Important Information. Please read carefully.

Melicron®

Gliclazide 80mg

Tablets

Composition
Each tablet contains gliclazide 80mg

Actions and Mode of Action
Gliclazide is a sulphonylurea hypoglycaemic agent which stimulates insulin secretion by the pancreatic ß cells and consequently are effective only when some residual pancreatic ß-cell activity is present. Its action on insulin secretion is mainly due to the restoration of the early phase; however, it is also effective in stimulating secretion of insulin throughout a meal. In addition to this pancreatic action, it has been demonstrated that gliclazide improves the metabolic utilization of glucose at a peripheral level. This extrapancreatic action may be due to the potentiation of the post-receptor pathways. Thus, gliclazide restores glycaemic control throughout 24 hours. It normalizes fasting and postprandial blood sugar.

The hypoglycaemic effect of gliclazide appears to be initiated by drug interaction with cell-surface receptors on the pancreatic ß cells; this results in reduced conductance of an ATP-sensitive K^+ channel. The drug thus resembles physiological secretagogues (eg., glucose, leucine), which also lowers the conductance of this channel. Reduced K^+ conductance causes membrane depolarization and influx of Ca^{2+} through voltage-sensitive Ca^{2+} channels.

Gliclazide has also been shown to reduce platelet hyperadhesiveness and hyperaggregation, to increase fibrinolytic activity and to oppose adrenaline vasoconstriction. These factors are thought to be contributors of the long-term complication of diabetes mellitus.

Pharmacokinetics
Gliclazide is readily absorbed from the gastrointestinal tract and peak plasma concentrations occur 2-4 hours after administration. It is extensively bound to plasma proteins. (85%) Gliclazide is extensively metabolized in the liver to metabolites without significant hypoglycaemic activity. Metabolites and a small amount of unchanged drug are excreted in the urine. 10-20 % of the dose is excreted in the faeces as metabolites. The half-life is about 10 to 12 hours.

Indication
Melicron is indicated for the treatment of non-insulin-dependent Diabetes Mellitus. It is used to supplement treatment by dietary modification when such modification has proved insufficient.

Dosage
In the majority of cases, 2 tablets daily (1 tablet with breakfast, 1 tablet with dinner). Dosage can vary from 1-4 tablets daily, adjusted according to the individual patient's severity of Diabetes. The usual initial dose is 40 to 80mg daily. Doses of more than 160mg should be given in 2 divided doses. Maximum dose is 320mg daily.

ME0900/ME0903-003

Contraindications
Melicron should not be used alone in insulin-dependent diabetes; juvenile-onset diabetes; diabetes complicated by ketosis and acidosis; pregnancy; diabetics undergoing surgery, after severe trauma or during infections; precoma or coma; insulin should be given together and specific care needed. **Melicron** is contraindicated in patients hypersensitive to any other sulphonylureas and related drugs and patients with severe renal or hepatic insufficiency. When major surgery is to be performed, insulin therapy should be substituted for oral hypoglycaemia.

Precautions
As gliclazide is metabolized and excreted extensively in the liver and renal respectively, caution is needed in the elderly and patients with hepatic and / or renal impairment and a small starting dose should be used with careful patient monitoring. Hypoglycaemia will occur if the patients' dietary intake is reduced or if they are receiving a larger dose of **Melicron. Melicron** should be used with caution during lactation.

Drug Interactions
Potentiation of the hypoglycaemic action of **Melicron** may occur with the concomitant administration of sulfonamides, chloramphenicol, co-trimoxazole, salicylates, phenylbutazone, beta-blockers, monoamine oxidase inhibitors (MAOIs), ketoconazole and miconazole. Clofibrates, eg. Gemfibrozil may improve glucose tolerance and have an additive effect.

Diminution of hypoglycaemic action of the drug may occur with concomitant administration of loop and thiazide diuretics, corticosteroides and estogens or oral contraceptives.

Side Effects / Adverse Reactions
Melicron is generally well tolerated. Hypoglycaemia may occur with all hypoglycaemic agents. Skin rashes and pruritus may occur and photosensitivity has been reported. Gastrointestinal disturbances such as nausea, vomiting, heartburn, anorexia, diarrhoea, and a metallic taste may occur with sulphonylureas and are usually mild and dose-dependent. Other severe effects of sulphonyureas may be manifestations of hypersensitivity reactions. They include cholestatic jaundice, leucopenia, thrombocytopenia, aplastic anaemia, agranulocytosis and hemolytic anaemia, erythema multiforme or the Steven-Johnson Syndrome, exfoliative dermatitis, and erythema nodosum. All these phenomenas are very rare.

Symptoms and Treatment for Overdosage
The symptom of overdose is hypoglycaemia. In acute poisoning the stomach should be emptied by emesis or lavage. Hypoglycaemia should be treated with urgency. The patient should be observed over several days in case hypoglycaemia recurs until the effect of the drug has ceased.

Shelf-life: The expiry date is indicated on the packaging.

Description: White round, 7.9mm diameter, flat-bevelled edge with a cross-line on one side and plain on reverse.

Packing / Pack sizes: Blister pack of 60's, 100's and 1000's. Not all pack sizes are available for sale.

Storage: Store at room temperature below 30°C
KEEP ALL MEDICINES OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK

For further information, please consult your pharmacist or physician.

Revision Date : 11-Oct-2021

Manufacturer and Product Registration Holder :
Xepa-Soul Pattinson (Malaysia) Sdn. Bhd.
1-5, Cheng Industrial Estate, 75250 Melaka, Malaysia.