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Glimet®

(Glibenclamide + Metformin HCl)
Tablet

گلائمٹ

COMPOSITION:
Glimet 1.25/250 Tablet:
Each film coated tablet contains:
Glibenclamide BP ..... 1.25 mg.
Metformin HCl BP ..... 250 mg.

Product Specs.: CCL Pharmaceuticals

Glimet 2.5/500 Tablet:
Each film coated tablet contains:
Glibenclamide BP ..... 2.5 mg.
Metformin HCl BP ..... 500 mg.

Product Specs.: CCL Pharmaceuticals

Glimet 5.0/500 Tablet:
Each film coated tablet contains:
Glibenclamide BP ..... 5.0 mg.
Metformin HCl BP ..... 500 mg.

Product Specs.: CCL Pharmaceuticals

DESCRIPTION:
GLIMET is available for oral administration in tablets containing 250 mg Metformin Hydrochloride with 1.25 mg Glibenclamide, 500 mg Metformin Hydrochloride with 2.5 mg Glibenclamide and 500 mg Metformin Hydrochloride with 5 mg Glibenclamide.

CLINICAL PHARMACOLOGY:
Mechanism of Action:
GLIMET combines Metformin Hydrochloride and Glibenclamide, two antihyperglycemic agents with complementary mechanisms of action, to improve glycemic control in patients with type 2 diabetes. Metformin Hydrochloride is an antihyperglycemic agent that improves glucose tolerance in patients with type 2 diabetes, lowering both basal and postprandial plasma glucose. Glibenclamide appears to lower blood glucose acutely by stimulating the release of insulin from the pancreas, an effect dependent upon functioning beta cells in the pancreatic islets.

INDICATIONS AND USES:
GLIMET is indicated as initial therapy, as an adjunct to diet and exercise, to improve glycemic control in patients with type 2 diabetes whose hyperglycemia cannot be satisfactorily managed with diet and exercise alone. GLIMET is indicated as second-line therapy when diet, exercise, and initial treatment with a sulfonylurea or Metformin do not result in adequate glycemic control in patients with type 2 diabetes.

DOSAGE AND ADMINISTRATION:
General considerations:
Dosage of GLIMET must be individualized on the basis of both effectiveness and tolerance while not exceeding the maximum recommended daily dose of 2000 mg Metformin HCl / 20 mg Glibenclamide. GLIMET (Metformin HCl and Glibenclamide) Tablets should be given with meals and should be initiated at a low dose, with gradual dose escalation, in order to avoid hypoglycemia (largely due to Glibenclamide), to reduce GI side effects (largely due to Metformin), and to permit determination of the minimum effective dose for adequate control of blood glucose for the individual patient.
GLIMET As Initial Therapy:
Recommended starting dose:
GLIMET 1.25 once or twice daily with meals.
For patients with type 2 diabetes whose hyperglycemia cannot be satisfactorily managed with diet and exercise alone, the recommended starting dose of GLIMET is 1.25 once a day with a meal. As initial therapy in patients with baseline HbA_{1c} > 9% or an FPG > 200 mg/dL, a starting dose of GLIMET 1.25 twice daily with the morning and evening meals may be used. Dosage increases should be made in increments of GLIMET 1.25 per day every two weeks up to the minimum effective dose necessary to achieve adequate control of blood glucose. In clinical trials of GLIMET as initial therapy, there was no experience with total daily doses greater than 2000mg/10mg per day. GLIMET 5 should not be used as initial therapy due to an increased risk of hypoglycemia.
GLIMET Use in Previously Treated Patients (Second-Line Therapy):
Recommended starting dose:
GLIMET 2.5 or 5 twice daily with meals.
For patients not adequately controlled on either Glibenclamide (or another sulfonylurea) or Metformin alone, the recommended starting dose of GLIMET is 2.5 or 5 twice daily with the morning and evening meals. In order to avoid hypoglycemia, the starting dose of GLIMET should not exceed the daily doses of Glibenclamide or Metformin already being taken. The daily dose should be titrated in increments of no more than GLIMET 5 up to the minimum effective dose to achieve adequate control of blood glucose or to a maximum dose of 2000 mg/20 mg per day.
For patients previously treated with combination therapy of Metformin plus Glibenclamide (or another sulfonylurea), if switched to GLIMET, the starting dose should not exceed the daily dose of Metformin and Glibenclamide (or equivalent dose of another sulfonylurea) already being taken.

SIDE EFFECTS:
Diarrhoea, Headache, Nausea / Vomiting, Abdominal pain and Dizziness may be encountered with the GLIMET therapy.

DRUG INTERACTIONS:
When the drugs like the thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs, and isoniazid are administered to a patient receiving GLIMET, the patient should be closely observed for loss of blood glucose control. When such drugs are withdrawn from a patient receiving GLIMET, the patient should be observed closely for hypoglycemia. Metformin HCl is negligibly bound to plasma proteins and is, therefore, less likely to interact with highly protein-bound drugs such as salicylates, sulfonamides, chloramphenicol, and probenecid as compared to sulfonylureas, which are extensively bound to serum proteins.

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WARNINGS:
Lactic acidosis is a rare, but serious, metabolic complication that can occur due to Metformin HCl accumulation.

PRECAUTIONS:
General:
Hypoglycemia – As with other hypoglycemic agent, GLIMET (Metformin HCl and Glibenclamide) Tablets is also capable of producing hypoglycemia or hypoglycemic symptoms, therefore, proper patient selection, dosing, and instructions are important to avoid potential hypoglycemic episodes. Renal or hepatic insufficiency may cause elevated drug levels of both Metformin Hydrochloride and Glibenclamide and the hepatic insufficiency may also diminish gluconeogenic capacity, both of which increase the risk of hypoglycemic reactions. Elderly, debilitated, or malnourished patients and those with adrenal or pituitary insufficiency or alcohol intoxication are particularly susceptible to hypoglycemic effects. Hypoglycemia may be difficult to recognize in the elderly, and in people who are taking beta-adrenergic blocking drugs.
Pregnancy:
Teratogenic Effects:
Pregnancy Category B:
There are no adequate and well-controlled studies in pregnant women with GLIMET or its individual components. No animal studies have been conducted with the combined products in GLIMET. The following data are based on findings in studies performed with the individual products.
Metformin Hydrochloride:
Metformin HCl alone was not teratogenic in rats or rabbits at doses up to 600 mg/kg/day.
Glibenclamide:
Reproduction studies were performed in rats and rabbits at doses up to 500 times the maximum recommended human daily dose of 20 mg of the Glibenclamide component of GLIMET based on body surface area comparisons and revealed no evidence of impaired fertility or harm to the fetus due to Glibenclamide.
Nursing mothers:
Because the potential for hypoglycemia in nursing infants may exist, a decision should be made whether to discontinue nursing or to discontinue GLIMET, taking into account the importance of the drug to the mother. If GLIMET is discontinued, and if diet alone is inadequate for controlling blood glucose, insulin therapy should be considered.
Pediatric Use: Safety and effectiveness of GLIMET in pediatric patients have not been established.

OVERDOSE:
Metformin hydrochloride:
Metformin HCl is dialyzable with a clearance of up to 170 mL/min under good hemodynamic conditions. Therefore, hemodialysis may be useful for removal of accumulated drug from patients in whom Metformin overdosage is suspected.
Glibenclamide:
Overdosage of sulfonylureas, including Glibenclamide tablets, can produce hypoglycemia. If hypoglycemic coma is diagnosed or suspected, the patient should be given a rapid intravenous injection of concentrated (50%) glucose solution. This should be followed by a continuous infusion of a more dilute (10%) glucose solution at a rate that will maintain the blood glucose at a level above 100 mg/dL.

CONTRAINDICATIONS:
GLIMET (Metformin HCl and Glibenclamide Tablets) is contraindicated in patients with:
- Renal disease or renal dysfunction (e.g., as suggested by serum creatinine levels ≥ 1.5 mg/dL [males], ≥ 1.4 mg/dL [females], or abnormal creatinine clearance) which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction, and septicemia.
- Congestive heart failure requiring pharmacologic treatment.
- Known hypersensitivity to Metformin Hydrochloride or Glibenclamide.
- Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin.

INSTRUCTIONS:
- Store below 30ºC.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:

Glimet 1.25/250 Tablet	:	Pack of 3x10 tablet.
Glimet 2.5/500 Tablet	:	Pack of 3x10 tablet.
Glimet 5.0/500 Tablet	:	Pack of 3x10 tablet.

ہدایات:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف ڈاکٹر کے نسخہ پر فروخت کریں۔

FOR FURTHER INFORMATION PLEASE CONTACT:

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