

Only for the use of medical professionals

Glitin®

Linagliptin

Description

Glitin® is a preparation of Linagliptin. It is an inhibitor of DPP-4, an enzyme that degrades the incretin hormones glucagon-like peptide-1 (GLP-1) and glucose-dependent insulintropic polypeptide (GIP). By inhibiting DPP-4, Linagliptin increases the concentrations of active incretin hormones and stimulates the release of Insulin in a glucose dependent manner and decreases the level of glucagon in the circulation and thus regulates the glucose homeostasis. Incretin hormones are secreted at a low basal level throughout the day and levels rise immediately after meal intake. GLP-1 and GIP increase Insulin biosynthesis and secretion from pancreatic beta-cells in the presence of elevated blood glucose levels. Furthermore, GLP-1 also reduces glucagon secretion from pancreatic alpha-cells, resulting in a reduction in hepatic glucose output.

Indication

Glitin® 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.
- In combination with Insulin with or without Metformin, when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.

Dosage and administration

The recommended dose of **Glitin®** is 5 mg once daily and can be taken with or without food. If added with Metformin, the dose of Metformin should be maintained and Linagliptin administered concomitantly. When used in combination with Sulfonylurea or with Insulin, a lower dose of Sulfonylurea or Insulin may be considered to reduce the risk of hypoglycemia.

No dosage adjustment is required for hepatic or renal impaired patients.

Pediatric patients: Safety and effectiveness of Linagliptin in patients below the age of 18 years have not been established.

Use in pregnancy and lactation

Pregnancy: Linagliptin is pregnancy category B. There are no adequate and well-controlled studies in pregnant women. Linagliptin should be used during pregnancy only if the potential benefit of mother justifies the potential risk of the fetus.

Lactation: Caution should be exercised when Linagliptin is administered to a nursing woman.

Side effects

The most common side effects of Linagliptin are stuffy or runny nose and sore throat. Hypoglycemia may occur when Linagliptin is combined with Insulin or Sulfonylurea and Metformin. Allergic reaction and muscle pain also may occur. The rare side effects are pancreatitis, angioedema and urticaria.

Contraindications

Linagliptin is contraindicated in patient with a history of hypersensitivity to Linagliptin or any of excipients.

Precautions

When used with an insulin secretagogue (e.g., Sulfonylurea) or Insulin, consider lowering the dose of the insulin secretagogue or insulin to reduce the risk of hypoglycemia. If pancreatitis is suspected, Linagliptin should be discontinued. There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with Linagliptin or any other antidiabetic drugs. Linagliptin should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

Drug interactions

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.

Overdose

During controlled clinical trials in healthy subjects, with single doses of up to 600 mg of Linagliptin (equivalent to 120 times the recommended daily dose), there were no dose-related clinical adverse drug reactions. There is no experience with doses above 600 mg in humans.

Pharmaceutical precautions

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

Presentation

Glitin® tablet: Each coated tablet contains Linagliptin INN 5 mg.

Package quantities

Glitin® tablet: Carton of 30 tablets in blister pack.

® Registered Trade Mark



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