SITAXA GM IR

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

Abbreviated Prescribing information for SITAXA GM IR (Sitagliptin 50 mg, Metformin Hydrochloride 1000 mg and Glimepiride 1/2 mg Tablets**)**

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Sitagliptin: 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. The DPP-4 inhibitors are a class of agents that act as incretin enhancers. By inhibiting the DPP-4 enzyme, sitagliptin increases the levels of two known active incretin hormones, glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP). The incretins are part of an endogenous system involved in the physiologic regulation of glucose homeostasis. When blood glucose concentrations are normal or elevated, GLP-1 and GIP increase insulin synthesis and release from pancreatic beta cells. GLP-1 also lowers glucagon secretion from pancreatic alpha cells, leading to reduced hepatic glucose production.

Metformin: Metformin may act via 3 mechanisms: • reduction of hepatic glucose production by inhibiting gluconeogenesis and glycogenolysis. • in muscle, by increasing insulin sensitivity, improving peripheral glucose uptake and utilization. • and delay of intestinal glucose absorption. Metformin stimulates intracellular glycogen synthesis by acting on glycogen synthase. Metformin increases the transport capacity of all types of membrane glucose transporters (GLUTs) known to date.

Glimepiride: 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: Dose: As directed by the Physician.

The recommended dose is one tablet daily. Each film coated tablet contains a fixed dose of Sitagliptin, Metformin Hydrochloride & Glimepiride.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients.

WARNINGS & PRECAUTIONS: ***Sitagliptin*** *Acute pancreatitis* - Use of DPP-4 inhibitors has been associated with a risk of developing acute pancreatitis. Patients should be informed of the characteristic symptom of acute pancreatitis: persistent, severe abdominal pain. *Hypoglycaemia when used in combination with other anti-hyperglycaemic medicinal products* In clinical trials of Sitagliptin as monotherapy and as part of combination therapy with medicinal products not known to cause hypoglycaemia, *Renal impairment* - Sitagliptin is renally excreted. To achieve plasma concentrations of sitagliptin similar to those in patients with normal renal function, lower dosages are recommended in patients with GFR < 45 mL/min, as well as in ESRD patients requiring haemodialysis or peritoneal dialysis. *Hypersensitivity reactions* - Post-marketing reports of serious hypersensitivity reactions in patients treated with sitagliptin have been reported. These reactions include anaphylaxis, angioedema, and exfoliative skin conditions including Stevens-Johnson syndrome, *Bullous pemphigoid* - If bullous pemphigoid is suspected, Sitagliptin should be discontinued. ***Metformin*** *Lactic acidosis*: 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. Metformin is contraindicated in patients with GFR <30 ml / min and should be temporarily discontinued in presence of conditions that alter renal function. *Cardiac function* Patients with heart failure are more at risk of hypoxia and renal insufficiency. In patients with chronic stable heart failure, metformin may be used with regular monitoring of cardiac and renal function. ***Glimepiride*** *Hypoglycemia* - All sulfonylureas, including glimepiride, can cause severe hypoglycemia .The patient's ability to concentrate and react may be impaired as a result of hypoglycaemia, *Hemolytic Anemia* - Sulfonylureas can cause hemolytic anemia in patients with glucose 6-phosphate dehydrogenase (G6PD) deficiency, *Increased Risk of Cardiovascular Mortality with Sulfonylureas*- The administration of oral hypoglycemic drugs has been reported to be associated with increased cardiovascular mortality as compared to treatment with diet alone or diet plus insulin

DRUG INTERACTION: Effects of other medicinal products on sitagliptin, Digoxin, Ciclosporin, Alcohol, Iodinated contrast agents, Inhibitors of OCT1 (such as verapamil), Inhibitors of OCT2 (such as cimetidine, dolutegravir, ranolazine, trimethoprime, vandetanib, isavuconazole), Miconazole, Cytochrome P450 2C9 Interactions, Concomitant Administration of Colesevelam,

ADVERSE REACTIONS: Thrombocytopenia, Hypersensitivity Reactions Including Anaphylactic Responses, Hypoglycaemia, Headache, Dizziness, Interstitial Lung Disease, Constipation, Vomiting, Acute Pancreatitis, Fatal and Non-Fatal Haemorrhagic And Necrotizing Pancreatitis, Angioedema, Impaired Renal Function, Arthralgia.

MANUFACTURED BY:

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IN/ SITAXA GM IR (50+1000+1 mg)(50+1000+2 mg)/Feb-2024/01/PI
(Additional information is available on request)