Information For the User Sitagliptin Phosphate I.P. 50mg Tablets

Istalab Tablet

Brand Name: Istalab Tablet

Dosage Form: Tablet

Therapeutic Category: Antidiabetic

Composition:

Each tablet contains:

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

Description:

Istalab Tablet contains **Sitagliptin Phosphate**, a **DPP-4** (**dipeptidyl peptidase-4**) **inhibitor**, which enhances insulin secretion and suppresses glucagon release in a glucose-dependent manner. This results in improved glycemic control in patients with **Type 2 Diabetes Mellitus**. Sitagliptin works by increasing the levels of **incretins**, a group of hormones that play a key role in the regulation of insulin and glucagon. By improving insulin release and reducing glucose production, it helps in maintaining better control of blood glucose levels.

Indications:

- Type 2 Diabetes Mellitus (non-insulin dependent)
- As an adjunct to diet and exercise to improve blood glucose control in adults with Type 2 Diabetes
- Can be used as monotherapy or in combination with other antidiabetic medications.

Dosage and Administration:

- **Recommended Dose**: 1 tablet (50 mg Sitagliptin) once daily, with or without food.
- **Renal Adjustment**: The dose should be reduced in patients with renal impairment (eGFR 30-50 mL/min/1.73 m²) to 25 mg once daily.
- **Maximum Dose**: 50 mg once daily.

Contraindications:

- Hypersensitivity to Sitagliptin or any of the excipients.
- Severe renal impairment (eGFR <30 mL/min/1.73 m²) or patients on dialysis.
- Diabetic ketoacidosis.

Precautions:

- Monitor renal function periodically as dose adjustments may be necessary in patients with renal impairment.
- Temporary discontinuation is recommended in patients undergoing surgery or during periods of acute illness or stress.
- Caution in patients with a history of pancreatitis.

• Risk of hypoglycemia when used in combination with other antidiabetic agents, especially insulin or sulfonylureas.

Adverse Effects:

- Common: Upper respiratory tract infections, headache, diarrhea, and nasopharyngitis.
- **Serious**: Pancreatitis, severe hypoglycemia (especially when used with other antidiabetic agents), allergic reactions (including anaphylaxis), and renal impairment.
- Others: Joint pain, swelling, and skin reactions.

Storage:

- Store at room temperature (15°C to 25°C).
- Keep the tablets in their original packaging to protect from moisture and light.
- Keep the container tightly closed.

Manufactured in India for:



(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,

Panchkula-134113

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