Diagluc® (Tablets)

21800

Ref. No: B2121800/22.01

Gliclazide
Hypoglycaemic

DIAGLUC® MR 30MG TABLETS
DIAGLUC® 80MG TABLETS

PRESENTATION:
Diagluc® MR 30mg Tablets: White, circular biconvex tablet plain on both sides. Each tablet contains: Gliclazide 30mg
Diagluc® 80mg Tablets: White circular biconvex tablet embossed 'C' on one side and a breakline on the other side. Each tablet contains: Gliclazide 80mg, Lactose and other excipients.

CLINICAL PHARMACOLOGY:
Gliclazide is a hypoglycaemic sulphonylurea differing from other related compounds by the addition of an azabicyclooctane ring. In man, apart from having similar hypoglycaemic effect to the other sulphonylureas, gliclazide has been shown to reduce the platelet adhesiveness and aggregation and increase fibrinolytic activity. These factors are thought to be implicated in the pathogenesis of long term complications of diabetes mellitus.
Gliclazide primarily enhances the first phase of insulin secretion, but also to a lesser degree its second phase. Both phases are diminished in non-insulin dependent diabetes mellitus.

Pharmacokinetics:
Gliclazide is readily absorbed from the gastrointestinal tract. It is extensively bound to plasma proteins. The half-life is about 10 to 12 hours. Gliclazide is extensively metabolised in the liver to metabolites that have no significant hypoglycaemic activity. Metabolites and a small amount of unchanged drug are excreted in the urine.

USES:
It is given orally in the treatment of type 2 diabetes mellitus and has a duration of action of up to 24 hours. Because its effects are less prolonged than those of chlorpropamide or glibenclamide it may be more suitable for elderly patients, who are prone to hypoglycaemia with longer-acting sulfonylureas.

DOSAGE AND ADMINISTRATION:
The usual initial dose for modified release tablets is 30mg once daily, increased if necessary upto a maximum of 120mg daily.
The usual initial dose for Diagluc® is 40 to 80mg daily, gradually increased, if necessary, up to 320mg daily. Doses of more than 160mg daily are given in 2 divided doses.
Children: Diagluc® as with other sulfonylureas, is not indicated for the treatment of juvenile onset diabetes mellitus.
Adults: The total daily dose may vary from 40mg to 320mg taken orally. The dose should be adjusted according to the individuals patients response, commencing with 40-80mg daily (1/2 to 1 tablet) and increasing until adequate control is achieved. A single dose should not exceed 160mg (2 tablets). When higher doses are required, Diagluc® should be taken twice daily and according to the main meals of the day. In obese patients or those not showing adequate response to Diagluc® alone, additional therapy may be required.
Elderly: Plasma clearance of gliclazide is not altered in the elderly and steady state plasma levels can therefore be expected to be similar to those in adults under 65 years. Care should be exercised, however, when prescribing sulfonylureas in the elderly due to a possible age related increased risk of hypoglycaemia.

CONTRA-INDICATIONS AND WARNINGS:
Diagluc® should not be used in:
- Juvenile onset diabetes.
- Diabetes complicated by ketosis and acidosis.
- Pregnancy.
- Diabetics undergoing surgery, after severe trauma or during infections.
- Patients known to have hypersensitivity to other sulphonylureas and related drugs.
- Diabetic pre-coma and coma.
- Severe renal or hepatic insufficiency.

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Precautions:
Hypoglycaemia: All sulphonylurea drugs are capable of producing moderate or severe hypoglycaemia, particularly in the following conditions:
- in patients controlled by diet alone,
- in cases of accidental overdose,
- when calorie or glucose intake is deficient

Care should not be exercised in patients with hepatic and/or renal impairment and a small starting dose should be used with careful patient monitoring.

Adverse Effects:
Abnormalities of hepatic function are not uncommon during Gliclazide therapy. There are rare reports of hepatic failure, hepatitis and jaundice following treatment with gliclazide. Mild gastro-intestinal disturbances including nausea, dyspepsia, diarrhoea, constipation have been reported but this type of adverse reaction can be avoided if Gliclazide is taken during a meal.
Skin reactions including rash, pruritis erythema, bullous eruption; blood dyscrasia including anaemia, leukopenia, thrombocytopenia and granulocytopenia have been observed during treatment with Gliclazide but are known to be directly attributable to the drug.

Overdosage:
The symptom to be expected of overdose would be hypoglycaemia. The treatment is gastric lavage and correction of the hypoglycaemia by appropriate means with continual monitoring of the patient's blood sugar until the effect of the drug has ceased.

Interactions:
Care should be taken when giving Diagluc® with drugs which are known to alter the diabetic state or potentiate the drug's action.
The hypoglycaemic effect of Diagluc® may be potentiated by phenylbutazone, salicylates, sulphonamides, coumarin derivatives, MAOI's beta adrenergic blocking agents, tetracycline compounds, chloramphenicol, clofibrate, disopyramide, miconazole (oral forms) and cimetidine.

Pregnancy and Lactation:
Pregnancy: There is no or limited amount of data (less than 300 pregnancy outcomes) from the use of gliclazide in pregnant women, even though there are few data with other sulfonylureas. As a precautionary measure, it is preferable to avoid the use of gliclazide during pregnancy.
Lactation: It is not known whether gliclazide or its metabolites are excreted in breast milk. Other sulfonylureas have been found in milk. Given the risk of neonatal hypoglycaemia, the product is contra-indicated in breast-feeding mothers.

PHARMACEUTICAL PRECAUTIONS:
Store in a dry place below 30^{0}C. Protect from light. Keep all medicines out of the reach of children.

LEGAL CATEGORY:
Prescription Only Medicine (POM)

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