Viglita™

Vildagliptin

COMPOSITION
Viglita™ 50 Tablet: Each tablet contains Vildagliptin INN 50 mg.

PHARMACOLOGY
Viglita™ 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, **Viglita**™ increases insulin release and decreases glucagon levels in the circulation in a glucose-dependent manner.

INDICATION AND USAGE
Viglita™ is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus.
- As monotherapy
- In dual combination with Metformin, a Sulphonylurea, a Thiazolidinedione, or Insulin when diet, exercise and a single antidiabetic agent do not result in adequate glycemic control.

DOSAGE AND ADMINISTRATION
The recommended dose of **Viglita**™ is
- 50 mg or 100 mg daily for monotherapy.
- 50 mg twice daily (morning and evening) when used in dual combination with Metformin or a Thiazolidinedione;
- 50 mg once daily in the morning when used in dual combination with a Sulphonylurea.

Viglita™ may be taken with or without a meal. No dosage adjustment is required in the elderly, or in patients with mild renal impairment.

PRECAUTIONS
Caution should be exercised in patients aged 75 years and older due to limited clinical experience. It is recommended that Liver Function Tests (LFTs) are monitored prior to initiation of Vildagliptin, at three-monthly intervals in the first year and periodically thereafter. If transaminase levels are increased, patients should be monitored with a second liver function evaluation to confirm the finding and be followed thereafter with frequent liver function tests until the abnormality (ies) return(s) to normal. If AST or ALT persist at 3 x ULN, Vildagliptin treatment should be stopped. Patients who develop jaundice or other signs of liver dysfunction should discontinue Vildagliptin. Following withdrawal of treatment with Vildagliptin and LFT normalization, treatment with Vildagliptin should not be reinitiated. Due to limited clinical experience, use with caution in patients with congestive heart failure of New York Heart Association (NYHA) functional class I–II, and do not use in patients with NYHA functional class III-IV. Vildagliptin is not recommended in patients with moderate to severe renal impairment.

CONTRAINDICATIONS
Vildagliptin is contraindicated in patients with:
- Hypersensitivity to the active substance or to any of the excipients
- Patients with type 1 diabetes or for the treatment of diabetic ketoacidosis

ADVERSE EFFECTS
The majority of adverse reactions were mild and transient, not requiring treatment discontinuations. Rare case of hepatic dysfunction is seen. Clinical trials of up to and more than 2 years' duration did not show any additional safety signals or unforeseen risks when use this drug.

DRUG INTERACTION
In pharmacokinetic studies, no interactions were seen with pioglitazone, metformin, glibenclamide, digoxin, warfarin, amlodipine, ramipril, valsartan or simvastatin. As with other oral antidiabetic medicinal products the glucose-lowering effect of Vildagliptin may be reduced by certain active substances, including thiazides, corticosteroids, thyroid products and sympathomimetics.

USE IN PREGNANCY & LACTATION
PREGNANCY: There are no adequate data on the use of Vildagliptin in pregnant women; hence the potential risk for human is unknown.
NURSING MOTHERS: It is not known whether Vildagliptin is excreted in human milk. Due to lack of human data, Vildagliptin should not be used during lactation.
PEDIATRIC USE: Vildagliptin is not recommended in patients 18 years of age.

STORAGE
Store in a cool and dry place. Protect from light and moisture. Keep out of the reach of the children.

HOW SUPPLIED
Viglita™ 50 Tablet: Each box contains 20 tablets in blister pack.

Manufactured by :

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH

TM - Trade Mark