Linita™

Linagliptin 5 mg tablet

PRESENTATION
Linita™ Tablet: Each film coated tablet contains Linagliptin INN 5 mg.

PHARMACOLOGY:
Linagliptin 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 reduce hepatic glucose production. By increasing and prolonging active incretin levels, Linagliptin increases insulin release and decreases glucagon levels in the circulation in a glucose-dependent manner.

PHARMACOKINETICS
After oral administration of a single 5-mg dose to healthy subjects, peak plasma concentrations (Tmax) of Linagliptin occurred at approximately 1.5 hours post dose; the mean plasma area under the curve (AUC) was 139 nmol/L and maximum concentration (Cmax) was 8.9 nmol/L. The absolute bioavailability of Linagliptin is approximately 30%. Following oral administration, the majority (about 90%) of Linagliptin is excreted unchanged.

INDICATION
Linita™ is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus.

DOSAGE AND ADMINISTRATION
The recommended dose of **Linita**™ is 5 mg once daily. No dosage adjustment is required for hepatic or kidney impaired patients.

SIDE EFFECTS
Side effects includes: Hypoglycemia, headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heart beat, sweating, stuffy or runny nose and sore throat.

ADVERSE REACTIONS
● Adverse reactions reported in 5% of patients treated with Linagliptin and more commonly than in patients treated with placebo included nasopharyngitis. ● Hypoglycemia was more commonly reported in patients treated with the combination of Linagliptin and sulfonylurea compared with those treated with the combination of placebo and sulfonylurea . ● Pancreatitis was reported more often in patients randomized to Linagliptin.

PRECAUTION
When used with an insulin secretagogue (e.g. sulfonylurea), consider lowering the dose of the insulin secretagogue to reduce the risk of hypoglycemia.

USE IN PREGNANCY AND LACTATION
Pregnancy: Pregnancy Category-B. There are no adequate and well-controlled studies in pregnant women. Linagliptin tablets should be used during pregnancy only if clearly needed. *Nursing Mothers:* It is not known if whether Linagliptin passes into breast milk or not. Caution should be exercised when Linitagliptin is administered to a nursing woman.

GERIATRIC USE
No dosage adjustment is required based solely on age.

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

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

DRUG INTERACTIONS
P-glycoprotein/CYP3A4 inducer: The efficacy of Linagliptin may be reduced when administered in combination (e.g., with rifampin). Use of alternative treatments is strongly recommended.

OVERDOSE
With single dose of up to 600 mg of Linagliptin there were no dose-related clinical adverse drug reactions. In the event of an overdose, contact with specialist doctor, hospital. It is also reasonable to employ the usual supportive measures, e.g., remove unabsorbed material from the gastrointestinal tract, use charcoal, employ clinical monitoring, and institute supportive treatment as dictated by the patient's clinical status.

STORAGE
Store in cool and dry place (at 25^0 c). Protect from light and moisture. Keep medicine out of the reach of children.

HOW SUPPLIED
Linita™ Tablet: Each box contains 20 tablets in blister pack.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH