Siglita™

Sitagliptin

PRESENTATION
Siglita™ 50: Each film coated tablet contains Sitagliptin 50 mg as Sitagliptin Phosphate Monohydrate INN
Siglita™ 100: Each film coated tablet contains Sitagliptin 100 mg as Sitagliptin Phosphate Monohydrate INN

PHARMACOLOGY
Sitagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor, which is believed to exert its actions in patients with type 2 diabetes by slowing the inactivation of incretin hormones. Incretin hormones, including glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP), are released by the intestine throughout the day, and levels are increased in response to a meal. These hormones are rapidly inactivated by the enzyme, DPP-4. 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 by intracellular signaling pathways involving cyclic AMP. GLP-1 also lowers glucagon secretion from pancreatic alpha cells, leading to reduced hepatic glucose production. By increasing and prolonging active incretin levels, Sitagliptin increases insulin release and decreases glucagon levels in the circulation in a glucose-dependent manner.

INDICATION & USAGE
Siglita™ is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus. It is also indicated for use in combination with Metformin, Sulfonylurea or Thiazolidinediones when diet and exercise plus the single agent does not provide adequate glycemic control.

DOSAGE AND ADMINISTRATION
- The recommended dose of **Siglita**™ is 100 mg once daily. **Siglita**™ can be taken with or without food.
- For patients with mild renal insufficiency (creatinine clearance [CrCl] ≥50 mL/min) no dosage adjustment for **Siglita**™ is required.
- For patients with moderate renal insufficiency (CrCl ≥30 to <50 mL/min), the dose of **Siglita**™ is 50 mg once daily.
- For patients with severe renal insufficiency (CrCl <30 mL/min) or with end-stage renal disease (ESRD) requiring hemodialysis or peritoneal dialysis, the dose of Siglita™ is 25 mg once daily. **Siglita**™ may be administered without regard to the timing of hemodialysis.

ADVERSE REACTIONS
The most common adverse reactions are; upper respiratory tract infection, nasopharyngitis and headache. Hypoglycemia may occur in patients treated with the combination of Sitagliptin and sulfonylurea and add-on to insulin.

PRECAUTION
Dosage adjustment is recommended in patients with moderate or severe renal insufficiency and in patients with ESRD

USE IN PREGNANCY AND LACTATION
Pregnancy: Pregnancy Category B.
Safety of Sitagliptin in pregnant women has not been established. Sitagliptin should be used during pregnancy only if the potential benefit justifies the potential risk of the fetus.
Nursing Mothers: It is not known whether sitagliptin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Sitagliptin is administered to a nursing woman.

GERIATRIC USE
No dosage adjustment is required based solely on age. The drug is excreted by the kidney. As elderly patients are more likely to have decreased renal function, caution should be taken in dose selection in the elderly.

PEDIATRIC USE
Safety and effectiveness of Sitagliptin in pediatric patients under 18 years of age have not been established.

CONTRAINDICATION
History of a serious hypersensitivity reaction to sitagliptin, such as anaphylaxis or angioedema.

DRUG INTERACTIONS
Co-administration of Digoxin and Sitagliptin may slightly increase the mean peak drug concentration of Digoxin. But no dosage adjustment of digoxin or Sitagliptin is recommended.

STORAGE
Keep away from light & moisture. Store below 30°C. Keep out of the reach of the children.

HOW SUPPLIED
Siglita™ 50: Each box contains 30 tablets in blister pack.
Siglita™ 100: Each box contains 10 tablets in blister pack.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH