Information For the User Sitagliptin Phosphate I.P. 100mg + Dapagliflozin Propanediol U.S.P. 10mg Tablets

Istalab D Tablet

Brand Name: Istalab D Tablet

Dosage Form: Tablet

Therapeutic Category: Antidiabetic

Composition:

Each tablet contains:

- **Sitagliptin Phosphate I.P.** 100 mg
- **Dapagliflozin Propanediol U.S.P.** 10 mg

Description:

Istalab D Tablet combines **Sitagliptin Phosphate** and **Dapagliflozin** for the management of Type 2 Diabetes Mellitus.

- **Sitagliptin** is a **DPP-4** (**dipeptidyl peptidase-4**) inhibitor that increases incretin levels, enhancing insulin secretion and decreasing glucagon release, leading to better blood glucose control.
- Dapagliflozin is an SGLT2 (sodium-glucose co-transporter 2) inhibitor that reduces glucose reabsorption in the kidneys, increasing glucose excretion in the urine and lowering blood glucose levels.

This combination helps improve glycemic control by addressing multiple mechanisms and is indicated for patients who need additional control beyond monotherapy.

Indications:

- Type 2 Diabetes Mellitus
- Used as an adjunct to diet and exercise to improve blood glucose control in adults with Type 2 Diabetes
- When metformin alone or Sitagliptin/Dapagliflozin alone is inadequate.

Dosage and Administration:

- **Initial Dose**: 1 tablet (100 mg Sitagliptin + 10 mg Dapagliflozin) once daily, preferably in the morning.
- **Dose Adjustment**: Based on individual response, renal function, and glucose levels.
- **Maximum Dose**: Typically, 1 tablet daily or as recommended by a healthcare professional.
- Renal function should be monitored, and dose adjustments may be needed in patients with impaired renal function.

Contraindications:

- Hypersensitivity to Sitagliptin, Dapagliflozin, or any components of the tablet.
- Severe renal impairment (eGFR <30 mL/min/1.73m²), or patients on dialysis.

- Diabetic ketoacidosis.
- Pregnancy and lactation (use only if necessary and under medical supervision).

Precautions:

- Monitor renal function regularly, as both Sitagliptin and Dapagliflozin require dose adjustments in renal impairment.
- Discontinue use in case of diabetic ketoacidosis or severe dehydration.
- Caution in patients with a history of bladder cancer (due to the potential association with SGLT2 inhibitors).
- Risk of urinary tract infections and genital mycotic infections with Dapagliflozin.
- Temporary discontinuation may be required prior to surgical procedures or during contrast imaging studies.

Adverse Effects:

- Common: Upper respiratory tract infections, headache, dizziness, nasopharyngitis, and nausea.
- **Serious**: Risk of diabetic ketoacidosis, severe hypoglycemia (especially when used with other antidiabetic agents), urinary tract infections, genital infections, and dehydration.
- Others: Increased urination, hypotension, and changes in renal function.

Storage:

- Store at room temperature (15°C to 25°C).
- 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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