

For consumer information only

Sitaflink[®]-50

(Sitagliptin Phosphate Tablet IP 50 mg)

Composition:

Each film coated tablets contains:

Sitagliptin Phosphate Monohydrate IP
eq. to Sitagliptin50 mg
Excipients..... q.s.

Clinical Pharmacology:

- Sitagliptin is an orally-active, potent, and highly selective inhibitor of the Dipeptidyl Peptidase 4 (DPP-4) enzyme for the treatment of type 2 diabetes.
- The DPP-4 inhibitors are a novel class of agents that act as incretin enhancers. Incretin hormones, including glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP), are released by the intestine throughout the day, and levels are increased in response to a meal.
- The incretins are part of an endogenous system involved in the physiologic regulation of glucose homeostasis. When blood glucose concentrations are normal or elevated, GLP-1 and GIP increase insulin synthesis and release from pancreatic beta cells by intracellular signaling pathways involving cyclic AMP. Progressive beta-cell failure is a feature characterizing the pathogenesis of type 2 diabetes.
- Treatment with GLP-1 or with DPP-4 inhibitors in animal models of type 2 diabetes has been demonstrated to improve beta cell responsiveness to glucose and stimulate insulin biosynthesis and release. With higher insulin levels, tissue glucose uptake is enhanced.

Indications: Sitagliptin 50 mg is indicated in the treatment of Type II diabetes mellitus.

Special Populations :

- **Pregnant Women:** Sitagliptin is not recommended for use in pregnancy.
- **Pediatrics :** Safety and efficacy of Sitagliptin pediatric patients has not been established;
- **Geriatrics:** (≥65 years of age) In clinical studies, no overall differences in safety or effectiveness were observed between subjects 65 years and over and younger subjects. While this and other reported clinical experience have not identified differences in

responses between the geriatric and younger patients, greater sensitivity of some older individuals cannot be ruled out.

Contraindications:

Patients who are hypersensitive to this drug or to any ingredient in the formulation

Warning and Precaution:

- Sitagliptin should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.
- Patients should be warned about driving or operating a vehicle or potentially dangerous machinery under conditions where a risk of hypoglycemia is present .
- **Hepatic:** There are limited clinical experiences in patients with moderate hepatic impairment and no clinical experience in patients with severe hepatic impairment. Use in patients with severe hepatic impairment is not recommended.
- **Hypersensitivity Reactions:** There have been post-marketing reports of serious hypersensitivity reactions in patients treated with Sitagliptin . These reactions include anaphylaxis, angioedema, and exfoliative skin conditions including Stevens-Johnson syndrome.

Adverse effects:

- Upset stomach, Diarrhea, Stomach pain, Upper respiratory infection

Overdosage: If Patient double up the dose or take it too close to their next scheduled time, Patient may be at higher risk of serious side effects such as severe gastrointestinal problems or a low blood sugar reaction.

Route of Administration: Oral

Type of Tablet: Film coated tablet.

Dosage: As directed by physician.

Storage: Store protected from light and moisture at a temperature not exceeding 30°C. Keep the Medicine out of reach of children.

Tablet should be swallowed whole not to be Chewed or crushed.

SCHEDULE H PRESCRIPTION DRUG

CAUTION- Not to be sold by retail without the Prescription of a Registered Medical Practitioner.

Presentation: Sitaflink- 50 Tablet is available as 10×10 Tablets.

Marketed by:



EPIONE PHARMACEUTICALS PVT.LTD.
804, Suyog Center, Gultekdi, Pune-411037 (MH), India.