LINAX PLUS

LINAGLIPTIN INN + METFORMIN HCL BP

Compositions:
Linax Plus 2.5/500 Tablet: Each film coated tablet contains Linagliptin INN 2.5 mg & Metformin HCl BP 500 mg. Linax Plus 2.5/850 Tablet: Each film coated tablet contains Linagliptin INN 2.5 mg & Metformin HCl BP 850 mg. Linax Plus 2.5/1000 Tablet: Each film coated tablet contains Linagliptin INN 2.5 mg & Metformin HCl BP 1000 mg. Linax Plus 5/1000 Extended Release Tablet: Each film coated tablet contains Linagliptin INN 5 mg & Metformin HCl BP 1000 mg.

Pharmacology:
Linagliptin and Metformin combination 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. Metformin reduces the absorption of sugar from the stomach, reduces the release of stored sugar from the liver and helps your body use sugar better. This medicine does not help patients who have insulin-dependent or type 1 diabetes.

Dosage And Administration:
The recommended dose of Linagliptin and Metformin combination is twice daily Linagliptin & Metformin combination tablets 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 severe renal impairment, acute or chronic metabolic acidosis, including diabetic ketoacidosis and a hypersensitivity reaction to Linagliptin and Metformin.

Warning And Precaution:
In a patient with lactic acidosis who is taking Metformin, the drug should be discontinued immediately and supportive therapy promptly instituted. There have been postmarketing reports of acute pancreatitis. If pancreatitis is suspected, promptly discontinue Linax Plus. Temporarily discontinue Linax Plus in patients undergoing radiologic studies with intravascular administration of iodinated contrast materials or any surgical procedures necessitating restricted intake of food and fluids. Metformin may lower Vitamin B12 levels; so hematologic parameters should be monitored annually.

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. Metformin-The most common adverse reactions due to initiation of Metformin are diarrhoea, nausea/vomiting, flatulence, asthenia, indigestion, abdominal discomfort and headache.

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

Drug Interaction:
Drug Interactions With Metformin Carbonic Anhydrase Inhibitors: Topiramate or other

carbonic anhydrase inhibitors (e.g., zonisamide, acetazolamide or dichlorphenamide) frequently cause a decrease in serum bicarbonate and induce non-anion gap, hyperchloremic metabolic acidosis. Drugs That Reduce Metformin Clearance: Drugs that are eliminated by renal tubular secretion (e.g., cationic drugs such as cimetidine) have the potential for interaction with metformin by competing for common renal tubular transport systems, and may increase the accumulation of metformin and the risk for lactic acidosis. In these case patient should be taken in close observation. Alcohol: Alcohol is known to potentiate the effect of metformin on lactate metabolism. Drug Interactions With Linagliptin 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. As linagliptin is a fixed-dose combination of linagliptin and metformin, use of alternative treatments (not containing 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 (e.g., sulfonylurea) 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:
In the event of an overdose with preparation, the usual supportive measures may be execute as per advise of the physician (e.g., remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring and institute supportive treatment) as depending upon the patient's clinical status. Removal of linagliptin by hemodialysis or peritoneal dialysis is unlikely. However, metformin is dialyzable with a clearance of up to 170 mL/min under good hemodynamic conditions. Therefore, hemodialysis may be useful partly for removal of accumulated metformin from patients in whom this preparation overdosage is suspected. Linagliptin: 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. Metformin: Overdose of metformin has occurred, including ingestion of amounts greater than 50 grams. Hypoglycemia was reported in approximately 10% of cases, but no causal association with metformin has been established. Lactic acidosis has been reported in approximately 32% of metformin overdose cases.

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

Packing:
Linax Plus 2.5/500 Tablet: Each box Contains 6 x 10's Tablet in Alu-Alu blister pack. Linax Plus 2.5/850 Tablet: Each box Contains 6 x 10's Tablet in Alu-Alu blister pack. Linax Plus 2.5/1000 Tablet: Each box Contains 6 x 10's Tablet in Alu-Alu blister pack. Linax Plus 5/1000 Extended Release Tablet: Each box Contains 3 x 10's Tablet in Alu-Alu blister pack.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.