Vilip®

Vildagliptin

COMPOSITION:
Vilip ® 50 Tablet: Each film coated tablet contains Vildagliptin INN 50 mg.

PHARMACOLOGY:
Vilip ® Tablet 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 protelytic enzyme, DPP-IV. 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, Vildagliptin increases insulin release and decreases glucagon levels in the circulation in a glucose-dependent manner.

INDICATION:
Vilip ® Tablet 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.

DOSE & ADMINISTRATION:
The recommended dose of Vilip ® Tablet is

* 50 mg or 100 mg daily for monotherapy .
* 50 mg twice daily (morning and evening) when used in dual combination with Metforin or a thiazolidinedione.
* 50 mg once daily in the morning when used in dual combination with a sulphonylurea. Vilip ® Tablet may be taken with or without a meal. No dosage adjustment is required in the elderly or in patients with mild renal impairment.

CONTRA-INDICATIONS:
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 aminotrans ferase (ALT) or aspartate aminotrasferase (AST) >3 times the upper limit of normal (ULN).
* Patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

WARNING AND PRECAUTION:
Caution should be exercised in patients aged 75 years and older due to limited clinical experience. It is recommended that Liver function test (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 3xULN, 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.

SIDE EFFECTS:
The most common side effects associated with Vildagliptin therapy include headache, tremor, dizziness, nausea and asthenia and less commonly constipations and hypoglycemia.

USE IN PREGNANCY & LACTATION:
Pregnancy: Vildagliptin should not be used in pregnancy.
Lactation: Vildagliptin should not be used during lactation.

USE IN CHILDREN & ADOLESCENTS:
Vildagliptin is not recommended in patients below 18 years of age.

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.

OVERDOSE:
Muscle pain, mild and transient paaesthesia, fever oedema and transient increase in lipse levels.

STORAGE:
Store in a dry and cool place below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

COMMERCIAL PACKING:
Vilip ® 50 Tablet: Each box contains 3x10's tablets in Alu-Alu blister pack.

Manufactured by
Team Pharmaceuticals Ltd.
B 75-79, BSCIC, Rajshahi, Bangladesh

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