Comprid®

Gliclazide BP

COMPOSITION
Comprid® tablet : Each tablet contains Gliclazide BP 80 mg.
Comprid® XR 30 tablet: Each extended release tablet contains Gliclazide BP 30 mg.
Comprid® XR 60 tablet: Each extended release tablet contains Gliclazide BP 60 mg.

PHARMACOLOGY
Gliclazide (**Comprid®**) stimulates the release of insulin from pancreatic beta-cells by facilitating Ca^{+2} transport across the beta-cell membranes. It lowers blood glucose by stimulating the release of insulin from the pancreas, an effect dependent upon functioning beta cells in the pancreatic islets. Extrapancreatic effects also may play a part in the mechanism of action of oral sulfonylurea hypoglycemic drugs. Two extrapancreatic effects shown to be important in the action of Gliclazide are an increase in insulin sensitivity and a decrease in hepatic glucose production. The anti-oxidant, platelet inhibiting and fibrinolytic actions of Gliclazide involve processes which have been implicated in the pathogenesis of vascular complications of type 2 diabetes.

INDICATION
Comprid®, **Comprid®** XR 30 and **Comprid®** XR 60 are indicated for the treatment of type 2 diabetes in association with dietary measures when dietary measures alone are inadequate to control blood glucose.

DOSAGE & ADMINISTRATION
The usual initial dose of **Comprid®** is 40 to 80 mg daily, gradually increased, if necessary up to 320 mg daily until adequate control is achieved. A single dose should not exceed 160 mg. When higher doses are required it should be taken twice daily, following the main meals of the day. For extended release tablet the initial recommended dose is 30 mg daily, even in elderly patients (>65 years); the daily dose may vary from 30 to 120 mg (1-4 tablets) taken orally, once daily. **Comprid®** XR 30 should be taken with food because there is increased risk of hypoglycemia if a meal is taken late. It is recommended that the medication be taken at breakfast time. If a dose is forgotten, the dose taken on the next day should not be increased. Dose titration should be carried out in steps of 30 mg, according to the fasting blood glucose response. Each step should last for at least two weeks. **Comprid®** XR 30 is an extended release tablet and therefore, should be neither broken nor chewed. **Comprid®** XR 30, can replace Gliclazide 80 mg tablets, tablet for tablet, for doses of 1 to 4 tablets per day. Comprid® XR 60 should be taken with food because there is increased risk of hypoglycemia if a meal is taken late. It is recommended that the medication be taken at breakfast time. If a dose is forgotten, the dose taken on the next day should not be increased. **Comprid®** XR 60 is an extended release tablet and therefore, should be neither broken nor chewed. **Comprid®** XR 60, can replace 02 Gliclazide 80 mg tablets, for doses of 1 to 2 tablets per day.
Elderly: Plasma clearance of Gliclazide is not altered in the elderly and steady state plasma levels are similar to those in adults under 65 years. Clinical experience in the elderly shows that it is effective and well tolerated. Children: Gliclazide as with other sulfonylureas is not indicated for the treatment of juvenile onset diabetes mellitus.

PRECAUTION
Care should be exercised with patients having hepatic and or renal impairment and a small starting dose should be used with careful patient monitoring. In long term clinical trials, patients with renal insufficiency have been treated satisfactorily using Gliclazide at reduced doses.

SIDE EFFECT
Hypoglycemia may occur in concurrent conditions such as hepatic & renal diseases, alcohol intoxication and adrenal and pituitary insufficiency. Mild gastro-intestinal disturbances including nausea, dyspepsia, diarrhea, and constipation have been reported but these types of adverse reactions can be avoided if Gliclazide is taken during a meal. Allergic dermatological reactions including rash, pruritus, erythema, bullous eruption have been reported during treatment with the drug but are not known to be directly attributable to it. More serious reactions like leucopenia, thrombocytopenia, agranulocytosis, pancytopenia, hemolytic anemia, cholestatic jaundice, GI hemorrhage have not been reported with Gliclazide.

CONTRAINDICATION
Gliclazide should not be used in juvenile onset diabetes, diabetes complicated by ketosis and acidosis, diabetes undergoing surgery, after severe trauma or during infections, patients known to have hypersensitivity to other sulfonylureas and related drugs, diabetic pre-coma & coma, severe renal or hepatic insufficiency, combination with miconazole tablets.

DRUG INTERACTION
The hypoglycemic effect of Gliclazide may be potentiated by NSAID (in particular aspirin), phenylbutazone, sulfonamides, coumarin derivatives, MAOIs, beta-adrenergic blockers, tetracyclines, chloramphenicol, clofibrate, cimetidine and miconazole tablets. Ingestion of alcohol may also increase the hypoglycemic effect of Gliclazide. Some drugs may on the contrary, reduce its activity e.g. barbiturates, corticosteroides, thiazide diuretics, thyroid hormones, laxatives and oral contraceptives.

USE IN PREGNANCY & LACTATION
Pregnancy: Gliclazide should not be used in pregnancy. Nursing mothers: No study has reported its presence in human breast milk. However, other sulfonylureas have been found in milk and there is no evidence to suggest that gliclazide differs from the group in this respect.

STORAGE
Store below 30° C, protect from light and moisture. Keep out of reach of children.

HOW SUPPLIED
Comprid® tablet: Each box containing 60 tablets in blister pack.
Comprid® XR 30 tablet: Each box containing 50 tablets in blister pack.
Comprid® XR 60 tablet: Each box containing 30 tablets in blister pack.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH