**Diapro® MR**

Gliclazide BP 30 mg modified release tablet

**Description**

**DIAPRO® MR** (Gliclazide 30 mg modified release tablet) is an oral ant-diabetic agent to control Type 2 Diabetes. Gliclazide is a second generation sulfonylurea that has hypoglycemic and potentially useful hemobiological 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 type 2 diabetes (NIDDM) patients treated with gliclazide.

**How DIAPRO® MR works in our body?**

The innovative formulation of Gliclazide modified release tablet ensures the sustained 24-hour glycemic control in type 2 diabetes patient. The consistent dissolution and release pattern of Gliclazide MR Tablet is not affected by variation of pH leading to predictable and reproducible blood glucose level over a 24 hour period with an excellent safety profile.

The concentration of modified release formulation of Diapro® MR increases during the **first 6 h**, followed by a plateau-shaped curve from the 6th h-12th h. Then progressively declines with **terminal half-life of 13-16 h** and finally results in **24 h glycemic control**.

**The innovative modified release profile of Diapro MR (Please add this point from Literature)**
Indications
Diapro MR® is indicated for the treatment of type 2 diabetes (Non-insulin dependent diabetes mellitus) when dietary modification has failed.

Dosage And Administration

The Tablets must not be chewed or crushed. Diapro® MR 30 mg modified release tablet cannot be split.

Diapro® MR tablet, the initial recommended dose is 30 mg daily, even in elderly patients; the daily dose may vary from 30 to 120 mg (1-4) tablets) taken orally, once daily. It is recommended that the medication be taken at breakfast time. The maximum recommended daily dose of is Diapro® MR 120 mg.

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

1 tablet of Diamicron 80 mg is comparable to 1 tablet of Diamicron 30 mg MR Tablets. Consequently the switch can be performed provided a careful blood monitoring.

Switching from another oral antidiabetic agent to Diamicron 30 mg MR Tablets:

Diamicron 30 mg MR Tablets can be used to replace other oral antidiabetic agents.
The dosage and the half-life of the previous antidiabetic agent should be taken into account when switching to Diamicron 30 mg MR Tablets.

A transitional period is not generally necessary. A starting dose of 30 mg should be used and this should be adjusted to suit the patient's blood glucose response, as described above.

When switching from a hypoglycaemic sulphonylurea with a prolonged half-life, a treatment free period of a few days may be necessary to avoid an additive effect of the two products, which might cause hypoglycaemia. The procedure described for initiating treatment should also be used when switching to treatment with Diamicron 30 mg MR Tablets, i.e. a starting dose of 30 mg/day, followed by a stepwise increase in dose, depending on the metabolic response.

It is recommended that the minimum daily starting dose of 30 mg is used.

**Dose In Renal Impaired Patient**

Patients with mild-to-moderate renal impairment(CrCl:>15 mL/min) should be started with DIAPRO®MR 30 mg with careful dosage adjustments

**Adverse Reactions:**
Gastrointestinal disturbance, Skin reactions (rare), Hematological disorders (rare), Hepatic enzyme rises (exceptional). Hypoglycemia (rare) Rhinitis, Bronchitis, Pharyngitis, Arthralgia, Arthritis (reported in at least 1.0% of diabetic patients)

**Contraindications:**
Type 1 diabetes, hypersensitivity to sulfonylureas, severe renal or hepatic failure, pregnancy and lactation, miconazole coprescription.

**HIGH RISK GROUPS**

**Neonates** - The drug is not used in neonates
**Nursing mothers** - The drug should not be used by breast-feeding mothers.

**Children** - Gliclazide is contraindicated in children

**Pregnant women** - Gliclazide, as other sulfonylurea, is contraindicated for use in pregnant women. No teratological changes have been shown in animals or humans, but diabetes can be controlled more tightly in pregnancy by insulin than by oral hypoglycemic agents.

**The 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**

**Potentially hazardous interactions** - These may be divided into those which will tend to increase the hypoglycemic effect and those tending to oppose it. In the first category come drugs which displace the sulfonylurea from protein binding, such as aspirin, non-steroidal anti-inflammatory drugs, phenylbutazone, clofibrate, sulfonamides and coumarin anticoagulants, or which inhibit, hepatic microsomal enzymes, for example cimetidine, sulfonamides, imidazole antifungal agents and the monoamine oxidase inhibitors (MAOI), which may increase the hypoglycemic effect of Gliclazide. Any effects, which result from protein-binding displacement, are transient, lasting from 12-24 h. Regular concomitant doses of these agents together with a constant dose of Gliclazide would not cause problems.
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, dizoxide, glucocorticoids, estrogens or sympathomimetic drugs. Early symptoms of hypoglycemia such as tremor, sweating and tachycardia may be masked by beta-adrenoreceptor blocking drugs, such as propranolol allowing severe hypoglycemic episodes without preceding warning symptoms. If beta-adrenoreceptor blocking drugs are required the more selective types, such as metoprolol or atenolol, are preferred in the diabetic patient.

**Pharmaceutical Precautions**

Store below 25 °C.

**Commercial Pack**

Box containing 30 tablets in 3 X 10’s blister strips.