

Glipxen

Linagliptin

COMPOSITION

Glipxen Tablet: Each film coated tablet contains Linagliptin INN 5 mg.

PHARMACOLOGY

Glipxen is a preparation of linagliptin which is indicated to improve glycemic control in patients with type 2 diabetes mellitus. Linagliptin is an inhibitor of DPP-4 (dipeptidyl peptidase-4), an enzyme that degrades the incretin hormones GLP-1 (glucagon like peptide-1) and GIP (glucose dependent insulintropic polypeptide). Thus, Linagliptin increases the concentrations of active incretin hormones, stimulating the release of insulin from pancreatic beta (1) cells in a glucose-dependent manner and decreasing the secretion of glucagon from pancreatic alpha (α) cells in the circulation.

INDICATION

Glipxen is indicated in the treatment of type 2 diabetes mellitus to improve glycaemic control in adults.

As monotherapy-in patients inadequately controlled by diet and exercise alone and for whom Metformin is inappropriate due to intolerance or contraindicated due to renal impairment.

As combination therapy-in combination with Metformin when diet and exercise plus Metformin alone do not provide adequate glycaemic control.

-In combination with a Sulfonylurea and Metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.

DOSAGE AND ADMINISTRATION

5 mg once daily. If added to Metformin, the dose of Metformin should be maintained and Linagliptin administered concomitantly. When used in combination with a Sulfonylurea, a lower dose of the Sulfonylurea may be considered to reduce the risk of hypoglycaemia.

Patients with renal impairment: No dose adjustment required. Linagliptin can be taken with or without a meal at any time of the day.

CONTRAINDICATION

Hypersensitivity to the active substance or to any of the excipients.

PRECAUTION

Linagliptin should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

SIDE EFFECT

There may be hypoglycaemia, nasopharyngitis, cough and pancreatitis in combination with Metformin and Sulfonylurea.

DRUG INTERACTION

Linagliptin is a weak competitive and a weak to moderate mechanism-based inhibitor of CYP isozyme CYP3A4, but does not inhibit other CYP isozymes. The risk for clinically meaningful interactions by other medicinal products on Linagliptin is low and in clinical studies Linagliptin had no clinically relevant effect on the pharmacokinetics of Metformin, Glyburide, Simvastatin, Warfarin, Digoxin or oral contraceptives.

PREGNANCY AND LACTATION

Pregnancy: Pregnancy category B. There are no adequate and well controlled studies in pregnant women. So, Linagliptin tablets should be used during pregnancy only if clearly needed.

Nursing mothers: It is not known whether Linagliptin passes into breast milk or not.

STORAGE CONDITION

Store in a cool (below 30°C) and dry place, away from light. Keep out of the reach of children.

COMMERCIAL PACK

Glipxen Tablet: Each commercial box contains 28 film coated tablets in Alu-Alu blister.