Sitap®

Sitagliptin

Description

Sitap® is a preparation of Sitagliptin Phosphate Monohydrate, a dipeptidyl peptidase-4 (DPP-4) inhibitor, which exerts its action by slowing the inactivation of incretin 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.

Indications

Sitap® is indicated as

- An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- As monotherapy and also indicated for use in combination with Metformin, Sulfonylurea or Thiazolidinediones as initial therapy.
- In patient with type 2 diabetes mellitus, to improve glycemic control in combination with Metformin plus Sulfonylurea and Metformin plus Thiazolidinediones when dual therapy in combination with these agents with diet and exercise does not provide adequate glycemic control.

Dosage and administration

The recommended dose of Sitagliptin is 100 mg once daily as monotherapy or as combination therapy with Metformin, a Sulfonylurea, a Thiazolidinediones or Metformin plus a Sulfonylurea or Metformin plus a Thiazolidinediones. Sitagliptin can be taken with or without food.

For patients with mild renal insufficiency (creatinine clearance, CrCl≥50ml/min), no dosage adjustment is required.

For patients with moderate renal insufficiency (CrCl≥30 to <50 ml/min women), the dose of Sitagliptin is 50 mg once daily.

For patients with severe renal insufficiency (CrCl<30 ml/min) or with end-stage renal disease (ESRD) requiring hemodialysis or peritoneal dialysis, the dose of Sitagliptin is 25 mg once daily.

Sitagliptin may be administered without regard to the timing of haemodialysis.

Use in pregnancy & lactation

Safety in pregnant women has not been established. Sitagliptin should be used during pregnancy only if clearly needed.

It is not known whether Sitagliptin is secreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Sitagliptin is administered to a nursing woman.

Geriatric use

No dosage adjustment is required based solely on age. Sitagliptin should be used with caution as age increases.

Pediatric use

Safety and effectiveness of Sitagliptin in pediatric patients under 18 years of age have not been established.

Side effects
The most common side effects are upper respiratory tract infection, nasopharyngitis and headache. Hypoglycemia may occur in patients treated with the combination of Sitagliptin and Sulfonylurea and add-on to insulin.

Contraindications

Sitagliptin is contraindicated in patients with known hypersensitivity to any of the components of the preparation.

Precautions
If pancreatitis is suspected, Sitagliptin should promptly be discontinued and appropriate management should be initiated. Dosage adjustment is recommended in patients with moderate or severe renal insufficiency and in patients with ESRD. Assessment of renal function should recommend prior to initiating Sitagliptin. When Sitagliptin is used in combination with a Sulfonylurea or with insulin, medication known to cause hypoglycemia. If a hypersensitivity reaction is suspected, Sitagliptin should be discontinued.

Drug interactions
Co-administration of Digoxin and Sitagliptin may slightly increase the mean peak drug concentration of Digoxin. But no dosage adjustment of Digoxin or Sitagliptin is recommended.

Overdose
There is no clinical syndrome experienced with over dosage of Sitagliptin up to 800 mg.

Pharmaceutical precautions
Store in a cool and dry place. Protect from light. Keep away from the reach of children.

Presentation
Sitap® 50 tablet: Each coated tablet contains Sitagliptin 50 mg as Phosphate Monohydrate INN.
Sitap® 100 tablet: Each coated tablet contains Sitagliptin 100 mg as Phosphate Monohydrate INN.

Package quantities
Sitap® 50 tablet: Each carton contains 30 tablets in blister pack.
Sitap® 100 tablet: Each carton contains10 tablets in blister pack.

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