

Viflink[®]-50

(Vildagliptin Tablets 50mg)

Composition:

Each Uncoated Tablet Contains:

Vildagliptin50mg

Excipients...q.s.

Clinical Pharmacology:

The administration of vildagliptin results in a rapid and complete inhibition of DPP-4 activity, resulting in increased fasting and postprandial endogenous levels of the incretin hormones GLP-1 (glucagon-like peptide 1) and GIP (glucose-dependent insulintropic polypeptide). Used in Type 2 diabetes mellitus.

Indications:

Vildagliptin is indicated in the treatment of type 2 diabetes mellitus in adults:

1) As mono therapy:

- In patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.

2) As dual oral therapy in combination with:

- Metformin, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin,
- Sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of a sulphonylurea and for whom metformin is inappropriate due to contraindications or intolerance.
- Thiazolidinedione, in patients with insufficient glycaemic control and for whom the use of a thiazolidinedione is appropriate.

3) As triple oral therapy in combination with:

- Sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.

Vildagliptin is also indicated for use in combination with insulin (with or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycaemic control. Do not exceed the maximum recommended daily dose of 100 mg vildagliptin. Should be given with meals.

Use in special population:**Pregnancy:**

There are no adequate data from the use of vildagliptin in pregnant women. Studies in animals have shown reproductive toxicity at high doses. The potential risk for humans is unknown. Due to lack of human data, Vildagliptin should not be used during pregnancy.

Breast-feeding:

It is unknown whether vildagliptin is excreted in human milk. Animal studies have shown excretion of vildagliptin in milk. Vildagliptin should not be used during breast-feeding.

Fertility:

No studies on the effect on human fertility have been conducted for Vildagliptin.

Contraindications:

Hypersensitivity to the active substance or to any of the excipients

Precautions and Warnings:

General: 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.

Renal impairment: Dosage adjustment may be required in patients with creatinine clearance between 30 and 90 mL/min.

Hepatic impairment: should not be used in patients with hepatic impairment, including those with pre-treatment aminotransferase (ALT) or aspartate aminotransferase (AST) > 3 times the upper limit of normal (ULN).

Geriatric patients: Dosage should be adjusted based on renal function which needs to be monitored.

Children (under 18 years of age): Not recommended

Drug Interactions:

Vildagliptin has a low potential for interactions with co-administered medicinal products. Since vildagliptin is not a cytochrome P (CYP) 450 enzyme substrate and does not inhibit or induce CYP 450 enzymes, it is not likely to interact with active substances that are substrates, inhibitors or inducers of these enzymes. As with other oral antidiabetic medicinal products the hypoglycaemic effect of vildagliptin may be reduced by certain active substances, including thiazides, corticosteroids, thyroid products and sympathomimetics.

Adverse effects:

Nasopharyngitis, headache and dizziness are the most common adverse effects associated with vildagliptin, occurring in 6 – 9% of patients.

Overdosage:

Individual cases of mild and transient paraesthesia, fever, oedema and a transient increase in lipase levels.

For Therapeutic Use.

Route of administration: Oral.

Type of tablet: Uncoated tablet.

Dosage: As directed by Physician.

Storage: Store protected from light & moisture, at a temperature not exceeding 25°C.
Keep all medicines out of reach of children.

SCHEDULE H PRESCRIPTION DRUG CAUTION: Not to be sold by retail without the prescription of a Registered Medical Practitioner.

Presentation: Viflink-50 uncoated tablet is available as 10 x 10 Tablet

Marketed By:



EPIONE PHARMACEUTICALS PVT.LTD.

804, Suyog Center, Gultekdi, Pune-411037 (MH), India.