For consumer information only

Viflink®-M

(Vildagliptin 50mg + Metformin 500 Tablets)

Composition:

Each Tablet Contains:
Vildagliptin.....50mg
Metformin…….500 Sustained release
Exicipents… .....q.s.

Clinical Pharmacology:
The administration of vildagliptin results in a rapid and complete inhibition of DPP-4 activity, resulting in increased fasting and postprandial endogenous levels of the incretin hormones GLP-1 (glucagon-like peptide 1) and GIP (glucose-dependent insulinotropic polypeptide).Used in Type 2 diabetes mellitus.

Metformin is a biguanide that improves glucose tolerance in patients with type 2 diabetes, lowering both basal and postprandial plasma glucose. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization. Metformin does not produce hypoglycemia in patients with type 2 diabetes or in healthy subjects except in special circumstances, and does not cause hyperinsulinemia. With metformin therapy, insulin secretion remains unchanged while fasting insulin levels and daylong plasma insulin response may actually decrease.

Indications:
In the treatment of type 2 diabetes mellitus:
treatment of adult patients who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone or who are already treated with the combination of vildagliptin and metformin as separate tablets.

In combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled with metformin and a sulphonylurea.

In triple combination therapy with insulin as an adjunct to diet and exercise to improve glycaemic control in patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control.

As an initial therapy in patients with T2DM whose diabetes is not adequately controlled by diet and exercise alone.

Use in special population:

Pregnancy:

There are no adequate data from the use of vildagliptin in pregnant women. Studies in animals have shown reproductive toxicity at high doses. The potential risk for humans is unknown. Due to lack of human data, Vildagliptin should not be used during pregnancy.

Breast-feeding:

It is unknown whether vildagliptin is excreted in human milk. Animal studies have shown excretion of vildagliptin in milk. Vildagliptin should not be used during breast-feeding.

Fertility:

No studies on the effect on human fertility have been conducted for Vildagliptin.

Contraindications:

Hypersensitivity to the active substances or to any of the excipients. Acute or chronic metabolic acidosis including lactic acidosis or diabetic ketoacidosis with or without coma. patients with creatinine clearance < 30 ml/min. Acute conditions with the potential to alter renal function. Acute or chronic disease which may cause tissue hypoxia. Hepatic impairment. Acute alcohol intoxication, alcoholism. Breast-feeding.

Precautions and Warnings:

Risk of lactic acidosis. Monitoring of renal function before treatment initiation and regularly thereafter. may affect renal function or metformin hydrochloride disposition. Should be temporarily discontinued in patients undergoing radiologic studies involving intravascular administration of iodinated contrast materials. Discontinue treatment in case of hypoxemia Temporary discontinuation in patients undergoing surgical procedure. Excessive alcohol intake to be avoided. Not recommended in patients with hepatic impairment including patients with a pretreatment ALT or AST >3x the upper limit of normal. Risk of decreased vitamin B12 serum levels. Should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. Risk of skin lesions, including blistering and ulceration. Risk of acute pancreatitis. Risk of hypoglycemia. Elderly patients taking Metformin should have their renal function

monitored regularly not recommended in pediatric patients. Severe and disabling arthralgia in patients taking DPP-4 inhibitors

Drug Interactions:
Vildagliptin has a low potential for interactions with co-administered medicinal products. Since vildagliptin is not a cytochrome P (CYP) 450 enzyme substrate and does not inhibit or induce CYP 450 enzymes, it is not likely to interact with active substances that are substrates, inhibitors or inducers of these enzymes. As with other oral antidiabetic medicinal products the hypoglycaemic effect of vildagliptin may be reduced by certain active substances, including thiazides, corticosteroids, thyroid products and sympathomimetics.

Cationic drugs: May reduce metformin elimination. Use with caution in patients who are taking cationic medications eliminated by renal tubular secretion.

Warning: To be sold by retail ON the prescription of a Registered Medical Practitioner only.

SCHEDULE G PRESCRIPTION DRUG- CAUTION it is dangerous to take this preparation except under medical supervision.

Adverse effects:
Nasopharyngitis, headache and dizziness are the most common adverse effects associated with vildagliptin, occurring in 6 – 9% of patients. The incidence and type of adverse reactions reported by >5% of patients for the combined metformin group versus placebo group are hypoglycemia, diarrhea, and nausea.

Route of administration: Oral.

Type of tablet: Uncoated tablet.

Dosage:
As directed by Physician, Dose more than 2 tablets a day is not recommended.

Storage:
Store in cool and dry place.

Presentation: Viflink-M tablet available is as 10 x 10 Tablet

Marketed By:

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