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

Istalab 50 Tablet

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Composition:

Each film-coated tablet contains:

- Sitagliptin Phosphate I.P. equivalent to Sitagliptin 50 mg
- Excipients q.s.
- Colour: Approved colour used

Dosage Form:

Tablet

Therapeutic Category:

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

Description:

Istalab 50 Tablet contains Sitagliptin, a potent and selective inhibitor of the Dipeptidyl Peptidase-4 (DPP-4) enzyme. It works by enhancing the body's natural incretin system, which regulates blood glucose levels by increasing insulin secretion and decreasing glucagon production. It offers glycemic control without causing weight gain and has a low risk of hypoglycemia when used alone. Sitagliptin is typically used in patients with type 2 diabetes mellitus, either as monotherapy or in combination with other antidiabetic agents.

Indications:

- Type 2 Diabetes Mellitus
- As monotherapy in patients inadequately controlled with diet and exercise
- As an add-on therapy with Metformin, Sulfonylureas, Thiazolidinediones, or Insulin when monotherapy does not provide adequate glycemic control

Mechanism of Action:

Sitagliptin inhibits the enzyme DPP-4, which breaks down incretin hormones such as GLP-1 and GIP. By preventing their breakdown, Sitagliptin increases the levels and activity of incretins, leading to improved glucose-dependent insulin release and reduced glucagon levels. This results in better control of both fasting and postprandial blood sugar levels.

Dosage and Administration:

- Recommended dose: 50 mg once daily with or without food
- Dose adjustment required in moderate to severe renal impairment
- To be used under the supervision of a registered medical practitioner

Contraindications:

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

Warnings and Precautions:

- Monitor renal function at baseline and periodically
- Use with caution in patients with a history of pancreatitis
- Not recommended for use in pediatric patients
- Should be used in combination with lifestyle interventions including diet and exercise

Drug Interactions:

- No significant pharmacokinetic interactions reported
- May require dose adjustment of sulfonylureas or insulin to avoid hypoglycemia when used in combination

Adverse Effects:

- Common: Headache, nasopharyngitis, upper respiratory tract infection
- Less common: Hypoglycemia when used with insulin or sulfonylureas
- Rare: Pancreatitis, allergic reactions such as rash, urticaria, or angioedema

Overdose:

- Limited experience with overdose
- In the event of overdose, supportive care should be provided
- Sitagliptin is modestly dialyzable

Storage:

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

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

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

Panchkula-134113

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