

AZULIX 1/2 MF Forte

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory
Abbreviated Prescribing information for AZULIX 1/2 MF forte (Glimepiride 1/2mg and Metformin Hydrochloride Sustained Release 1000mg Tablets) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: *Glimepiride:* Glimepiride is an oral blood-glucose-lowering drug of the sulfonylurea class. *Metformin:* improves glucose tolerance in patients with type 2 diabetes, lowering both basal and postprandial plasma glucose.

INDICATION: In the treatment of patients with type 2 diabetes mellitus when diet, exercise and the single agent do not result in adequate glycemic control.

DOSAGE AND ADMINISTRATION: Should be given once daily with a full meal & should be started at a low dose.

CONTRINDICATIONS: *Glimepiride:* Hypersensitivity reaction with Glimepiride or any of the product's ingredients (hypersensitivity reactions include cutaneous eruptions with or without pruritus as well as more serious reactions (e.g. anaphylaxis, angioedema, Stevens-Johnson syndrome, dyspnea)). Sulfonamide derivatives: an allergic reaction to sulfonamide derivatives may develop an allergic reaction to Glimepiride. *Metformin:* Renal disease or renal dysfunction, Congestive heart failure, hypersensitivity to Metformin hydrochloride, Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma.

WARNINGS & PRECAUTIONS: *Glimepiride:* Hypoglycemia, Hypersensitivity Reactions, Hemolytic Anemia, Increased Risk of Cardiovascular Mortality with Sulfonylureas, Macrovascular Outcomes. *Metformin:* Lactic Acidosis, Metformin is not recommended for use in pregnancy.

DRUG INTERACTIONS: *Glimepiride:* *Drugs Affecting Glucose Metabolism:* Increase the glucose-lowering effect e.g. oral anti-diabetic medications, pramlintide acetate, insulin, angiotensin converting enzyme (ACE) inhibitors, H2 receptor antagonists, fibrates, propoxyphene, pentoxifylline, somatostatin analogs, phenylramidol. Reduce the glucose-lowering effect e.g. danazol, somatropin, protease inhibitors, atypical antipsychotic medications (e.g., olanzapine and clozapine), barbiturates, diazoxide, laxatives, rifampin, thiazides and other diuretics, corticosteroids. Oral miconazole and sulfonylureas leading to severe hypoglycemia. *Cytochrome P450 2C9 Interactions:* inhibitors (e.g., fluconazole) and inducers (e.g., rifampin). *Concomitant Administration of Colesevelam:* Reduce the maximum plasma concentration. *Metformin:* Alcohol, barbiturates, salicylate and phenothiazines may precipitate lactic acidosis. Furosemide increased the Metformin plasma and blood C_{max}. Nifedipine appears to enhance the absorption of Metformin.

ADVERSE REACTIONS: *Glimepiride:* Hypoglycemia, Headache, Flu Syndrome, Nausea, Dizziness, Weight gain, Allergic Reactions, Elevated Serum Alanine Aminotransferase (ALT), Serious hypersensitivity reactions (including anaphylaxis, angioedema, and Stevens-Johnson Syndrome), Porphyria cutanea tarda, photosensitivity reactions, allergic vasculitis, Leukopenia, agranulocytosis, aplastic anemia, pancytopenia, Thrombocytopenia, Hepatic porphyria reactions, disulfiram-like reactions, onatremia and syndrome of inappropriate antidiuretic hormone secretion (SIADH). *Metformin:* lactic acidosis, congestive heart failure, trauma, severe dehydration, intravenous pyelography, arteriography, acute asthmatic attack, status

epilepticus, nausea, vomiting, abdominal pain, and diarrhea. Megaloblastic anemia, GI symptoms, Sensitivity reactions such as rash, urticaria and pruritis.

MARKETED BY:



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(Additional information is available on request)