

VIPTIN

Vildagliptin 50 mg Tablet

Presentation

Each film coated tablet contains Vildagliptin INN 50 mg.

Pharmacodynamic Properties

Vildagliptin is a potent and selective dipeptidyl-peptidase-4 (DPP-4) inhibitor that improves glycemic control by rapid and complete inhibition of DPP-4 activity. In patients with type 2 diabetes, administration of Vildagliptin inhibits the DPP-4 enzyme activity for a period of 24 hour.

Pharmacokinetic Properties

Vildagliptin is rapidly absorbed with an absolute bioavailability of 85%. The peak plasma concentration is achieved at 1.75 hours. Co-administration with food slightly reduces the absorption and delays the peak plasma concentration. The plasma protein binding of Vildagliptin is 9.3%. Metabolism is the major elimination pathway of excretion for Vildagliptin which is 69% of the dose. Following oral administration, approximately 85% of the dose is excreted into the urine and 15% of the dose is recovered in the faeces.

Indications

Vildagliptin is indicated as an adjunct to diet and exercise to improve glycemic control in patient with type 2 diabetes mellitus as monotherapy or in combination with metformin or with a sulphonylurea or with a thiazolidinedione.

Dosage and Administration

Adult (over 18 years): The recommended dose of Vildagliptin is 50 mg or 100 mg daily as monotherapy whereas the 100 mg dose is administered in two divided doses of 50 mg given in morning and evening. In combination with metformin or a thiazolidinedione, 50 mg twice daily. In combination with a sulphonylurea, 50 mg daily in the morning or as directed by the registered physician.

Paediatric (under 18 years): Vildagliptin is not recommended for use in children and adolescents due to a lack of data on safety and efficacy.

Contraindications

It is contraindicated for patients with known hypersensitivity to Vildagliptin, diabetic ketoacidosis, hepatic impairment, kidney dysfunction.

Side Effects

The most common side effects associated with Vildagliptin therapy include headache, tremor, dizziness, nausea and asthenia and less commonly constipation, hypoglycemia.

Precautions

Caution should be employed for elderly patients. It should be used with caution in patients with impaired hepatic function and heart failure.

Drug Interactions

As a result of studies, no clinically relevant interactions with other oral antidiabetics (glibenclamide, pioglitazone, metformin), amlodipine, digoxin, ramipril, simvastatin, valsartan or warfarin were observed after co-administration with Vildagliptin.

Use in Pregnancy and Lactation

Pregnancy: There are no adequate data from the use of Vildagliptin in pregnant women. So, Vildagliptin should not be used during pregnancy.

Lactation: It is unknown whether Vildagliptin is excreted in human milk. So, Vildagliptin should not be used during lactation.

Overdose

Muscle pain, mild and transient paraesthesia, fever, oedema and transient increase in lipase levels.

Storage conditions

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

Commercial Pack

Each box contains 3 blister packs of 10 tablets.

Manufactured by:



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