**For consumer information only**

# Homet®-G1

**(Glimepiride & Metformin Hydrochloride (SR) Tablets)**

**Composition:**

**Each Uncoated Bilayered Tablet Contains:**
Glimepiride IP… ..... 1 mg
Metformin Hydrochloride IP… ..... 500 mg (In Sustained Release form)
Excipients… ..... q.s.
Colour: Indigo Carmine & Brilliant Blue 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.

**Indications:**
For the management of patients with type 2 diabetes mellitus when diet, exercise and single agent (glimepiride or metformin alone) 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.

**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

**Adverse effects:**
Common adverse reactions include hypoglycemia, headache, nausea, and dizziness.

**Overdosage:**
Overdose may causes 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.**

**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 ofa Registered Medical Practitioner.**
**SCHEDULE G PRESCRIPTION DRUG- CAUTION it is dangerous to take this preparation exceptunder medical supervision.**

**Presentation:** Homet-G1 is available as 10 x 10 Tablets.

**Marketed By:**


**EPIONE PHARMACEUTICALS PVT.LTD.**

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