

Linaptin

Linagliptin 5 mg Tablet

Presentation

Linaptin: Each film coated tablet contains Linagliptin INN 5 mg.

Pharmacodynamic Properties

Linagliptin is an inhibitor of DPP-4, an enzyme that degrades the incretin hormones glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP). Thus, Linagliptin increases the concentrations of active incretin hormones, stimulating the release of insulin in a glucose-dependent manner and decreasing the levels of glucagon in the circulation. Linagliptin binds selectively to DPP-4 and selectively inhibits DPP4 but not DPP-8 or DPP-9 activity.

Pharmacokinetic Properties

The absolute bioavailability of Linagliptin is approximately 30%. The peak plasma concentration is found at 1.5 hours post dose. The majority (about 90%) of Linagliptin is excreted unchanged, indicating that metabolism represents a minor elimination pathway. A small fraction of absorbed Linagliptin is metabolized to a pharmacologically inactive metabolite.

Indications

Linagliptin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. It may be given as monotherapy or combination therapy.

Dosage & Administration

Adult: The recommended dose of Linagliptin is 5 mg once daily as monotherapy or combination therapy.

In combination with an insulin secretagogue (e.g. sulfonylurea) or with insulin, a lower dose of the insulin secretagogue or insulin may be required to reduce the risk of hypoglycemia.

Linagliptin can be taken with or without food.

Paediatrics: Safety and efficacy of Linagliptin in paediatric patients have not been established.

Contraindications

Linagliptin is contraindicated in patients with a history of a hypersensitivity reaction to Linagliptin, such as urticaria, angioedema or bronchial hyperreactivity. Linagliptin should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

Side-Effects

The side effects are mild to moderate which include Nasopharyngitis, Hyperlipidemia, Cough, Hypertriglyceridemia, Weight increase & Hypoglycemia.

Precautions

The use of Linagliptin in combination with an insulin secretagogue (e.g. sulfonylurea) was associated with a higher rate of hypoglycemia. The use of Linagliptin in combination with insulin in subjects with severe renal impairment was associated with a higher rate of hypoglycemia. Therefore, a lower dose of the insulin secretagogue or insulin may be required to reduce the risk of hypoglycemia when used in combination with Linagliptin.

Drug Interactions

Inducers of P-glycoprotein or CYP3A4 Enzymes: Rifampin decreased Linagliptin exposure suggesting that the efficacy of Linagliptin may be reduced when administered in combination with a strong P-gp or CYP3A4 inducer. Therefore, use of alternative treatments is strongly recommended when linagliptin is to be administered with a P-gp or CYP3A4 inducer.

Use in Pregnancy and Lactation

Use in pregnancy: Pregnancy Category B

There are, however, no adequate and well-tolerated studies in pregnant women. So, Linagliptin should be used during pregnancy only if clearly needed.

Nursing Mother: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Linagliptin is administered to a nursing woman.

Over Dose

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.

Storage Conditions

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

Commercial Pack

Linaptin: Each box contains 1 blister pack of 15 Tablets.

Manufactured by :

 **GENERAL**
Pharmaceuticals Ltd.
Gazipur, Bangladesh



Revision No: 00