

FRONT

GLIMICRON 80 mg TABLET

VIGLI10-1var (MY)

DESCRIPTION

Round, 8.0 mm in diameter, white to off-white uncoated tablet, flat faces, bevel-edged, cross score embossed on one face.

COMPOSITION

Gliclazide 80 mg / tablet

ACTION & PHARMACOLOGY

Gliclazide, a sulphonylurea, acts by promoting release of insulin from the beta cells of pancreatic islet tissue by an unknown process. Insulin production is not increased. Hepatic glycogenolysis and gluconeogenesis are decreased. Insulin sensitivity is increased at peripheral target sites. Therefore, sulphonylureas are effective only in patients whose pancreas are capable of producing insulin.

PHARMACOKINETICS

- **Absorption**
It is readily absorbed from the gastro-intestinal tract.
- **Protein Binding**
Gliclazide is very extensively bound to plasma proteins.
- **Metabolic Reactions**
It is extensively metabolized in the liver to metabolites without significant hypoglycaemic activity.
- **Half-life**
Plasma half-life is about 10 to 12 hours.
- **Excretion**
Both unchanged drug and metabolites are excreted in the urine.

INDICATIONS

Gliclazide is indicated in non-insulin dependent diabetes mellitus.

CONTRAINDICATIONS

- Except under special circumstances, this medication should not be used when the following medical problems exist: Acidosis, burns, diabetic coma, infection, ketoacidosis, ketosis, surgery and trauma.
- Risk-benefit should be considered when the following medical problems exist: Adrenal insufficiency, pituitary insufficiency, fever, nausea, vomiting, thyroid function impairment, debilitated physical condition, hepatic function impairment, malnourishment, renal function impairment, sensitivity to oral antidiabetic agents and patients with acute porphyria.

PRECAUTIONS/WARNINGS

- Patients sensitive to one of the oral antidiabetic agents may be sensitive to the others also.
- Oral antidiabetic agents must not be used during pregnancy. Abnormal blood glucose levels have been associated with a higher incidence of congenital abnormalities during early pregnancy, and with increased perinatal morbidity and mortality later in pregnancy.

- It should not be used in insulin-dependent diabetes mellitus.
- It should not be given in severe impairment of renal or hepatic function because of an increased risk of hypoglycaemia or severe impairment of thyroid function.
- Its antidiuretic effect may cause problems in patients with conditions associated with fluid retention.
- It is not known whether gliclazide is excreted in breast milk. However other sulphonylureas have been found in breast milk and there is no evidence to suggest that gliclazide differs from the group in this respect.
- Geriatric patients and patients with renal insufficiency may be more sensitive to the effects of this medication because of reduced metabolism and excretion. Dosage should therefore be initiated at a lower level and adjusted cautiously. In the elderly, hypoglycaemia may be more difficult to recognize and may cause more neurological symptoms. These symptoms include anxiety, confusion, difficulty in concentrating, drowsiness, nervousness or unusual tiredness.
- Dental: The leukopenic and thrombocytopenic effects of sulphonylureas may result in an increased incidence of microbial infection, delayed healing and gingival bleeding. If leukopenia or cytopenia occurs, dental work should be deferred until blood counts have returned to normal. Patients should be instructed in the proper oral hygiene required during this period. This includes cautious use of regular toothbrushes, dental floss and toothpicks.
- Cross-sensitivity to other sulfonamide or thiazide-type medications may also occur.

PREGNANCY AND LACTATION

Not recommended in pregnancy and lactation.

MAIN SIDE/ADVERSE EFFECTS

- Gastro-intestinal disturbances such as nausea, vomiting, heart burn, anorexia, diarrhoea and a metallic taste are usually mild and dose-dependant.
- Skin rashes and pruritus.
- Severe, prolonged and sometimes fatal hypoglycaemia.
- Other severe effects may be manifestations of a hypersensitivity reaction which includes cholestatic jaundice, leucopenia, thrombocytopenia, aplastic anaemia, agranulocytosis, haemolytic anaemia, erythema multiforme or Stevens-Johnson syndrome, exfoliative dermatitis and erythema nodosum.
- A syndrome of inappropriate secretion of antidiuretic hormone (SIADH) characterized by water retention, hyponatraemia and central nervous effects may infrequently be induced.
- Photosensitivity.

BACK

GLIMICRON 80 mg TABLET

DRUG INTERACTIONS

- An odd interaction involves alcohol intolerance which is similar to disulfiram-alcohol interaction. There is also an increased risk of hypoglycaemia with alcohol.
- Compounds that may diminish the hypoglycaemic effect and thus necessitate an increase in the dosage requirement of the sulfonylurea include rifampicin and thiazide diuretics, corticosteroids and estrogens.
- Compounds that may increase the hypoglycaemic effect of sulfonylureas and necessitate a reduction in their dosage requirement include anti-infective agents such as chloramphenicol, guanethidine, monoamine oxidase inhibitors, salicylates, sulfonamides, trimethoprim, phenylbutazone, ketoconazole, miconazole, fluconazole, sulphapyrazone and azapropazone.
- A reversible decrease in thrombocyte count in patients receiving ketotifen concomitantly with oral antidiabetic agents has been observed in a few cases. Concurrent administration of ketotifen should therefore be avoided.
- Beta-blockers may mask some of the symptoms of hypoglycaemia. Also, beta-blockers may have hypoglycaemic or hyperglycaemic actions of their own.
- The hypoglycaemic effect may be enhanced when administered concurrently with insulin.
- If administered concurrently with anticoagulants, increased plasma concentrations of both the anticoagulant and sulfonylurea may occur initially; with continued therapy, decreased anticoagulant plasma concentrations and increased hepatic metabolism of the sulphonylurea may occur; dosage adjustments of one or both medications may be required.

OVERDOSAGE

Clinical features:

- Nausea and vomiting.
- Abdominal pain, (rarely) haematemesis and melaena.
- Drowsiness, coma, twitching, convulsions.
- Depressed limb reflexes with extensor plantar responses.
- Hyperapnoea, acute pulmonary oedema.
- Sinus tachycardia, hypotension, circulatory failure.
- Absence of sweating.
- Hypoglycaemia, hyperkalaemia, metabolic (lactic) acidosis, leucocytosis.
- Late complication cholestasis jaundice.

Treatment:

- Emesis or gastric lavage, if appropriate. Administration of repeated doses of oral activated charcoal with appropriate cathartic may also be used.
- Supportive measures.
- 50 ml of 50% glucose IV repeated as necessary and/or glucagon 1 - 2 mg IV to correct hypoglycaemia, followed by an IV infusion of 5 - 10% dextrose for 24 to 72 hours as necessary.
- Treat mild hypoglycaemia with immediate ingestion of a source of sugar.

DOSAGE & ADMINISTRATION

Adults:

Oral, 40 to 80 mg daily, gradually increased, if necessary, up to 320 mg daily. Doses of more than 160 mg daily should be given in 2 divided doses.

Storage:

Store below 30°C. Protect from moisture.

Presentation/Packing:

Blisters of 10 x 10's.

Product Registration Holder: HOVID Bhd.

121, Jalan Tunku Abdul Rahman, 30010 Ipoh, Malaysia.

Manufactured by: HOVID Bhd.

Lot 56442, 7 1/2 Miles, Jalan Ipoh/Chemor,
31200 Chemor, Malaysia.

Revision date: August 2021