W=100 mm

Lino™

Tablet

Linagliptin

Composition
Each film-coated tablet contains Linagliptin INN 5 mg.

Pharmacology
Linagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor, which exerts its action by slowing the inactivation of incretin hormones. Incretin hormones, including glucagon-like peptide 1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP), are released by the intestine throughout the day and levels are increased in response to a meal. These hormones are rapidly inactivated in the physiologic regulation of glucose homeostasis. When blood glucose concentrations are normal or elevated, GLP-1 and GIP increase insulin synthesis and release from pancreatic beta cells by intracellular signaling pathways involving cyclic AMP. GLP-1 also lowers glucagon secretion from pancreatic alpha cells, leading to reduced hepatic glucose production.

Indication
Linagliptin 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 sulphonylurea 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
Route of administration : Oral.
• The recommended dose of Linagliptin is 5 mg once daily.
• Linagliptin can be taken with or without food at any time of the day. If a dose is missed, it should be taken as soon as the patient remembers. A double dose should not be taken on the same day.
• For patients with renal insufficiency no dosage adjustment is required
• Pharmacokinetic studies suggest that no dose adjustment is required for patients with hepatic impairment
• When Linagliptin is added to Metformin the dose of Metformin should be maintained and Linagliptin administered concomitantly.
• When Linagliptin is used in combination with a sulphonylurea or with Insulin, a lower dose of the Sulphonylu rea or Insulin, may be considered to reduce the risk of hypo glycaemia.

Contraindication
Linagliptin should not be prescribed for patients with a history of a hypersensitivity reaction to this drug, such as urticaria, angioedema, or bronchial hyper-reactivity.

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

Side Effects
Common side effects : Side effects includes : Hypoglycemia, headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heart beat, sweating stuffy or runny nose and sore throat.
Rare side effects : Inflammation of pancreas (pancreatitis), Rash, Mouth ulceration.

Use in Pregnancy & Lactation
Pregnancy : Pregnancy Category B.
There are no adequate and well-controlled studies in pregnant women. Linagliptin tablets should be used during pregnancy only if clearly needed
Nursing Mother : It is not known if whether Linagliptin passes into breast milk or not. Caution should be exercised when Linagliptin is administered to a nursing woman.

Drug Interaction
Linagliptin is a weak competitive and a weak to moderate mechanism-based inhibitor of CYP isozyme CYP3A4, but dose not inhibit other CYP isozymes. The risk for clinically meaningful interactions by other medicainal 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, single doses of up to 600 mg Linagliptin (equivalent to 120 times the recommended dose) were generally well tolerated. There is no experience with doses above 600 mg in humans.
In the event of an overdose, it is reasonable to employ the usual supportive measures, e.g., remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring and institute clinical measures if required.

Storage
Store below 30^0 C temperature and dry place, protected from light.
Keep all medicines out of reach of the children.

Packing
Each box contains 3 x 10 tablets in Alu-Alu blisters.

***Further information is available on request**

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Manufactured by:
The ACME Laboratories Ltd.
Dhulivita, Dhamrai, Dhaka, Bangladesh

For Health, Vigour and Happiness