Lijenta-MX

Linagliptin INN & Metformin Hydrochloride BP
Extended Release Tablet

COMPOSITION

Lijenta-MX 2.5 Tablet: Each extended release tablet contains Linagliptin INN 2.5 mg and Metformin Hydrochloride BP 1000 mg.
Lijenta-MX 5 Tablet: Each extended release tablet contains Linagliptin INN 5 mg and Metformin Hydrochloride BP 1000 mg.

PHARMACOLOGY

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 decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity by an increase in peripheral glucose uptake and utilization. Thus, Metformin Hydrochloride lowers both basal and postprandial plasma glucose.

INDICATION

Lijenta-MX 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-MX** should be individualized on the basis of both effectiveness and tolerability, while not exceeding the maximum recommended total daily dose of Linagliptin 5 mg and Metformin Hydrochloride 2000 mg. **Lijenta-MX** should be given once daily with a meal.

Recommended starting dose:
In patients currently not treated with metformin, initiate **Lijenta-MX** treatment with 5 mg Linagliptin/1000 mg Metformin Hydrochloride extended-release once daily with a meal.
In patients already treated with Metformin, start **Lijenta-MX** with 5 mg of Linagliptin total daily dose and a similar total daily dose of Metformin once daily with a meal.
In patients already treated with Linagliptin and Metformin or **Lijenta-M**, switch to **Lijenta-MX** containing 5 mg of Linagliptin total daily dose and a similar total daily dose of Metformin once daily with a meal.

Lijenta-MX 5 mg Linagliptin/1000 mg Metformin Hydrochloride extended-release tablet should be taken as a single tablet once daily. Patients using 2.5 mg Linagliptin/1000 mg Metformin extended release tablets should take two tablets together once daily.

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-MX**. Temporarily discontinue **Lijenta-MX** 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 B_{12} levels; so hematologic parameters should be monitored annually.

SIDE EFFECT

Common side effects of Linagliptin and Metformin Hydrochloride extended-release includes: Runny or stuffy nose, Diarrhea, Cough, Hypersensitivity (hives, skin swelling, bronchospasm), Decreased appetite, Nausea, Vomiting, Itching and Pancreatitis.

USE IN PREGNANCY AND LACTATION

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 excercised when it is administered to a lactating mother.

DRUG INTERACTION

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

OVERDOSE

In the event of an overdose with **Lijenta-MX** the usual supportive measures (i.e. remove unabsorbed material from the gastrointestinal tract, perform clinical monitoring, and institute supportive treatment) should be employed. Removal of linagliptin by hemodialysis or peritoneal dialysis is unlikely but metformin is dialyzable.

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.

Metformin
Overdose of metformin has occurred in case of 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 CONDITION

Keep below 25°C temperature, protect from light and moisture. Keep out of the reach of children.

HOW SUPPLIED

Lijenta-MX 2.5 Tablet: Each box contains 16 tablets in Alu-Alu blister pack.
Lijenta-MX 5 Tablet: Each box contains 16 tablets in Alu-Alu blister pack.

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NIPRO JMI Pharma

Manufactured by:
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