

Lijenta-M

Linagliptin &
Metformin Hydrochloride Tablet

Lijenta-M is a combination of linagliptin and Metformin Hydrochloride with complementary mechanism of action 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 (β) cells in a glucose-dependent manner and decreasing the secretion of glucagon from pancreatic alpha (α) cells in the circulation.

Metformin Hydrochloride is a biguanide type oral antihyperglycemic drug used in the management of type 2 diabetes. It lowers both basal and postprandial plasma glucose. Its mechanism of action is different from those of sulfonylureas and it does not produce hypoglycemia. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity by an increase in peripheral glucose uptake and utilization.

COMPOSITION

Lijenta-M 500 Tablet: Each film coated tablet contains Linagliptin INN 2.5 mg and Metformin Hydrochloride BP 500 mg.

Lijenta-M 850 Tablet: Each film coated tablet contains Linagliptin INN 2.5 mg and Metformin Hydrochloride BP 850 mg.

Lijenta-M 1000 Tablet: Each film coated tablet contains Linagliptin INN 2.5 mg and Metformin Hydrochloride BP 1000 mg.

INDICATION

Lijenta-M is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate.

DOSAGE AND ADMINISTRATION

The dosage of **Lijenta-M** should be individualized on the basis of both effectiveness and tolerability. Maximum recommended dose of 2.5 mg Linagliptin and 1000 mg Metformin Hydrochloride twice daily with meals. Dose escalation should be gradual to reduce the gastrointestinal (GI) side effects associated with Metformin use.

Recommended starting dose:

In patients currently not treated with Metformin, initiate treatment with 2.5 mg Linagliptin and 500 mg Metformin Hydrochloride twice daily.

In patients already treated with Metformin, start with 2.5 mg Linagliptin and the current dose of Metformin Hydrochloride twice daily.

Patients already treated with linagliptin and metformin, individual components may be switched to this combination containing the same doses of each component.

CONTRAINDICATION

Although Linagliptin undergoes minimal renal excretion, Metformin is known to be substantially excreted by the kidney. The risk of Metformin accumulation and lactic acidosis increases with the degree of renal impairment. Therefore, this combination is contraindicated in patients with renal impairment. It is also contraindicated in acute or chronic metabolic acidosis (diabetic ketoacidosis) and in hypersensitivity to Linagliptin or Metformin.

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 **Lijenta-M**. Temporarily discontinue **Lijenta-M** 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 EFFECT

Most common side effects are nasopharyngitis and diarrhea. Hypoglycemia is more common in patients treated with this combination and sulfonylureas.

DRUG INTERACTION

Cationic drugs (amiloride, digoxin, morphine, ranitidine, trimethoprim etc.): May reduce metformin elimination. P-glycoprotein/CYP3A4 inducer (i.e. rifampin): The efficacy of **Lijenta-M** may be reduced when administered in combination.

USE IN PREGNANCY AND LACTATION

Pregnancy category B. There are no adequate and well-controlled studies in pregnant women with this combination or its individual component; so it should be used during pregnancy only if clearly needed. Caution should also be exercised when it is administered to a lactating mother.

STORAGE CONDITION

Keep in a dry place away from light and heat. Keep out of the reach of children.

HOW SUPPLIED

Lijenta-M 500 Tablet: Each box contains 20's tablets in Alu-Alu blister pack.

Lijenta-M 850 Tablet: Each box contains 16's tablets in Alu-Alu blister pack.

Lijenta-M 1000 Tablet: Each box contains 16's tablets in Alu-Alu blister pack.

Manufactured by:

NIPRO JMI Pharma Ltd.
Comilla, Bangladesh.

