

Istalab 100 Tablet

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Composition:

Each film-coated tablet contains:

- Sitagliptin Phosphate I.P. equivalent to Sitagliptin 100 mg
- Excipients q.s.
- Colour: Approved colour used

Dosage Form:

Tablet

Therapeutic Category:

Dipeptidyl Peptidase-4 (DPP-4) Inhibitor – Oral Antidiabetic Agent

Description:

Istalab 100 Tablet contains Sitagliptin, a selective DPP-4 inhibitor that enhances the body's own ability to regulate blood glucose levels by increasing incretin levels (GLP-1 and GIP). It helps improve glycemic control in adults with type 2 diabetes mellitus by increasing insulin synthesis and release from pancreatic beta cells and decreasing hepatic glucose production. It is used as monotherapy or in combination with other antidiabetic agents.

Indications:

- Type 2 Diabetes Mellitus – as monotherapy or in combination with Metformin, Sulfonylureas, or Thiazolidinediones
- In patients inadequately controlled on diet and exercise alone
- For those requiring an add-on to existing antidiabetic therapy

Mechanism of Action:

Sitagliptin inhibits the enzyme DPP-4, which leads to increased levels of active incretin hormones. These hormones regulate glucose homeostasis by increasing insulin synthesis and release in a glucose-dependent manner, and by suppressing glucagon secretion. This dual action reduces fasting and postprandial blood glucose levels without causing hypoglycemia.

Dosage and Administration:

- Recommended dose: 100 mg once daily with or without food
- Dose adjustment required in patients with moderate to severe renal impairment
- Use as directed by the physician

Contraindications:

- Hypersensitivity to Sitagliptin or any component of the formulation
- Type 1 Diabetes Mellitus or for the treatment of diabetic ketoacidosis

Warnings and Precautions:

- Monitor renal function periodically
- Caution in patients with a history of pancreatitis
- Not recommended in pediatric patients
- Should be used as part of a comprehensive diabetes management plan including diet and exercise

Drug Interactions:

- May be used with Metformin, Sulfonylureas, or Insulin; dose of insulin/sulfonylureas may need to be reduced
- No clinically significant interactions reported with common medications

Adverse Effects:

- Common: Nasopharyngitis, headache, upper respiratory tract infection
- Rare: Pancreatitis, hypersensitivity reactions including anaphylaxis, angioedema, and exfoliative skin conditions
- Low risk of hypoglycemia when used as monotherapy

Overdose:

- Limited experience with overdose
- In case of overdose, supportive treatment should be initiated
- Sitagliptin is moderately dialyzable; hemodialysis may be considered

Storage:

Store below 30°C in a dry and dark place
Protect from direct sunlight and moisture
Keep out of reach of children

Manufactured in India for:

CafoliTM
L I F E C A R E
Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,
Panchkula-134113

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