

AZULIX SM IR

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

Abbreviated Prescribing information for AZULIX SM IR [Sitagliptin Phosphate, Metformin Hydrochloride & Glimepiride Tablets (50+1000+1/2 mg), (50+500+1/2 mg)]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: *Sitagliptin* phosphate is an orally-active, potent, and highly selective inhibitor of the dipeptidyl peptidase 4 (DPP-4) enzyme for the treatment of type 2 diabetes. *Metformin* may act via 3 mechanisms: (A) Reduction of hepatic glucose production by inhibiting gluconeogenesis and glycogenolysis. (B) In muscle, by increasing insulin sensitivity, improving peripheral glucose uptake and utilization and (C) Delay of intestinal glucose absorption. *Glimepiride* primarily lowers blood glucose by stimulating the release of insulin from pancreatic beta cells. Sulfonylureas bind to the sulfonylurea receptor in the pancreatic beta- cell plasma membrane, leading to closure of the ATP-sensitive potassium channel, thereby stimulating the release of insulin.

INDICATION: It is indicated for the treatment of as an adjunct to diet an exercise to improve Glycemic control in adults with type 2 diabetes mellitus

DOSAGE AND ADMINISTRATION: As directed by physician.

CONTRAINDICATION: *Sitagliptin and Glimepiride* are contraindicated in patients with a history of a hypersensitivity reaction to Sitagliptin or Glimepiride or any of the product's ingredients. *Metformin:* Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis) Diabetic pre-coma,Sever 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: *Sitagliptin:* It should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, Use of DPP-4 inhibitors has been associated with a risk of developing acute pancreatitis, It is renally excreted. lower dosages are recommended in patients with GFR < 45 mL/min, as well as in ESRD patients requiring haemodialysis or peritoneal dialysis, bullous pemphigoid. *Metformin:* Lactic acidosis is a very rare, but serious (high mortality in the absence of prompt treatment), metabolic complication most often occurs at acute worsening of renal function or cardiorespiratory illness or sepsis, Renal function: GFR should be assessed before treatment initiation and regularly, Cardiac function Patients with heart failure are more at risk of hypoxia and renal insufficiency. *Glimepiride:* Hypoglycemia- All sulfonylureas, including glimepiride, can cause severe hypoglycaemia, Hypersensitivity Reactions hypersensitivity reactions in patients treated with glimepiride, including serious reactions such as anaphylaxis, angioedema, and Stevens- Johnson Syndrome, Hemolytic Anemia Sulfonylureas can cause hemolytic anemia in patients with glucose 6-phosphate dehydrogenase (G6PD) deficiency.

DRUG INTERACTIONS: *Sitagliptin:* sitagliptin and a single 600 mg oral dose of ciclosporin increased the AUC and Cmax of sitagliptin by approximately 29 % and 68 %, respectively, Sitagliptin had a small effect on plasma digoxin concentrations. *Metformin:* Alcohol, Iodinated contrast agents. *Glimepiride:* Drugs Affecting Glucose Metabolism, Miconazole, Cytochrome P450 2C9 Interactions, Concomitant Administration of Colesevelam.

ADVERSE REACTIONS: *Sitagliptin:* thrombocytopenia, hypersensitivity reactions including anaphylactic responses, hypoglycaemia, headache, dizziness, constipation, pruritus, vomiting, acute pancreatitis, fatal and non-fatal haemorrhagic and necrotizing pancreatitis, angioedema, rash, urticarial,

cutaneous vasculitis, exfoliative skin conditions including Stevens-Johnson syndrome, bullous pemphigoid, arthralgia, myalgia, pain in extremity, back pain, arthropathy, impaired renal function, acute renal failure. *Metformin*: nausea, vomiting, diarrhoea, abdominal pain and loss of appetite, Lactic acidosis, liver function tests abnormalities or hepatitis, Skin reactions such as erythema, pruritus, urticaria. *Glimepiride*: Hypoglycemia, Hemolytic anemia, 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, Hepatic porphyria reactions and disulfiram-like reactions, Hyponatremia and syndrome of inappropriate antidiuretic hormone secretion, Dysgeusia, Alopecia.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

IN/AZULIX SM IR (50+1000+1/2 mg), (50+500+1/2 mg)/MAR-2024/01/ABPI

(Additional information is available on request)