Vigamet®

Vildagliptin INN and Metformin Hydrochloride BP
Film Coated Tablet

DESCRIPTION

Vigamet® is a combined preparation of two antihyperglycemic agents with different mechanisms of action to improve glycaemic control in patients with type 2 diabetes: Vildagliptin, a member of the DPP-4 (dipeptidyl-peptidase- 4) inhibitor class and Metformin Hydrochloride, a member of the biguanide class. Vildagliptin, a member of the islet enhancer class, is a potent and selective dipeptidyl-peptidase-4 (DPP-4) inhibitor that improves glycaemic control. Metformin Hydrochloride improves glucose tolerance in patients with type 2 diabetes, lowering both basal and postprandial plasma glucose. Metformin Hydrochloride decreases hepatic glucose production, decrease intestinal absorption of glucose and improves insulin sensitivity by increasing peripheral glucose uptake and utilization.

INDICATIONS

Vildagliptin and Metformin Hydrochloride combination is indicated as an adjunct to diet and exercises to improve glycaemic control in patients with type 2 diabetes mellitus whose diabetes is not adequately controlled on Metformin Hydrochloride or Vildagliptin alone or who are already treated with the combination of Vildagliptin and Metformin Hydrochloride, as separate tablets.

DOSAGE AND ADMINISTRATION

The recommended starting dose of this combination should be based on the patient's current regimen of Vildagliptin and/or Metformin Hydrochloride. This combination should be given with meals to reduce the gastrointestinal side effects associated with Metformin Hydrochloride.

- **Starting dose for patients inadequately controlled on Vildagliptin monotherapy:** Based on the starting doses of Metformin Hydrochloride (850 mg daily), this combination may be initiated at the 50/850 mg tablet strength once daily and gradually titrated after assessing adequacy of therapeutic response.

- **Starting dose for patients inadequately controlled on Metformin Hydrochloride monotherapy:** Based on the patient's current dose of Metformin Hydrochloride, this combination may be initiated at either the 50 mg/500 mg or 50 mg/850 mg tablet strength twice daily.

- **Starting dose for patients switching from combination therapy of Vildagliptin plus Metformin Hydrochloride as separate tablets:** This combination may be initiated with either the 50 mg/500 mg or 50 mg/850 mg tablet strength based on the dose of Vildagliptin or Metformin Hydrochloride already being taken.

CONTRAINDICATIONS

- Hypersensitivity
- Active renal disease
- Congestive heart failure
- Diabetic ketoacidosis
- Radiologic Studies

SIDE EFFECTS

- Dizziness
- Constipation
- Headache

PRECAUTION AND WARNING

Vildagliptin and Metformin Hydrochloride combination is not a substitute for insulin in insulin-requiring patients. It should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. Vildagliptin is not recommended in patients with hepatic impairment. Lactic acidosis is a very rare but serious metabolic complication that can occur due to Metformin accumulation. Reported cases of lactic acidosis in patients on Metformin have occurred primarily in diabetic patients with significant renal failure.

USE IN PREGNANCY AND LACTATION

There are no adequate and well-controlled studies in pregnant women. 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.

PHARMACEUTICAL PRECAUTION

Do not store above 25 °C temperature. Keep away from light and wet place. Keep out of the reach of children.

PACKAGING

Vigamet® 50/500 tablet: Box containing 2 strips of 10 tablets each. Each flim coated tablet contains Vildagliptin INN 50 mg and Metformin Hydrochloride BP 500 mg.

Vigamet® 50/850 tablet: Box containing 3 strips of 6 tablets each. Each flim coated tablet contains Vildagliptin INN 50 mg and Metformin Hydrochloride BP 850 mg.

SK+F
Manufactured by
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