

Viglita[®]

Vildagliptin

COMPOSITION

Viglita[®] 50Tablet: 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, Sitagliptin 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 and 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 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 3x 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.

CONTRAINDICATIONS

Vildagliptin is contraindicated in patients with:

- Hypersensitivity to the active substance or to any of the excipients
- Patients with moderate to severe renal impairment
- Patients with Hepatic Impairment: patients with pre-treatment alanine aminotransferase (ALT) or aspartate aminotransferase (AST) >3 times the upper limit of normal (ULN).
- Patients with type 1 diabetes

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 combination.

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: Vildagliptin should not be used in pregnancy

NURSING MOTHERS: Vildagliptin should not be used during lactation.

PEDIATRIC USE

Vildagliptin is not recommended in patients 18 years of age.

STORAGE

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

HOW SUPPLIED

Viglita[®] 50 Tablet: Each box contains 20 tablets in blister pack.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH