Vilip Plus®

Vildagliptin and Metformin Hydrochloride

COMPOSITION:

Vilip Plus® 850 Tablet: Each film coated tablet contains Vildagliptin INN 50 mg. & Metformin Hydrochloride BP 850 mg.

PHARMACOLOGY:

Vilip Plus® combines two antihyperglycemic agents with complimentary mechanism of action to improve glycemic control in patients with type 2 diabetes. Vildagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, and Metformin HCl, a member of the biguanide class. Vildagliptin 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, Vildagliptin increases insulin release and decreases glucagon levels in the circulation in glucose-dependent manner.

The mechanism of action of Metformin is different from other classes of oral antihyperglycemic agents. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose, and increases peripheral glucose uptake and utilization.

INDICATION:

Vilip Plus® is indicated in patients with type 2 diabetes who are unable to achieve sufficient glycemic control at their maximally tolerated dose of oral Metformin alone or who are already treated with the combination of Vildagliptin and Metformin as separate tablets.

DOSE & ADMINISTRATION:

Adults: Based on the patient's current dose of Metformin, this Vilip Plus® may be initiated, 1 tablet in the morning and the other in the evening. Patients receiving Vildagliptin and Metformin from separate tablets may be switched to this combination containing the same doses of each component. Doses higher than 100 mg of vildagliptin are not recommended. there is no clinical experience of Vildagliptin and Metformin in triple combination with other antidiabetic agents. taking this Vilip Plus® with or just after food may reduce gastrointestinal symptoms associated with Metformin.

CONTRA-INDICATIONS:

This combination is contraindicated in patients with known hypersensitivity to Vildagliptin or Metformin Hydrochloride or to any of the excipients. It is contraindicated in patients with renal disease or renal dysfunction, acute myocardial infraction, and septicemia. It is also contraindicated in patients with congestive heart failure patients and in patients with acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. It should be temporarily discontinued in patients undergoing radiologic studies involving intravascular administration of iodinated contrast materials, because use of such products may result in acute alteration of renal function.

WARNING AND PRECAUTION:

If metabolic acidosis is suspected, treatment should be discontinued and the patient should be hospitalized immediately. Serum creatinine should be monitored at least once a year in patients with normal renal function and 2 - 4 times a year in patients with serum creatinine levels at the upper limit of normal and in elderly patients. Special caution should be exercised in elderly patients where renal function may become impaired (e.g. when initiating antihypertensives, diuretics or NSAIDs). It is recommended that Liver Function Tests (LFTs) are monitored prior to initiation of this drug, at three-month 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 return to normal. If AST or ALT persist at 3 x ULN, Vildagliptin & Metformin tablets should be stopped Patients who develop jaundice or other signs of liver dysfunction. Following withdrawal of treatment with Vildagliptin & Metformin and LFT normalization, treatment with Vildagliptin & Metformin should not be reinitiated.

SIDE EFFECTS:

The most common side effects are headache, tremor, dizziness, nausea, hypoglycemia etc.

USE IN PREGNANCY & LACTATION:

There are no adequate and well controlled studies in pregnant women and therefore, Vilip Plus should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus. No studies have been conducted with the components of this combination. As it is not known whether Vildagliptin and/or Metformin Hydrochloride is excreted in human milk this combination should not be administered to breast-feeding women.

USE IN CHILDREN & ADOLESCENTS:

This combination is not recommended in patients below 18 years of age.

USE IN ADULT :

Elderly (≥65 years): As Metformin is excreted via the kidney, and elderly patients have a tendency to decreased renal function, elderly patients taking combination of Vildagliptin & Metformin should have their renal function monitored regularly. Combination of Vildagliptin & Metformin has not been studied in patients >75 years. Therefore, the use of combination of Vildagliptin & Metformin is not recommended in this population.

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 paraesthesia, fever edema and transient increase in lipase levels.

STORAGE:

Store in a dry and cool place below 30^0 C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Vilip Plus® 850 Tablet: Each box contains 5 X 4's Tablets in Alu-Alu blister pack.

Manufactured by

Team Pharmaceuticals Ltd.

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