or something containing sugar.

- 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 hypoglycaemic effect of AZUKON MR may be potentiated by phenylbutazone, salicylates, sulphonamides, coumarin derivatives; monoamine oxidase inhibitors, beta-adrenergic blocking agents, tetracycline compounds, chloramphenicol, clofibrate, disopyramide, oral forms of miconazole and cimetidine.

The hypoglycaemic action of AZUKON MR may be diminished by corticosteroids, oral contraceptives, thiazide diuretics, phenothiazine derivatives, thyroid hormones and abuse of laxatives.

How to use Azukon MR

- How much to use

The modified release formulation allows convenient once daily dosing of 1-4 tabs/day recommended to be taken followed by a meal.

The recommended starting dose is 30 mg daily.

Switching from Gliclazide 80 mg tablets to Gliclazide 30 mg modified release tablets:

1 tablet of Gliclazide 80 mg is comparable to 1 tablet of Azukon MR 30 mg tablets.

Consequently the switch can be performed provided a careful blood monitoring.

Switching from another oral antidiabetic agent to Gliclazide 30 mg MR Tablets.

Azukon MR 30 mg Tablets can be used to replace other oral antidiabetic agents.

Combination treatment with other antidiabetic agents

Azukon MR 30 mg Tablets can be given in combination with biguanides (Such as metformin and phenformin), alpha glucosidase inhibitors (Such as Voglibose) or insulin.

- When to use it

This tablet is to be taken orally and should be taken with food (Take immediately before meals. Swallow whole, do not chew / crush)

- How long to use it

Continue taking AZUKON MR 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.

AZUKON MR

Gliclazide Modified Release Tablets 30mg

- 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.

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 AZUKON MR.

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 AZUKON MR to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Every administration of AZUKON MR must be accompanied by a meal. You should inform your doctor if you have liver and/or kidney problem.

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.

Please ask your doctor whether you can drive or operate machine.

Side effects

Like all medicines, AZUKON MR 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.

Following adverse effects occurred during the use of AZUKON MR:

- Moderate to severe hypoglycaemia; (low blood sugar);
- Abnormalities of liver function, less frequent reports of liver failure, hepatitis and jaundice (yellowing of the skin or whites of the eyes caused by liver or blood problems)
- Mild gastrointestinal disturbances including nausea, dyspepsia (indigestion), diarrhea and constipation, weight change;
- Skin reactions including rash, pruritus (itching), erythema (abnormal redness of the skin due to capillary congestion (as in inflammation), bullous eruption (characterized by the presence or formation of vesicles), blood dyscrasia (an imbalance of components of the blood) including anaemia (Reduction in red blood cells which can make the skin pale and cause weakness), decrease in the number of white blood cells (leucopenia), Decrease of platelets in blood (thrombocytopenia) and granulocytopenia (deficiency of blood granulocytes)

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 Azukon MR

- Storage

- Store below 30°C.
- Protected from moisture.
- 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 no longer required. These measures will help to protect the environment.

Product description

- What it looks like

White to off-white colored, capsule shaped uncoated tablets plain on both sides.

- Ingredients

- Active ingredient(s)

Gliclazide

- Inactive ingredients

Hypromellose
CHP anhydrous
Hypromellose
Magnesium Stearate

- MAL number(s):

MAL11030083A

Manufacturer

TORRENT PHARMACEUTICALS LTD.

Indrad-382 721, Dist. Mehsana, INDIA.

Product registration holder

Laboratories Torrent (Malaysia) Sdn Bhd., Suite E-08-08 Plaza Mont Kiara, No. 2 Jalan Kiara Mont Kiara. 50480 Kuala Lumpur Malaysia.

Date of revision

10/07/2014