AZULIX

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

Abbreviated Prescribing information for AZULIX [Glimepiride 1 mg, 2 mg, 3 mg, and 4 mg Tablets I.P.]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Glimepiride acts mainly by stimulating insulin release from pancreatic beta cells. As with other sulphonylureas this effect is based on an increase of responsiveness of the pancreatic beta cells to the physiological glucose stimulus. In addition, glimepiride seems to have pronounced extra pancreatic effects also postulated for other sulphonylureas.

INDICATIONS: 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: The starting dose is 1 mg glimepiride per day. If control is unsatisfactory, the dose should be increased, based on the glycaemic control, in a stepwise manner with an interval of about 1 to 2 weeks between each step, to 2, 3 or 4 mg glimepiride per day. A dose of more than 4 mg glimepiride per day gives better results only in exceptional cases. The maximum recommended dose is 6 mg glimepiride per day. For oral administration. Tablets should be swallowed without chewing with some liquid.

CONTRAINDICATION: •Hypersensitivity to glimepiride, other sulfonylureas or sulfonamides or to any of the excipients. • Diabetes Mellitus type I. • Diabetic coma. • Ketoacidosis • Severe renal or hepatic function disorders.

WARNINGS & PRECAUTIONS: Glimepiride must be taken shortly before or during a meal. When meals are taken at irregular hours or skipped altogether, treatment with "Glimepiride Tablets" may lead to hypoglycaemia. The clinical picture of a severe hypoglycaemic attack may resemble that of a stroke. Severe hypoglycaemia or prolonged hypoglycaemia, only temporarily controlled by the usual amounts of sugar, require immediate medical treatment and occasionally hospitalisation. Treatment of patients with G6PD-deficiency with sulfonylurea agents can lead to hemolytic anaemia. Since glimepiride belongs to the class of sulfonylurea agents, caution should be used in patients with G6PD-deficiency and a non-sulfonylurea alternative should be considered. Glimepiride Tablets contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

DRUG INTERACTIONS: Glimepiride is metabolized by cytochrome P450 2C9 (CYP2C9). Its metabolism is known to be influenced by concomitant administration of CYP2C9 inducers (e.g. rifampicin) or inhibitors (e.g. fluconazole). H2 antagonists, beta-blockers, clonidine, and reserpine may lead to either potentiation or weakening of the blood-glucose-lowering effect. Alcohol intake may potentiate or weaken the hypoglycaemic action of glimepiride in an unpredictable fashion.

ADVERSE REACTIONS: Thrombocytopenia, leukopenia, granulocytopenia, agranulocytosis, erythropenia, haemolytic anemia, pancytopenia, severe thrombocytopenia, leukocytoclastic vasculitis, mild hypersensitivity reactions, cross-allergenicity with sulfonylureas, sulfonamides or related substances, hypoglycemia, visual disturbances, nausea, vomiting, diarrhoea, abdominal distension, discomfort and pain, dysgeusia, hepatic function abnormal, hepatitis, hepatic failure, hepatic enzymes increased, alopecia, blood sodium decrease, weight gain.

MARKETED BY:

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IN/AZULIX 1mg, 2mg, 3mg, 4mg/JUL-2025/02/ABPI

(Additional information is available on request)