Diapré® 30 & 60 MR
Gliclazide Tablet

Description
Gliclazide is a second-generation sulfonylurea that has hypoglycemic and potentially useful hemodynamic properties. It stimulates the influx of calcium ions into pancreatic beta cells and, as a result, increases insulin secretion. Moreover, in vivo studies have demonstrated changes in thrombin-induced platelet aggregation in NIDDM patients treated with gliclazide.

Indications
Non-insulin-dependent diabetes mellitus (type-II) when dietary modification has failed.

Dosage and Administration
Initially 40-80 mg daily, adjusted according to response; up to 160 mg as a single dose, with breakfast; higher doses divided; maximum 320 mg daily.

Switching from Gliclazide 80 mg tablets to Gliclazide 30 mg & 60 mg modified release tablets:
- 1 tablet of Gliclazide 80 mg is comparable to 1 tablet of Gliclazide 30 mg modified release tablets. Consequently, the switch can be performed provided a careful blood monitoring.
- One Gliclazide 60 mg modified release tablet is equivalent to two Gliclazide 30 mg modified release tablets. Gliclazide 60 mg modified release tablets can be used to replace other oral antidiabetic agents.

Adverse Reactions
Potentially life-threatening effects - All hypoglycemic agents have the potential to cause severe hypoglycemia and may cause severe brain damage or death. Gliclazide used in standard dose is less likely than glyburide to cause hypoglycemia. Hypoglycemia may be favored by concurrent conditions such as hepatic and renal disease, malnutrition, anaemia, sensitivity, alcohol intoxication or adrenal and pituitary insufficiency.

Severe or irreversible adverse effects - Approximately 2% of patients have been withdrawn from therapy because of adverse reactions, namely hypoglycemia (overdose effect), gastrointestinal disturbances and dermatological reactions.

Symptomatic adverse effects - Side effects of Gliclazide treatment are similar to those of other sulfonylureas. Headache, gastrointestinal upset, nausea and dizziness have been reported and skin reactions, including rash, pruritus, erythema and bullous eruptions may occur. Abnormalities of liver function are not uncommon.

High Risk Groups
- Neonates - The drug is not used in neonates.
- Nursing mothers - The drug should not be used in nursing mothers.
- Children - Gliclazide is contraindicated in children.
- Pregnant women - Gliclazide, as other sulfonylureas, is contraindicated for use in pregnant women. No teratological changes have been shown in animals or human, but diabetes can be controlled more tightly in pregnancy by insulin than by oral hypoglycemic agents.
- Elderly - All sulfonylureas should be used with caution in the elderly because of the greater likelihood of their missing meals and the more severe outcome of significant hypoglycemia.

Concurrent disease - Definite hepatic disease should contraindicate the use of Gliclazide, since it is almost completely metabolized in the liver. Renal disease does not appear significantly to alter the pharmacokinetics, although it may be wise to limit the maximum dose when the serum creatinine starts to rise.

Drug Interactions
The hypoglycemic action of sulfonylureas may be opposed by the induction of hepatic enzymes, which metabolize the drug causing lower plasma concentrations and less hypoglycemic effect. Common inducers include rifampicin, barbiturates, phenytoin and alcohol, or by drugs that inhibit the release or action of insulin, e.g. thiazide diuretics, ciprofloxacin, glucocorticoids, estrogens or sympathomimetic drugs. Early symptoms of hypoglycemia such as tremor, sweating and tachycardia may be masked by beta-adrenoceptor blocking drugs, such as propranolol allowing severe hypoglycemic episodes without preceding warning symptoms.

Pharmaceutical Precautions
Keep in a cool & dry place. Protect from light. Keep out of the reach of children.

Commercial Pack
Diapré® 30 MR Tablet: Box containing 30 tablets in 5x10’s blister packs. Each modified release tablet contains Gliclazide BP 30 mg.
Diapré® 60 MR Tablet: Box containing 30 tablets in 5x10’s blister packs. Each modified release tablet contains Gliclazide BP 60 mg.

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