For consumer information only

Sitaflink®-M

(Sitagliptin Phosphate 50 mg & Metformin Hydrochloride (SR) 500 mg Tablet)

Composition:

Each film coated bilayered tablets contains:
Sitagliptin Phosphate Monohydrate IP
eq. to Sitagliptin ..... 50 mg
Metformin Hydrochloride IP… ..... 500 mg
(as sustained release)
Excipients. ..... q.s.

Clinical Pharmacology:

Sitagliptin :

- Sitagliptin is an orally-active, potent, and highly selective inhibitor of the Dipeptidyl Peptidase 4 (DPP-4) enzyme for the treatment of type 2 diabetes.
- The DPP-4 inhibitors are a novel class of agents that act as incretin enhancers. Incretin hormones, including glucagon-like peptide-1 (GLP-1) and glucose-dependent insulin tropic polypeptide (GIP), are released by the intestine throughout the day, and levels are increased in response to a meal.
- The incretins are part of an endogenous system involved in the physiologic regulation of glucose homeostasis. When blood glucose concentrations are normal or elevated, GLP-1 and GIP increase insulin synthesis and release from pancreatic beta cells by intracellular signaling pathways involving cyclic AMP. Progressive beta-cell failure is a feature characterizing the pathogenesis of type 2 diabetes.
- Treatment with GLP-1 or with DPP-4 inhibitors in animal models of type 2 diabetes has been demonstrated to improve beta cell responsiveness to glucose and stimulate insulin biosynthesis and release. With higher insulin levels, tissue glucose uptake is enhanced.

Metformin :

- 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:

Sitagliptin + Metformin (SR) are indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus inadequately controlled on metformin or in patients already being treated with the combination of sitagliptin and metformin.

Contraindications:

- Unstable and/or insulin-dependent (Type I) diabetes mellitus. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma, history of ketoacidosis with or without coma. Diabetic ketoacidosis should be treated with insulin.
- In patients with a history of lactic acidosis, irrespective of precipitating factors..
- In cases of cardiovascular collapse and in disease states associated with hypoxemia such as cardio respiratory insufficiency, which are often associated with hyperlactacidemia.
- During stress conditions, such as severe infections, trauma or surgery and the recovery phase thereafter. In patients suffering from severe dehydration.
- In patients suffering from severe dehydration.
- During pregnancy and breastfeeding.

Warning and Precaution:

- **General** : Sitagliptin Metformin Combination should not be used in patients with type 1diabetes or for the treatment of diabetic ketoacidosis.
- **Patient Selection and Follow-up**: Careful selection of patients is important. It is imperative that there be rigid attention to diet and careful adjustment of dosage. Regular thorough follow-up examinations are necessary.
- **Pancreatitis:** There have been reports of acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, in patients taking Sitagliptin Metformin Combination.
- **Hypersensitivity Reactions**: There have been post-marketing reports of serious hypersensitivity reactions in patients treated with sitagliptin.
- **Hypoglycemia**: When sitagliptin and metformin were used in combination with a sulfonylurea or in combination with insulin; the incidence of hypoglycemia was

increased over that of placebo and metformin used in combination with a sulfonylurea or in combination with insulin. To reduce the risk of hypoglycemia associated with these regimens, a lower dose of sulfonylurea or insulin may be considered.

Drug Interaction:
Metformin and sitagliptin combination is used to treat high blood sugar levels caused by type 2 diabetes. 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.

Adverse effects: Bloated or feeling of fullness, Excess air or gas in the stomach or intestines, Indigestion, Muscle aches, Passing gas, Sore throat

Route of Administration: Oral

Type of Tablet: Film coated bilayered tablet.

Dosage: As directed by physician.

Storage: Store protected from light and moisture at a temperature not exceeding 30˚C.
Keep the Medicine out of reach of children.
Tablet should be swallowed whole not to be Chewed or crushed.

SCHEDULE H PRESCRIPTIPN DRUG CAUTION- Not to be sold by retail without the Prescription of a Registered Medical Practitioner.

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

Presentation: Sitaflink-M Tablet is available as 10 × 10 Tablet.

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