Information For the User Sitagliptin Phosphate I.P. 50mg + Metformin HCL I.P. 500mg Tablets

Istalab 50-500 Tablet

Brand Name: Istalab 50/500 Tablet

Dosage Form: Tablet

Therapeutic Category: Antidiabetic

Composition:

Each tablet contains:

• **Sitagliptin Phosphate I.P.** – 50 mg

• Metformin HCl I.P. -500 mg

Description:

Istalab 50/500 Tablet is a combination of two anti-diabetic agents, **Sitagliptin** and **Metformin**, used in the management of Type 2 Diabetes Mellitus. Sitagliptin works by inhibiting the enzyme DPP-4 (Dipeptidyl peptidase-4), which increases the levels of incretin hormones, leading to enhanced insulin secretion. Metformin reduces hepatic glucose production and improves insulin sensitivity in peripheral tissues, leading to better control of blood glucose levels.

Indications:

- Type 2 Diabetes Mellitus
- Adjunct to diet and exercise for the control of blood sugar in adult patients
- Can be used alone or in combination with other antidiabetic agents when diet and exercise do not provide adequate blood glucose control.

Dosage and Administration:

- **Initial Dose**: 1 tablet once daily with food.
- **Maintenance Dose**: Can be increased based on individual response, typically up to 2 tablets (1000 mg Metformin) daily.
- The dose should be individualized based on glycemic control and patient tolerance.
- To be taken with meals to minimize gastrointestinal side effects.

Contraindications:

- Hypersensitivity to Sitagliptin, Metformin, or any of the tablet's components.
- Severe renal impairment (eGFR <30 mL/min/1.73m²)
- Acute or chronic metabolic acidosis, including diabetic ketoacidosis.
- Pregnancy and breastfeeding unless advised by the healthcare provider.

Precautions:

- Caution should be exercised in patients with renal impairment or hepatic dysfunction.
- Regular monitoring of kidney function is recommended during treatment.
- Caution in patients with a history of pancreatitis, as Sitagliptin may increase the risk of pancreatitis.

Adverse Effects:

- **Common**: Nausea, vomiting, diarrhea, abdominal pain, and loss of appetite (more common with Metformin).
- **Serious**: Lactic acidosis (rare, but serious side effect of Metformin), pancreatitis, allergic reactions.

Storage:

- Store at room temperature (15°C to 25°C).
- Keep the container tightly closed.
- Protect from moisture and direct sunlight.

Manufactured in India for:



(An ISO 9001: 2015 Certified Co.) Plot no.: 367-FF, Industrial Area Phase-I,

Panchkula-134113

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