AZULIX-3

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

Abbreviated Prescribing information for **AZULIX-3** [Glimepiride Tablets I.P. 3mg] [Please refer the complete prescribing information available at www.torrentpharma.com]. **PHARMACOLOGICAL PROPERTIES**: The primary mechanism of action of glimepiride in lowering blood glucose appears to be dependent on stimulating the release of insulin from functioning pancreatic beta cells. **INDICATION**: Azulix is indicated as an adjunct to diet and exercise to lower the blood glucose in patients with non-insulin dependent (type-II) diabetes mellitus whose hyperglycemia cannot be controlled by diet and exercise alone. **DOSAGE AND ADMINISTRATION**: Glimepiride should be administered with breakfast or the first main meal of the day. The 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. **CONTRAINDICATION:** Glimepiride is contraindicated in patients with a history of a hypersensitivity reaction to Sulfonamide derivatives. **WARNINGS & PRECAUTIONS**: Close supervision of high-risk patients should accompany with hypoglycemia, hypersensitivity reactions, hemolytic anemia, increased Risk of cardiovascular mortality with sulfonylureas and macro vascular outcomes**. DRUG INTERACTIONS**: A number of medications affect glucose metabolism and may require Glimepiride dose adjustment and these are following are examples of medications that may increase the glucose-lowering effect of sulfonylureas including Glimepiride, increasing the susceptibility to and/or intensity of hypoglycemia: 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, and those drugs that are highly protein-bound, such as fluoxetine, nonsteroidal anti-inflammatory drugs, salicylates, sulfonamides, chloramphenicol, coumarins, probenecid and monoamine oxidase inhibitors, and other drugs which worsen glycemic control are danazol, glucagon, somatropin, protease inhibitors, atypical antipsychotic medications (e.g., olanzapine and clozapine), barbiturates, diazoxide, laxatives, rifampin, thiazides and other diuretics, corticosteroids, phenothiazines, thyroid hormones, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics (e.g., epinephrine, albuterol, terbutaline), and isoniazid. Beta-blockers, clonidine, and reserpine may lead to either potentiation or weakening of Glimepiride's glucose-lowering effect. Micanazole may potential interaction with sulfonyl urea and there may be an interaction between glimepiride and inhibitors (e.g., fluconazole) and inducers (e.g., rifampin) of cytochrome P450 2C9. Colesevelam can reduce the maximum plasma concentration and total exposure of glimepiride when the two are co-administered. **ADVERSE REACTIONS**: Serious hypersensitivity reactions, including anaphylaxis, angioedema, and Stevens-Johnson Syndrome, Hemolytic anemia in patients with and without G6PD deficiency, Impairment of liver function (e.g. with cholestasis and jaundice), as well as hepatitis, which may progress to liver failure, Porphyria cutanea tarda, photosensitivity reactions and allergic vasculitis, Leukopenia, agranulocytosis, aplastic anemia, and pancytopenia, Thrombocytopenia (including severe cases with platelet count less than 10,000/µL) and thrombocytopenic purpura, Hepatic porphyria reactions and disulfiram-like reactions, Hyponatremia and syndrome of inappropriate antidiuretic hormone secretion (SIADH), most often in patients who are on other medications or who have medical conditions known to cause hyponatremia or increase release of antidiuretic hormone

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(Additional information is available on request)