

VOGLITOR MF

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for **Voglitor MF** [(1)Voglibose I.P 0.2mg and Metformin hydrochloride I.P. 500mg (2) Voglibose I.P 0.3mg and Metformin hydrochloride I.P. 500mg tablets]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Voglibose and Metformin are two oral antihyperglycemic drugs used in the management of type 2 diabetes. Voglibose is an alpha-glucosidase inhibitor and thereby delaying the digestion and absorption of carbohydrate, resulting in improvement of postprandial hyperglycemia. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose, and improve insulin sensitivity by increasing peripheral glucose uptake and utilization.

INDICATION: As 2nd line treatment of type II Diabetes mellitus when diet, exercise and the single agent do not result in adequate glycaemic control.

DOSAGE AND ADMINISTRATION: Must be swallowed whole and not crushed or chewed. The usually recommended dose for adult is one tablet of Voglitor MF (0.2mg+500mg), three times a day, just before each meal, dose may be increased to one tablet of Voglitor MF (0.3 mg +500 mg), three times a day just before each meal. The maximum daily dose of metformin 2550 mg/day and voglibose 0.9 mg/day should not be exceeded.

CONTRAINDICATION: Patient with acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma, patient with severe infections, before and after operation, with serious trauma and patients, with renal disease and with a history of hypersensitivity to any of the ingredients of this product.

WARNINGS & PRECAUTIONS: Monitoring for lactic acidosis occurrence, careful monitoring of renal function in elder. Withheld in the presence of any condition associated with hypoxemia, dehydration, or sepsis, cautioned against excessive alcohol intake, discontinued prior to any intravascular radiocontrast study and for any surgical procedure, history of laparotomy or ileus. Caution is advised in chronic intestinal disease, with severe cirrhosis, serious hepatic and renal dysfunction. Limited to the patients with diabetes mellitus and used when the fasting blood sugar is about 140 mg/dl or more. Caution to be made with concomitant use of anionic drug, caution to be exercised with use of iodinated contrast, in Elderly, debilitated, or malnourished patients and those with adrenal or pituitary insufficiency or alcohol intoxication are particularly susceptible to hypoglycemic.

DRUG INTERACTIONS: Derivatives of sulfonamide and sulfonyleurea, biguanide derivatives, insulin preparations and improving agents for insulin resistance, b-blockers, salicylic acid preparations, monoamine oxidase inhibitors, fibrate derivatives for treatment of hyperlipemia, warfarin, epinephrine, adrenocortical hormone, thyroid hormone, furosemide, nifedipine, amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim or vancomycin

ADVERSE REACTIONS: Voglibose: Hypoglycemia, abdominal swelling, increased flatus, intestinal obstruction like symptom due to an increase in intestinal gas, fluminant hepatitis, and serious hepatic dysfunction with increased AST (GOT). ALT (gamma-GPT) and jaundice. The other reactions reported in voglibose treated patients also included diarrhea, loose stools, borborygmus. abdominal pain, constipation, anorexia, nausea, vomiting, heart burn, stomatitis, thirst, taste abnormality,

pneumatosis cystoides intestinalis, pruritus, photosensitivity, headache, dizziness, light headedness, sleepiness, thrombocytopenia, numbness, edema of face, hot flushes, malaise, weakness, hyperkalemia, increased serum amylase, decreased HDL cholesterol, diaphoresis, alopecia, and granulocytopenia.

Metformin hydrochloride: Diarrhea, nausea, vomiting, flatulence, abdominal discomfort, and chills. Hypoglycemia, myalgia, lightheaded, dyspnea, nail disorder, rash, sweating increased, taste disorder, chest discomfort, chills, flu syndrome, flushing, and palpitation.

MARKETED BY:



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(Additional information is available on request)