

# Vigatin<sup>®</sup>

## Vildagliptin INN Film Coated Tablet

### DESCRIPTION

Vigatin<sup>®</sup> is a preparation of Vildagliptin. Vildagliptin, a member of the class that enhances islet cell insulin secretion via an augmented incretin effect, is a high affinity dipeptidyl-peptidase-4 (DPP-4) inhibitor that improves glycaemic control. The administration of Vildagliptin results in rapid and near-complete inhibition of DPP-4 activity. Vildagliptin shows weak inhibition of, and rapid dissociation from DPP-8 and DPP-9, compared to DPP-4. In patients with type 2 diabetes, administration of Vildagliptin led to inhibition of DPP-4 enzyme activity for a 24-hour period. Vildagliptin inhibition of DPP-4 results in increased fasting and postprandial endogenous levels of the incretin hormones GLP-1 (glucagon-like peptide 1) and GIP (glucose-dependent insulinotropic polypeptide).

### INDICATIONS

Treatment of diabetes mellitus type 2 in persons 18 years of age and older, as an adjunct to diet and exercise to improve glycaemic control in patients with type 2 diabetes with one of metformin, a sulfonylurea or pioglitazone when diet, exercise and the single agent do not result in adequate glycaemic control.

### DOSAGE AND ADMINISTRATION

The management of antidiabetic therapy should be individualised. When used in dual combination with metformin, a thiazolidinedione (clinical experience is with pioglitazone as dual therapy), the recommended dose of Vildagliptin is 50 mg or 100 mg daily. The 50 mg dose should be administered once daily in the morning. The 100 mg dose should be administered as two divided doses of 50 mg given in the morning and evening. When used in dual combination with a sulphonylurea (clinical experience is with glimepiride as dual therapy), the recommended dose of Vildagliptin is 50 mg once daily administered in the morning. In this patient population, Vildagliptin 100 mg daily was no more effective than Vildagliptin 50 mg once daily and was associated with a higher rate of hypoglycaemia than the 50 mg dose. Doses greater than 100 mg are not recommended. Vildagliptin can be administered with or without a meal.

#### CONTRAINDICATIONS

Hypersensitivity to Vildagliptin.

#### SIDE EFFECTS

- Dizziness
- Constipation
- Headache

#### PRECAUTION AND WARNING

Vildagliptin is not a substitute for insulin in insulin-requiring patients. Vildagliptin should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. There is limited experience in patients with moderate or severe chronic kidney disease and in patients with End Stage Renal Disease (ESRD) on haemodialysis. Therefore, the use of Vildagliptin is not recommended in these patients. Vildagliptin is not recommended in patients with hepatic impairment, including patients with a pre-treatment ALT or AST above normal limit.

#### PREGNANCY AND LACTATION

Pregnancy Category B3. There are no adequate and well-controlled studies in pregnant women. Vildagliptin should not be used during pregnancy unless the benefit to the mother outweighs the potential risk to the foetus. Attainment of strict normoglycaemia during pregnancy may require conversion to insulin monotherapy. As it is not known whether Vildagliptin is excreted in human milk, Vildagliptin should not be administered to breastfeeding mother.

#### PHARMACEUTICAL PRECAUTION

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

#### PACKAGING

Vigatin® tablet:

Box containing 2 strips of 10 tablets each. Each film coated tablet contains Vildagliptin INN 50 mg.

# SK+F

Manufactured by

**ESKAYEF BANGLADESH LIMITED**

GAZIPUR, BANGLADESH

® REGD. TRADEMARK

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