LINAX

LINAGLIPTIN INN

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

Pharmacology:
Linagliptin is used to treat high blood sugar levels caused by type 2 diabetes. Linagliptin helps to control blood sugar levels by increasing substances in the body that make the pancreas release more insulin. It also signals the liver to stop producing sugar (glucose) when there is too much sugar in the blood. This medicine does not help patients who have insulin-dependent or type 1 diabetes.

Dosage And Administration:
The recommended dose of Linagliptin is once daily. Linagliptin tablet can be taken with or without food. No dose adjustment is required for renal or hepatic impairment.

Contraindications:
Linagliptin is contraindicated in patients with a history of a hypersensitivity reaction to Linagliptin; such as urticaria, angioedema or bronchial hyperreactivity.

Warning And Precaution:
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 drug.

Side Effects:
Linagliptin-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 a sulfonylurea-type drug. Allergic reactions and muscle pain also may occur. Pancreatitis also has been reported.

Use in Pregnancy and Lactation:
Pregnancy Category B. Caution should be exercised to a nursing woman.

Drug Interaction:
Inducers of P-glycoprotein and CYP3A4 enzymes: Rifampin decreased Linagliptin exposure, suggesting that the efficacy of Linagliptin may be reduced when administered in combination with a strong P-gp inducer or CYP 3A4 inducer. Use of alternative treatments (except Linagliptin) is strongly recommended when concomitant treatment with a strong P-gp or CYP 3A4 inducer is necessary. Insulin secretagogues or insulin: Coadministration of Linagliptin with an insulin secretagogue or insulin may require lower doses of the insulin secretagogue or insulin to reduce the risk of hypoglycemia. Drugs affecting glycemic control: Certain drugs tend to produce hyperglycemia and may lead to loss of glycemic control. These drugs include the thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs and isoniazid. When such drugs are administered to a patient receiving linagliptin, the patient should be closely observed to maintain adequate glycemic control. When such drugs are withdrawn from a patient receiving linagliptin, the patient should be observed closely for hypoglycemia.

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. There is no experience with doses above 600 mg in humans.

Storage:
Linax Tablet should be stored between 15°C to 30°C. Keep away from light and moisture.

Packing:
Linax Tablet: Each box Contains 6 x 10's Tablet in Alu-Alu blister pack.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.