Formet-V

Metformin Hydrochloride & Vildagliptin

COMPOSITION

Formet-V 500/50 Tablet: Each film coated tablet contains Metformin Hydrochloride BP 500 mg and Vildagliptin INN 50 mg.

PHARMACOLOGY

Formet-V 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 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 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.

INDICATION AND USAGE

Formet-V 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 Metformin Hydrochloride and Vildagliptin as separate tablets.

DOSAGE AND ADMINISTRATION

Adults: Based on the patient's current dose of Metformin, combination of Formet V 500/50 mg may be initiated at either 500 mg/50 mg twice daily, 1 tab in the morning and the other in the evening. The recommended daily dose is 2,000 mg Metformin Hydrochloride & Vildagliptin 100 mg. Patients receiving Metformin Hydrochloride and Vildagliptin from separate tablets may be switched to combination of Metformin Hydrochloride and Vildagliptin containing the same doses of each component. Doses higher than 100 mg of Vildagliptin are not recommended. There is no clinical experience of Metformin Hydrochloride and Vildagliptin in triple combination with other antidiabetic agents. Taking combination of Metformin Hydrochloride and Vildagliptin with or just after food may reduce gastrointestinal symptoms associated with Metformin.

PRECAUTIONS

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 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 3x ULN, Metformin Hydrochloride & Vildagliptin tablets should be stopped Patients who develop jaundice or other signs of liver dysfunction. Following withdrawal of treatment with Metformin Hydrochloride & Vildagliptin and LFT normalization, treatment with Metformin Hydrochloride & Vildagliptin should not be reinitiated.

CONTRAINDICATIONS

Combination (Metformin Hydrochloride & Vildagliptin) is contraindicated in patients with: Hypersensitivity to the active substance or to any of the excipients Patients with Renal Impairment: Creatinine clearance 2.5 times the upper limit of normal (ULN). 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.

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. 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 Metformin Hydrochloride & Vildagliptin tablets may need to be adjusted during concomitant therapy and on its discontinuation.

USE IN PREGNANCY & LACTATION

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

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

PEDIATRIC USE: Combination of Metformin Hydrochloride & Vildagliptin is not recommended in patients 18 years of age.

GERIATRIC USE: 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 Metformin Hydrochloride & Vildagliptin should have their renal function monitored regularly. Combination of Metformin Hydrochloride & Vildagliptin has not been studied in patients >75 years. Therefore, the use of combination of Metformin Hydrochloride & Vildagliptin is not recommended in this population.

STORAGE

Keep away from light & moisture. Store below 30ºC. Keep out of the reach of the children.

Commercial Pack

Formet-V 500/50 Tablet: Each box contains 3 X 10 tablets in Alu-Alu blister pack.

Manufactured by

BIOPHARMA
LIMITED
A-116, BSCIC Industrial Estate
TONGI, GAZIPUR, BANGLADESH

For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.