AZULIX 0.5 MF

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

Abbreviated Prescribing information for AZULIX 0.5 MF (Metformin Hydrochloride (As Prolonged-Release) AND Glimepiride**)**

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: AZULIX 0.5 MF contains Metformin Hydrochloride and Glimepiride. Metformin exerts its glucose-lowering effect by reduction of hepatic glucose production through inhibition of gluconeogenesis and glycogenolysis; by modestly increasing insulin sensitivity, improving peripheral glucose uptake and utilisation; and by delaying intestinal glucose absorption. Glimepiride acts mainly by stimulating insulin release from pancreatic beta cells. As with other sulfonylureas this effect is based on an increase of responsiveness of the pancreatic beta cells to the physiological glucose stimulus.

DOSAGE AND ADMINISTRATION: AZULIX 0.5 MF tablets should be administered orally as directed by the Physician. Tablets should be swallowed whole with a glass of water and should not be chewed or crushed.

CONTRAINDICATION: Hypersensitivity to metformin or to glimepiride or other sulfonylureas or sulphonamides or to any of the excipients, Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis), Diabetic pre-coma, Severe renal failure (GFR < 30 mL/min), Acute conditions with the potential to alter renal function such as: dehydration, severe infection, shock, Disease which may cause tissue hypoxia (especially acute disease, or worsening of chronic disease) such as: decompensated heart failure, respiratory failure, recent myocardial infarction, shock, Hepatic insufficiency, acute alcohol intoxication, alcoholism.

WARNINGS & PRECAUTIONS:

Metformin:

Metformin accumulation occurs at acute worsening of renal function and increases the risk of lactic acidosis. Metformin is contraindicated in patients with GFR<30 mL/min. Patients with heart failure are more at risk of hypoxia and renal insufficiency. Administration of iodinated contrast agents: Intravascular administration of iodinated contrast agents may lead to contrast induced nephropathy, resulting in metformin accumulation and an increased risk of lactic acidosis. Metformin alone does not cause hypoglycaemia, but caution is advised when it is used in combination with insulin or other oral antidiabetics (e.g. sulfonylureas or meglitinides).

Glimepiride: Glimepiride may lead to hypoglycaemia if meals are taken at irregular hours or skipped, severe hypoglycaemic attack may resemble that of a stroke. 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, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

DRUG INTERACTION:

Metformin: Concomitant use not recommended: Alcohol intoxication is associated with an increased risk of lactic acidosis, particularly in case *Iodinated contrast agents*. Combinations requiring precautions for use: NSAIDs, including selective cyclo-oxygenase (COX) II inhibitors, ACE inhibitors, angiotensin II receptor antagonists and diuretics increase the risk of lactic acidosis.
Glimepiride: If glimepiride is taken simultaneously with certain other medicinal products, both undesired increases and decreases in the hypoglycaemic action of glimepiride can occur. Alcohol intake may potentiate or weaken the hypoglycaemic action of glimepiride in an unpredictable fashion. Glimepiride may either potentiate or weaken the effects of coumarin derivatives

ADVERSE REACTIONS: Metformin: Lactic acidosis, Taste disturbance, Skin reactions such as erythema, pruritus, urticarial, Gastrointestinal disorders such as nausea, vomiting, diarrhoea, abdominal pain and loss of appetite.

Glimepiride: Thrombocytopenia, leukopenia, granulocytopenia, agranulocytosis, erythropenia, haemolytic anaemia and pancytopenia, Visual disturbances, Hepatic function abnormal, Blood sodium decrease, leukocytoclastic vasculitis.

Marketed BY:
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(Additional information is available on request)