AFOGLIP M

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

Abbreviated Prescribing information for AFOGLIP M (Teneligliptin Hydrobromide hydrate 20 mg + Metformin Hydrochloride 500/1000 mg Tablets) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: **Teneligliptin:** The glucagon-like peptide-1 (GLP-1) is secreted from alimentary canal in response to meal that promotes insulin secretion from pancreas and regulates blood sugar post meal by controlling glucagon secretion. Teneligliptin exhibits a hypoglycemic effect by controlling the decomposition of GLP-1 by inhibiting dipeptidyl peptidase-4 (DPP-4) activity and thereby increasing blood concentration of active form GLP-1. **Metformin:** Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization. **INDICATIONS**: As an adjunct to diet and exercise to improve glycemic control in adult with type 2 diabetes mellitus when treatment with both Teneligliptin and Metformin is appropriate. **DOSAGE AND ADMINISTRATION**: The usual adult starting dosage of Afoglip M is 20 mg teneligliptin and 500 mg or 1000 mg metformin hydrochloride extended release administered orally once daily. If efficacy is insufficient, the teneligliptin and metformin hydrochloride extended release dose may be increased up to 40 mg and 2000 mg once daily respectively. Afoglip M should be administered with food to reduce the gastrointestinal side effects. **CONTRAINDICATIONS**: Afoglip M is contraindicated in patients with: Hypersensitivity to the drug or any of the excipients, Acute or chronic metabolic acidosis, Severe trauma, Renal failure or renal dysfunction, Acute or chronic disease which may cause tissue hypoxia such as: cardiac or respiratory failure, recent myocardial infarction, shock, Hepatic insufficiency, acute alcohol intoxication, alcoholism. **WARNINGS AND PRECAUTIONS:** Should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. In pancreatitis, Afoglip M should be discontinued. Risk of hypoglycemia, Lactic acidosis, Impairment of renal function, impaired hepatic function, decrease in Vitamin B12 levels, Hypoxic States, avoid the medication in the patients having: QT prolongation, Torsade's de pointes. **DRUG INTERACTIONS**: **Teneligliptin:** Precautions for Co-administration with: Drugs for diabetes, Drugs increasing hypoglycemia action, Drugs decreasing hypoglycemia action, Drugs known to cause QT prolongation. **Metformin:** Furosemide, Nifedipine, Cationic drugs (e.g., amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, or vancomycin), thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs, and isoniazid. **ADVERSE REACTIONS**:
Teneligliptin+metforminin: diarrhoea, abdominal pain, hepatic steatosis, rash and edema. **Teneligliptin:** hypoglycemia, constipation, dizziness, headache, diarrhea, pyrexia, Intestinal Obstruction, Liver dysfunction, Interstitial pneumonia. **Metformin:** Diarrhoea, nausea, vomiting, upper respiratory tract infection, abdominal pain, distension of abdomen, constipation, flatulence, dyspepsia / heartburn, dizziness, headache, taste disturbances, rash/ dermatitis, lactic acidosis and unpleasant metallic taste.

MARKETED BY:

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(Additional information is available on request)