Sucosit
Sitagliptin

Presentation

Sucosit 50 tablet: Each film coated tablet contains Sitagliptin Phosphate Monohydrate INN equivalent to Sitagliptin 50 mg.

Sucosit 100 tablet: Each film coated tablet contains Sitagliptin Phosphate Monohydrate INN equivalent to Sitagliptin 100 mg.

Description

Sitagliptin is a potent oral hypoglycemic agent which prevents the hydrolysis of incretin hormones by dipeptidyl peptidase 4 (DPP-4), thereby increasing plasma concentrations of the active forms of GLP-1 and GIP. By enhancing active incretin levels, Sitagliptin increases Insulin release from pancreatic beta cells and decreases glucagon levels from pancreatic alpha cells in a glucose-dependent manner. In patients with type 2 diabetes with hyperglycemia, these changes in Insulin and glucagon levels lead to lower hemoglobin A_{1C} (HbA_{1C}) and lower fasting and postprandial glucose concentrations in blood.

Indication

Sucosit is indicated for patients with type 2 diabetes mellitus. It can be used as mono-therapy and also be used with Metformin, Sulfonylurea or Thiazolidinediones. **Sucosit** is successfully used in type 2 diabetes mellitus patients when unable to achieve adequate glycemic control by using Metformin plus Sulfonylurea and Metformin plus Thiazolidinediones dual therapy with physical exercise and diet control. **Sucosit** can also be used as add-on to Insulin (with or without Metformin) when diet and exercise plus stable dose of Insulin do not provide adequate glycemic control.

Dosage and Administration

The dose of **Sucosit** is 100 mg once daily with or without food. When **Sucosit** is used with Metformin and/or a Thiazolidinediones, the dose of Metformin and/or Thiazolidinediones should be maintained.

Special patients		Recommended dose
Renal impairment	Mild (CrCl≥50 ml/min)	100 mg once daily
	Moderate (CrCl ≥ 30 to <50 ml/min)	50 mg once daily
	Severe (CrCl < 30 ml/min) or ESRD requiring haemodialysis or peritoneal dialysis	25 mg once daily
Hepatic impairment	Mild to Moderate	100 mg once daily
	Severe	Not recommended
Elderly		100 mg once daily
Children (<18 yrs)		Not recommended

Contraindication

Sitagliptin is contraindicated in patients with known hypersensitivity to Sitagliptin or any of the components of the preparation. Sitagliptin may exhibit anaphylaxis, angioedema and exfoliative skin conditions including Stevens-Johnson syndrome as hypersensitivity reactions.

Side Effect

Most common adverse reactions like upper respiratory tract infection, nasopharyngitis and headache can occur. Hypoglycemia may occur in patients treated with the combination of Sitagliptin and Sulfonylurea, with or without Metformin.

Drug Interaction

Co-administration of Sitagliptin and Digoxin slightly increases the mean peak drug concentration of Digoxin but there is no recommendation of dose adjustment of the Sitagliptin and Digoxin. In clinical studies, Sitagliptin did not meaningfully alter the pharmacokinetics of Metformin, Glyburide, Simvastatin, Rosiglitazone, Warfarin or Oral Contraceptives.

Overdose

No dose-related clinical adverse effects observed with Sitagliptin with doses of up to 600 mg /day for periods of up to 10 days and 400 mg /day for periods of up to 28 days. In the event of an overdose should be taken a supportive measures, e.g., remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring (including obtaining an electrocardiogram), and institutional supportive therapy if required.

Precaution

If pancreatitis is initiated after dosing of Sitagliptin should be promptly discontinued the dose and proper management should be taken. Dosage adjustment is recommended in patients with moderate or severe renal insufficiency and in patients with ESRD (End Stage Renal Disease). When Sitagliptin used with a Sulfonylurea at lower dose of Sulfonylurea may be reduced the risk of hypoglycemia.

Pregnancy & Lactation

Pregnancy: Safety in pregnant women has not been established. Sitagliptin should be used during pregnancy only if the potential benefit justifies the potential risk of the fetus.

Lactation: It is not known whether Sitagliptin is secreted in human milk, it should not be administered in lactating mother.

Storage

Store in a cool & dry place, protected from light and keep out of the reach of children.

Commercial pack

Sucosit 50 tablet: Each box contains 3x10 tablets in Alu-Alu strips.

Sucosit 100 tablet: Each box contains 2x10 tablets in Alu-Alu strips.

Manufactured by:

Globe Pharmaceuticals Ltd.

Noakhali, Bangladesh