Front

GALZA™ (VILDAGLIPTIN)

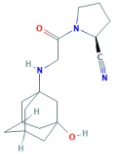
50 MG
TABLET

گیلزا

COMPOSITION:
Each tablet contains:
Vildagliptin ..... 50 mg.

Product Specs.: CCL Pharmaceuticals

DESCRIPTION:
Chemically vildagliptin is (S)-1-[2-(3-Hydroxy-adamantan-1-ylamino)acetyl]pyrrolidine-2-carbonitrile with molecular formula $C_{17}H_{25}N_3O_2$ and molecular weight of 303.406 and its structural formula is:



CLINICAL PHARMACOLOGY:
Mechanism of Action: 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 insulinotropic polypeptide).
Pharmacokinetics:
Absorption: Following oral administration in the fasting state, vildagliptin is rapidly absorbed, with peak plasma concentrations observed at 1.7 hours. Food slightly delays the time to peak plasma concentration to 2.5 hours, but does not alter the overall exposure (AUC), so Galza can be given with or without food. The absolute bioavailability is 85%.
Distribution: The plasma protein binding of vildagliptin is low (9.3%) and vildagliptin distributes equally between plasma and red blood cells.
Metabolism: Metabolism is the major elimination pathway for vildagliptin in humans, accounting for 69% of the dose. The major metabolite (LAY 151) is pharmacologically inactive. Vildagliptin is not metabolised by CYP 450 enzymes to any quantifiable extent. Therefore, vildagliptin is not likely to affect metabolic clearance of co-medications metabolized by CYP 1A2, CYP 2C8, CYP 2C9, CYP2C19, CYP 2D6, CYP 2E1 or CYP 3A4/5.
Elimination: Following oral administration of [14C] vildagliptin, approximately 85% of the dose was excreted into the urine and 15% of the dose is recovered in the faeces. Renal excretion of the unchanged vildagliptin accounted for 23% of the dose after oral administration. The elimination half-life after oral administration is approximately 3 hours.

INDICATIONS AND USAGE:
Vildagliptin is indicated in the treatment of type 2 diabetes mellitus in adults in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.

DOSAGE and ADMINISTRATION:
When used as monotherapy, in combination with metformin, in combination with thiazolidinedione, in combination with metformin and a sulphonylurea, or in combination with insulin (with or without metformin), the recommended daily dose of vildagliptin is 100 mg, administered as one dose of 50 mg in the morning and one dose of 50 mg in the evening. Doses higher than 100 mg are not recommended. If a dose of Galza is missed, it should be taken as soon as the patient remembers. A double dose should not be taken on the same day.

DOSE MODIFICATION RECOMMENDATIONS:
Elderly (≥ 65 years): No dose adjustments are necessary in elderly patients.
Renal impairment: No dose adjustment is required in patients with mild renal impairment (creatinine clearance ≥ 50 ml/min). In patients with moderate or severe renal impairment or with end-stage renal disease (ESRD), the recommended dose of Galza is 50 mg once daily.
Hepatic impairment: Galza should not be used in patients with hepatic impairment, including patients with pretreatment alanine aminotransferase (ALT) or aspartate aminotransferase (AST) > 3x the upper limit of normal (ULN)
Pediatric population:
Galza is not recommended for use in children and adolescents (< 18 years). The safety and efficacy of Galza in children and adolescents (< 18 years) have not been established. No data are available.

CONTRAINDICATIONS:
Hypersensitivity to the active substance.

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WARNINGS AND PRECAUTIONS:
General: Galza is not a substitute for insulin in insulin-requiring patients. Galza should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.
Renal impairment: There is limited experience in patients with ESRD on haemodialysis. Therefore, Galza should be used with caution in these patients.
Hepatic impairment: Galza should not be used in patients with hepatic impairment, including patients with pre-treatment ALT or AST > 3x ULN.
Liver enzyme monitoring: Rare cases of hepatic dysfunction (including hepatitis) have been reported. Liver function tests should be performed prior to the initiation of treatment with Galza in order to know the patient's baseline value. Liver function should be monitored during treatment with Galza. Should an increase in AST or ALT of 3x ULN or greater persist, withdrawal of Galza therapy is recommended. Patients who develop jaundice or other signs suggestive of liver dysfunction should discontinue Galza.
Cardiac failure: A clinical trial of vildagliptin in patients with New York Heart Association (NYHA) functional class I-III showed that treatment with vildagliptin was not associated with a change in left-ventricular function or worsening of pre-existing congestive heart failure (CHF) versus placebo. Clinical experience in patients with NYHA functional class III treated with vildagliptin is still limited and results are inconclusive. There is no experience of vildagliptin use in clinical trials in patients with NYHA functional class IV and therefore use is not recommended in these patients.
Skin disorders: In keeping with routine care of the diabetic patient, monitoring for skin disorders, such as blistering or ulceration, is recommended.
Acute pancreatitis: Use of vildagliptin has been associated with a risk of developing acute pancreatitis. Patients should be informed of the characteristic symptom of acute pancreatitis. If pancreatitis is suspected, vildagliptin should be discontinued; if acute pancreatitis is confirmed, vildagliptin should not be restarted. Caution should be exercised in patients with a history of acute pancreatitis.
Hypoglycaemia: Sulphonylureas are known to cause hypoglycaemia. Patients receiving vildagliptin in combination with a sulphonylurea may be at risk for hypoglycaemia. Therefore, a lower dose of sulphonylurea may be considered to reduce the risk of hypoglycaemia.

DRUG INTERACTIONS:
Use in specific populations:
Pregnancy:
There are no adequate data from the use of vildagliptin in pregnant women. The potential risk for humans is unknown. Due to lack of human data, Galza should not be used during pregnancy.
Nursing mothers:
It is unknown whether vildagliptin is excreted in human milk. Animal studies have shown excretion of vildagliptin in milk. Galza should not be used during breast-feeding.

ADVERSE REACTIONS:
In clinical trial experience with Vildaglpitin montherapy, following adverse reactions were observed; Nasopharyngitis, Hypoglycaemia, Dizziness, Headache, Oedema, Constipation, Arthralgia.

OVERDOSAGE:
Information regarding overdose with vildagliptin is limited.
Symptoms: There were cases of muscle pain and mild and transient paraesthesia, fever, oedema and a transient increase in lipase levels, oedema of the feet and hands, and increases in creatine phosphokinase (CPK), aspartate aminotransferase (AST), C-reactive protein (CRP) and myoglobin levels. All symptoms and laboratory abnormalities resolved without treatment after discontinuation of the study medicinal product.
Management: In the event of an overdose, supportive management is recommended. Vildagliptin cannot be removed by haemodialysis.

INSTRUCTIONS:
- Store below 30°C.
- Protect from heat, sunlight and moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:
Galza Tablet 50 mg : Pack of 4x7 tablets.

ہدایات:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف ڈاکٹر کے نسخہ پر فروخت کریں۔

FOR FURTHER INFORMATIONS PLEASE CONTACT:

CCL
Manufactured by:
CCL Pharmaceuticals (Pvt.) Ltd.
62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan.

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