VIPTIN PLUS

Vildagliptin & Metformin Hydrochloride Tablet

Presentation

Viptin Plus 500 Tablet: Each film coated tablet contains Vildagliptin INN 50 mg and Metformin Hydrochloride BP 500 mg.

Viptin Plus 850 Tablet: Each film coated tablet contains Vildagliptin INN 50 mg and Metformin Hydrochloride BP 850 mg.

Pharmacology

The preparation combines two antihyperglycemic agents with complementary mechanisms of action to improve glycemic control in patients with type 2 diabetes: Vildagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, and Metformin Hydrochloride, 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 a glucose-dependent manner. The pharmacologic 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.

Indications

The preparation 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.

Dosage and Administration

Adults: Based on the patient's current dose of Metformin, Combination of Vildagliptin & Metformin may be initiated at either 50 mg/500 mg or 50 mg/850 mg twice daily, 1 tab in the morning and the other in the evening. The recommended daily dose is 100 mg Vildagliptin plus 2000 mg Metformin Hydrochloride. Patients receiving Vildagliptin and Metformin from separate tablets may be switched to Combination of Vildagliptin & Metformin 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 Combination of Vildagliptin & Metformin with or just after food may reduce gastrointestinal symptoms associated with Metformin.

Pediatric Use: Combination of Vildagliptin & Metformin is not recommended in patients under 18 years of age.

Geriatric Use: 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.

Contraindications

Combination (Vildagliptin & Metformin Hydrochloride) is contraindicated in patients with

- Hypersensitivity to the active substance or to any of the excipients,
- Patients with Renal Impairment: Creatinine clearance <60 mL/min,
- Patients with acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin
- Patients with type 1 diabetes

Side Effects

The majority of adverse reactions were mild and transient, not requiring treatment discontinuations. Lactic acidosis can occur due to Metformin. Rare cases of hepatic dysfunction. Some common side effects like tremor, headache, dizziness, nausea, hypoglycaemia, fatigue are 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 combinatin.

Precautions

Lactic acidosis can occur due to Metformin accumulation. 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-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 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. Vildagliptin & Metformin tablets should be discontinued 48 hours before elective surgery with general anaesthesia and should not usually be resumed earlier than 48 hours afterwards.

Drug Interactions

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. Close monitoring of glycemic control is required, when cationic drugs are co-administered. Glucocorticoids, beta-2 agonists, diuretics and ACE inhibitors may alter blood glucose. The patient should be informed and more frequent blood glucose monitoring performed, especially at the beginning of treatment. If necessary, the dosage of Vildagliptin & Metformin tablets may need to be adjusted during concomitant therapy and on its discontinuation.

Use in pregnancy and lactation

Use in pregnancy: There are no adequate data on the use of Vildagliptin & Metformin in pregnant women; hence the potential risk for human is unknown.

Nursing Mother: It is not known whether Vildagliptin is excreted in human milk. Due to lack of human data, Vildagliptin & Metformin should not be used during lactation.

Over Dose

Vildagliptin: Symptoms of over dosage include muscle pain, mild and transient paraesthesia, fever, oedema, transient increase in lipase levels. All symptoms and laboratory abnormalities resolved after study drug discontinuation.

Metformin Hydrochloride: Symptoms of over dosage include Overdose hypoglycaemia and lactic acidosis.

Storage Conditions

Store in a cool and dry place, away from light. Keep out of reach of children.

Commercial Pack

Viptin Plus 500 Tablet: Each box contains 2 blister packs of 10 tablets.

Viptin Plus 850 Tablet: Each box contains 2 blister packs of 10 tablets.

Manufactured by:

general GENERAL Pharmaceuticals Ltd.

Kaliakair, Gazipur, Bangladesh

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