Sitazid®

Sitagliptin Phosphate Monohydrate BP Film Coated Tablet

DESCRIPTION

Sitazid® is a preparation of Sitagliptin. Sitagliptin is a DPP-4 inhibitor, which is believed to exert its actions in patients with type 2 diabetes by slowing the inactivation of incretin hormones. Concentrations of the active intact hormones are increased by Sitagliptin, thereby increasing and prolonging the action of these hormones. 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. These hormones are rapidly inactivated by the enzyme, DPP-4. 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. GLP-1 also lowers glucagon secretion from pancreatic alpha cells, leading to reduced hepatic glucose production. By increasing and prolonging active incretin levels, Sitagliptin increases insulin release and decreases glucagon levels in the circulation in a glucose-dependent manner. Sitagliptin demonstrates selectivity for DPP-4 and does not inhibit DPP-8 or DPP-9 activity in vitro at concentrations approximating those from therapeutic doses.

INDICATIONS

Sitagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Sitagliptin should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

DOSAGE & ADMINISTRATION

The recommended dose of Sitagliptin is 100 mg once daily. Sitagliptin can be taken with or without food.
Dosage adjustment is recommended for patients with moderate or severe renal insufficiency or end-stage renal disease.

Dosage Adjustment in Patients With Moderate, Severe and End Stage Renal Disease (ESRD)	
50 mg once daily	25 mg once daily
Moderate: CrCl ≥30 to <50 mL/min ~Serum Cr levels [mg/dL] Men: >1.7– ≤3.0; Women: >1.5– ≤2.5	Severe and ESRD: CrCl <30 mL/min ~Serum Cr levels [mg/dL] Men: >3.0; Women: >2.5; or on dialysis

CONTRAINDICATIONS

Hypersensitivity reaction to Sitagliptin, such as anaphylaxis or angioedema.

SIDE EFFECTS

- Hypoglycemia
- Upper respiratory tract infection
- Nasopharyngitis
- Headache

WARNING AND PRECAUTION

- There have been post-marketing reports of acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. If pancreatitis is suspected, promptly discontinue Sitagliptin.
- There have been post-marketing reports of acute renal failure, sometimes requiring dialysis. Dosage adjustment is recommended in patients with moderate or severe renal insufficiency and in patients with ESRD. Assessment of renal function is recommended prior to initiating Sitagliptin and periodically thereafter.
- There is an increased risk of hypoglycemia when Sitagliptin is added to an insulin secretagogue (e.g., sulfonylurea) or insulin therapy. Consider lowering the dose of the sulfonylurea or insulin to reduce the risk of hypoglycemia.
- Heart failure has been observed with two other members of the DPP-4 inhibitor class. Consider risks and benefits of Sitagliptin in patients who have known risk factors for heart failure. Monitor patients for signs and symptoms.
- Severe and disabling arthralgia has been reported in patients taking DPP-4 inhibitors. Consider as a possible cause for severe joint pain and discontinue drug if appropriate.

USE IN PREGNANCY & LACTATION

There are no adequate data from the use of Sitagliptin in pregnant women. Studies in animals have shown reproductive toxicity at high doses. The potential risk for humans is unknown. Due to lack of human data, Sitagliptin should not be used during pregnancy.

Sitagliptin is secreted in the milk of lactating rats at a milk to plasma ratio of 4:1. It is not known whether Sitagliptin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Sitagliptin is administered to a nursing woman.

PHARMACEUTICAL PRECAUTION

Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Sitazid® 50 tablet : Box containing 2 strips of 10 tablets. Each film coated tablet contains Sitagliptin Phosphate Monohydrate BP equivalent to Sitagliptin 50 mg.

Sitazid® 100 tablet : Box containing 1 strip of 10 tablets. Each film coated tablet contains Sitagliptin Phosphate Monohydrate BP equivalent to Sitagliptin 100 mg.

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