

**COMPOSITION**

Each film coated tablet contains Linagliptin INN 5 mg.

**PHARMACOLOGY**

**Lijenta 5** 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 insulinotropic polypeptide). Thus, Linagliptin increases the concentrations of active incretin hormones, stimulating the release of insulin from pancreatic beta ( $\beta$ ) cells in a glucose-dependent manner and decreasing the secretion of glucagon from pancreatic alpha ( $\alpha$ ) cells in the circulation.

**INDICATION**

**Lijenta 5** is indicated in the treatment of type-2 diabetes mellitus to improve glycemic 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 glycemic control in combination with a Sulphonylurea and Metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycemic 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 Sulphonylurea, a lower dose of the Sulphonylurea 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.

**WARNING AND PRECAUTION**

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

**SIDE EFFECTS**

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

**USE IN 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.

**USE IN CHILDREN AND ADOLESCENTS**

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

**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.

**OVERDOSAGE**

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**

Store below 30°C temperature in a cool & dry place. Protect from light & moisture. Keep out of the reach of children.

**HOW SUPPLIED**

Each box contains 30 tablets in Alu-Alu blister pack.