

AZULIX

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory
Abbreviated Prescribing information for AZULIX (Glimepiride 1mg, 2mg, 3mg and 4mg
Tablets) [Please refer the complete prescribing information available at
www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Glimepiride is an oral blood-glucose-lowering drug of the sulfonylurea class. **INDICATION:** An adjunct to diet and exercise to lower the blood glucose in patients with non-insulin dependant (type-II) diabetes mellitus whose hyperglycemia cannot be controlled by diet and exercise alone. **DOSAGE AND ADMINISTRATION:** Recommended starting dose of Glimepiride is 1 mg or 2 mg once daily. Patients at increased risk for hypoglycemia (e.g., the elderly or patients with renal impairment) should be started on 1 mg once daily. The maximum recommended dose is 8 mg once daily. **CONTRINDICATIONS:** 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. **WARNINGS & PRECAUTIONS:** Hypoglycemia, Hypersensitivity Reactions, Hemolytic Anemia, Increased Risk of Cardiovascular Mortality with Sulfonylureas, no evidence for macrovascular Outcomes. **DRUG INTERACTIONS:** *Drugs Affecting Glucose Metabolism:* medications that may 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, phenyramidol, guanethidine, fluconazole, sulfapyrazone, tetracyclines, clarithromycin, disopyramide, quinolones and those drugs that are highly protein-bound, such as fluoxetine, nonsteroidal anti-inflammatory drugs, salicylates, sulfonamides, chloramphenicol, coumarins, probenecid and monoamine oxidase inhibitors. Medications that may reduce the glucose-lowering effect e.g. danazol, glucagon, somatropin, protease inhibitors, atypical antipsychotic medications (e.g., olanzapine and clozapine), barbiturates, diazoxide, laxatives, rifampin, thiazides and other diuretics, corticosteroids. A potential interaction between 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 and total exposure of glimepiride when the two are coadministered. **ADVERSE REACTIONS:** Hypoglycemia, headache, flu Syndrome, nausea, dizziness, weight gain, allergic reactions, hemolytic anemia in patients with and without G6PD deficiency, serious hypersensitivity reactions(including anaphylaxis, angioedema, and stevens-johnson syndrome), impairment of liver function including hepatitis, porphyria cutanea tarda, photosensitivity reactions, allergic vasculitis, leukopenia, agranulocytosis, aplastic anemia, pancytopenia, thrombocytopenia, hepatic porphyria reactions, disulfiram-like reactions, hyponatremia and syndrome of inappropriate antidiuretic hormone secretion (SIADH).

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

IN/ AZULIX /1,2,3,4mg/FEB 2015/01/AbPI

(Additional information is available on request)