

For consumer information only

Homet[®]-500

(Metformin Hydrochloride Sustained Release Tablets I.P. 500 mg)

Composition:

Each Uncoated Sustained Release Tablet Contains:

Metformin hydrochloride I.P.....500mg
Excipients...q.s.

Clinical Pharmacology:

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.

Indications:

Metformin is a biguanide indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

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.

Contraindications:

- Renal impairment.
- Metabolic acidosis, including diabetic ketoacidosis.
- Hypersensitivity to metformin hydrochloride.
- Heart failure.
- Chronic liver disease.

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 macro vascular risk reduction with METFORMIN or any other antidiabetic drug.

Drug Interactions:

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

Adverse effects:

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

Overdosage:

Overdose 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.

Dosage: As Directed by the physician.

Keep out of reach of children.

Storage: Store in cool, dry & dark place.
Keep out of reach of children.

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

Presentation: Homet-500 available as 10x 10 Tablet.

Marketed By:



EPIONE PHARMACEUTICALS PVT.LTD.

804, Suyog Center, Gultekdi, Pune-411037 (MH), India.

