

TRIVOGLITOR FORTE

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

Abbreviated Prescribing information for Trivoglitator Forte (Metformin Hydrochloride (SR) 500mg, Glimepiride 1mg/2mg and Voglibose 0.3mg Tablets) [Please refer the complete prescribing information for details]

PHARMACOLOGICAL PROPERTIES: Oral antihyperglycemic agents.

INDICATIONS: Treatment of patients with type 2 diabetes mellitus when diet, exercise and the therapy with two agents do not result in adequate glycemic control.

DOSAGE AND ADMINISTRATION: Trivoglitator Forte should be given once daily before a full meal. Therapy should be started with Trivoglitator Forte 1 or 2 one tablet daily based on previous drug treatment and glycemic status of the patient. Depending upon the glycemic control, dose may be titrated to 2 tablets once daily.

CONTRAINDICATIONS: Contraindicated in the patients with history of hypersensitivity to any of the ingredients of this product or with sulfonamide derivatives, renal disease or renal dysfunction, congestive heart failure, acute or chronic metabolic acidosis, diabetic ketoacidosis, patients with severe ketosis, diabetic coma or pre-coma, severe infections, before and after operation, or with serious trauma.

WARNINGS & PRECAUTIONS: Metformin: Lactic acidosis, use in pregnancy and lactation and pediatric use.

Glimepiride: Hypoglycemia, hypersensitivity reactions, hemolytic anemia, increased risk of cardiovascular mortality with sulfonylureas.

Voglibose: History of laparotomy or ileus, chronic intestinal disease, roemheld's syndrome, severe hernia, serious hepatic dysfunction, renal dysfunction and elderly patients

DRUG INTERACTIONS: Metformin: Alcohol, barbiturates, salicylate and phenothiazines may precipitate lactic acidosis and alcohol may precipitate hypoglycemia. Furosemide and nifedipine.

Glimepiride: Increase the glucose-lowering effect: Oral anti-diabetic medications, pramlintide acetate, insulin, angiotensin converting enzyme (ACE) inhibitors, H₂ receptor antagonists, fibrates, propoxyphene, pentoxifylline, somatostatin analogs, anabolic steroids and androgens, cyclophosphamide, phenyramidol, guanethidine, fluconazole, sulfinpyrazone, tetracyclines, clarithromycin, disopyramide, quinolones, fluoxetine, nonsteroidal anti-inflammatory drugs, salicylates, sulfonamides, chloramphenicol, coumarins, probenecid and monoamine oxidase inhibitors. **Reduce the glucose-lowering effect:** Danazol, glucagon, somatropin, protease inhibitors, atypical antipsychotic medications, barbiturates, diazoxide, laxatives, rifampin, thiazides and other diuretics, corticosteroids, phenothiazines, thyroid hormones, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, and isoniazid. Beta-blockers, clonidine, reserpine, acute and chronic alcohol intake, sympatholytic drugs, miconazole, fluconazole, rifampin and colesevelam.

Voglibose: Beta-blockers, salicylic acid preparations, monoamine oxidase inhibitors, fibrate derivatives, epinephrine, adrenocortical hormone, thyroid hormone.

ADVERSE REACTIONS: Metformin: lactic acidosis, acute or chronic renal impairment, nausea, vomiting, abdominal pain, diarrhea, megaloblastic anemia, rash, urticaria and pruritis.

Glimepiride: Hypoglycemia, hemolytic anemia, headache, accidental injury, flu syndrome, nausea, dizziness, weight gain, allergic reactions, anaphylaxis, angioedema, stevens-johnson syndrome, porphyria cutanea tarda, leukopenia, agranulocytosis, pancytopenia, hepatic porphyria, hyponatremia and SIADH.

Voglibose: Abdominal swelling, increased flatus, intestinal obstruction-like symptom, increase in intestinal gas, Serious hepatic dysfunction accompanied with jaundice, increased AST or ALT, fulminant hepatitis, Diarrhoea, loose stools, Stomatitis, thirst or borborygmus, abdominal taste abnormality pain, constipation, anorexia, nausea, vomiting or heartburn, Increased AST, ALT, LDH, γ -GTP or ALP, Anaemia, Numbness, edema of face etc., blurred vision, hot flushes, malaise, weakness, hyperkalemia, increased serum amylase, decreased HDL cholesterol, diaphoresis or alopecia.