Glucowell® (Tablets)

1334
Ref. No.:INS334/09.18

Vildagliptin

Dipeptidyl peptidase - 4 (DPP-4) inhibitors

GLUCOWELL® 50MG TABLETS

PRESENTATION:
Glucowell® 50mg Tablets: White, circular, biconvex tablets embossed 'C' on one side and breakline on the other side. Each tablet contains: Vildagliptin 50mg, Lactose and other excipients.

CLINICAL PHARMACOLOGY:
Vildagliptin a high affinity (DPP-4) inhibitor enhances insulin secretion via augmented incretin effect. 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). By increasing the endogenous levels of these incretin hormones, vildagliptin enhances the sensitivity of beta cells to glucose, thus enhance glucose-dependent insulin secretion. Treatment with vildagliptin 50-100 mg daily in patients with type 2 diabetes significantly improved markers of beta cell function including HOMA-β (Homeostasis Model Assessment-β), proinsulin to insulin ratio and measures of beta cell responsiveness from the frequently-sampled meal tolerance test. In non-diabetic (normal glycaemic) individuals, vildagliptin does not stimulate insulin secretion or reduce glucose levels.
By increasing endogenous GLP-1 levels, vildagliptin also enhances the sensitivity of alpha cells to glucose, resulting in reduced glucagon secretion. The increase in the insulin/glucagon ratio with hyperglycaemia due to increased incretin hormone levels results in a decrease in fasting and postprandial hepatic glucose production, leading to reduced glycaemia. The known effect of increased GLP-1 levels delaying gastric emptying is not observed with vildagliptin treatment.

Pharmacokinetics:
Vildagliptin is rapidly absorbed from the gastrointestinal tract and peak plasma concentrations occur about 1.7 hours after an oral dose. It has a bioavailability of 85%. About 69% of a dose is metabolized, mainly by hydrolysis in the kidney. About 85% of a dose is excreted in the urine (23% is unchanged drug), and 15% in the faeces. The elimination half-life after oral administration is approximately 3 hours.

USES:
Glucowell® Tablets is used to treat adult patients with type 2 diabetes mellitus in adults. It is used when diabetes cannot be controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications and intolerance.

DOSAGE AND ADMINISTRATION:
Glucowell® Tablets can be administered with or without a meal.
The usual dose of Glucowell® is either:
- 50mg daily taken as one dose in the morning if you are taking Glucowell® with another medicine called sulphonylurea.
- 100mg daily taken as 50 mg in the morning and 50 mg in the evening if you are taking Glucowell® alone or with another medicine called metformin or a glitazone or with a combination of metformin and a sulphonylurea, or with insulin.
- 50 mg daily in the morning if you have moderate or severe kidney disease or if you are on dialysis.

Doses higher than 100 mg are not recommended.
Elderly (≥ 65 years)
No dosage adjustments are necessary.
Paediatrics
Glucowell® Tablets is not recommended for use in children and adolescents (<18 years).

CONTRA-INDICATIONS AND WARNINGS:
Hypersensitivity to the active substance or to any of the excipients.

Glucowell® (Tablets)

Precautions and Warnings:
Glucowell® Tablets 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.
Glucowell® Tablets should not be used in patients with hepatic impairment; liver function should be tested before starting the drug, and monitored during therapy. Vildagliptin should be stopped if there is a persistent increase of 3 or more times the upper limit of normal in alanine aminotransferase (ALT) or aspartate aminotransferase (AST), or if the patient develops jaundice or other signs of liver dysfunction; in such cases, it should be restarted.

Adverse Effects
Nausea, peripheral oedema, headache, tremor, asthenia, dizziness, less common: constipation, hypoglycaemia, arthralgia, Rarely: hepatic dysfunction, Very rarely: nasopharyngitis, also reported pancreatitis, exfoliative and bullous skin reactions.

Overdosage
Information regarding overdose with vildagliptin is limited. In the event of an overdose, supportive management is recommended. Vildagliptin cannot be removed by haemodialysis. However, the major hydrolysis metabolite (LAY 151) can be removed by haemodialysis.

Interactions
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor may wish to alter your dose of Glucowell® if you are taking other medicines such as: thiazides or other diuretics, corticosteroids and thyroid medicines.
Pregnancy and Breast-feeding
This medicine should not be used during pregnancy and breast feeding.

PHARMACEUTICAL PRECAUTIONS:
Store in a dry place below 30°C. Protect from light. Keep all medicines out of the reach of children.

LEGAL CATEGORY:
Prescription Only Medicine (POM)

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COSMOS

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