

Homet[®]-GV1

(Voglibose, Glimepiride, Metformin Hydrochloride (SR) Tablets)

Composition:

Each Tablet Contains:

- Glimepiride IP..... 1 mg
- Voglibose IP 0.2 mg
- Metformin Hydrochloride IP..... 500 mg
(In Sustained Release form)
- Excipients... q.s.
- Colour: Sunset Yellow FCF

Clinical Pharmacology:

Metformin:

Metformin is a biguanide that improves glucose tolerance in patients with type 2 diabetes, lowering both basal and postprandial plasma glucose. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization. Metformin does not produce hypoglycemia in patients with type 2 diabetes or in healthy subjects except in special circumstances, and does not cause hyperinsulinemia. With metformin therapy, insulin secretion remains unchanged while fasting insulin levels and daylong plasma insulin response may actually decrease.

Glimepiride :

Glimepiride primarily lowers blood glucose by stimulating the release of insulin from pancreatic beta cells. Sulfonylureas bind to the sulfonylurea receptor in the pancreatic beta-cell plasma membrane, leading to closure of the ATP-sensitive potassium channel, thereby stimulating the release of insulin.

Voglibose:

Voglibose is alpha glucosidase enzyme inhibitor. Voglibose has anti-hypoglycaemic action which results from a reversible inhibition of membrane bound intestines α glycosidase hydrolyze

enzymes which hydrolyze oligosaccharides and disaccharides to glucose and other monosaccharides in the brush border of the small intestine.

Indications:

As third line treatment of Type II diabetes mellitus in adult patients when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control.

Use in special population:

- **Pediatric Use:**

Safety and effectiveness in children younger than 18 years of age have not been established.

- **Geriatric Use:**

Caution should be used when prescribing to elderly patients because reduced renal functions are associated with increasing age.

- **Pregnancy:**

Not recommended

- **Patients with moderate chronic kidney disease:**

Metformin use in people with chronic kidney disease in two ways. First, they included people who had worse kidney function. Second, they moved away from using the serum creatinine blood test as the marker of kidney disease

Contraindications:

For Metformin: Renal impairment, Metabolic acidosis, including diabetic ketoacidosis , Hypersensitivity to metformin hydrochloride , Chronic Liver Disease.

For Glimepiride: in patients hypersensitive to glimepiride, other sulfonylureas, other sulfonamides, in pregnant women.in breast-feeding women. In patients with severe impairment of hepatic function, change-over to insulin is indicated, not least to achieve optimal metabolic control.

For Voglibose: History of hypersensitivity to voglibose or to any other ingredient of this product. Patients with severe ketosis or in a state of diabetic coma or precoma. Severe infections, before or after operation or with severe trauma. Gastrointestinal obstruction or predisposed to it.

Precautions and Warnings:

- Lactic acidosis: Warn against excessive alcohol intake. Metformin is not recommended in hepatic impairment and is contraindicated in renal impairment. Ensure normal renal function before initiating and at least annually thereafter.
- Temporarily discontinue in patients undergoing radiologic studies with intravascular administration of iodinated contrast materials or any surgical procedures necessitating restricted intake of food and fluids.
- Vitamin B12 deficiency: Metformin may lower vitamin B12 levels. Monitor hematologic parameters annually.
- Macrovascular outcomes: No conclusive evidence of macrovascular risk reduction with METFORMIN or any other antidiabetic drug.
- Hypoglycemia: May be severe. Ensure proper patient selection, dosing, and instructions, particularly in at-risk populations (e.g., elderly, renally impaired) and when used with other anti-diabetic medications.

Drug Interactions:

Cationic drugs: May reduce metformin elimination. Use with caution in patients who are taking cationic medications eliminated by renal tubular secretion.

Certain medications may affect glucose metabolism, requiring GLIMEPIRIDE dose adjustment and close monitoring of blood glucose.

Miconazole: Severe hypoglycemia can occur when GLIMEPIRIDE and oral miconazole are used concomitantly. Cytochrome P450 2C9 interactions: Inhibitors and inducers of cytochrome P450 2C9 may affect glycemic control by altering glimepiride plasma concentrations. Colesevelam: Coadministration may reduce glimepiride absorption. GLIMEPIRIDE should be administered at least 4 hours prior to colesevelam.

When voglibose is used in combination with derivative(s) of sulfonamide, sulfonlurea or biguanide, or with insulin, hypoglycemic symptoms may occur. Therefore, when used in combination with any of these drugs, care should be taken, such as starting the administration at a low dose.

Adverse effects:

Common adverse reactions include hypoglycemia, headache, nausea, and dizziness.

Overdosage:

Overdose may cause epigastric discomfort, nausea, and vomiting followed by diarrhea, drowsiness, weakness, dizziness, malaise and headache. Severe hypoglycemia with coma, seizure, or neurological impairment.

For Therapeutic Use only

Route of administration: Oral.

Type of tablet: Uncoated Bilayered Tablet.

Dosage: As Directed by the physician.

Storage: Store in cool, dry & dark place.

Keep out of reach of children.

SCHEDULE H PRESCRIPTION DRUG- CAUTION not to be sold by retail without the Prescription of a Registered Medical Practitioner.

SCHEDULE G PRESCRIPTION DRUG- CAUTION it is dangerous to take this preparation except under medical supervision.

Presentation: Homet-GV1 is available as 10 x 10 Tablets

Marketed By:



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