

Incrit™

Sitagliptin Phosphate Monohydrate INN



50037

Presentation

Incrit 50mg Tablet Each coated tablet contains: Sitagliptin Phosphate Monohydrate INN 64.25mg equivalent to Sitagliptin 50mg.

Incrit 100mg Tablet: Each coated tablet contains: Sitagliptin Phosphate Monohydrate INN 128.50mg equivalent to Sitagliptin 100mg.

Indications

Sitagliptin is used alone or with other medications (like Metformin, Sulfonylurea, Thiazolidinedione) to control high blood sugar along with proper diet and exercise program in patients with type 2 (non-insulin-dependent) diabetes.

This medication should not be used to treat patients with type 1 diabetes (insulin-dependent diabetes) as it is not effective.

Mechanism of Action

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 (like, glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP)). Concentrations of the active intact hormones are increased by Sitagliptin, thereby increasing and prolonging the action of these hormones. GLP-1 and 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. 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.

Thus Sitagliptin increases insulin release and decreases glucagon levels in the circulation in a glucose-dependent manner.

Dosage and Administration

The recommended dose of Sitagliptin is 50mg twice a day and 100mg once daily. Sitagliptin can be taken with or without food.

Patients with Renal Insufficiency

For patients with mild renal insufficiency (creatinine clearance [CrCl] < 50 mL/min or serum creatinine levels of < 1.7 mg/dL in men and < 1.5 mg/dL in women), no dosage adjustment for sitagliptin is required.

For patients with moderate renal insufficiency (CrCl < 30 to < 50 mL/min, or serum creatinine levels of > 1.7 to < 3.0 mg/dL in men and > 1.5 to < 2.5 mg/dL in women), the dose of Sitagliptin is 50 mg once daily.

For patients with severe renal insufficiency (CrCl < 30 mL/min or serum creatinine levels of > 3.0 mg/dL in men and > 2.5 mg/dL in women) 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 hemodialysis.

Adverse Reactions

The most common adverse reactions include: headache, upper respiratory tract infection and nasopharyngitis. Hypoglycemia may occur in patients treated with the combination to Sitagliptin and sulfonylurea and add-on to insulin.

Warnings and Precautions

If pancreatitis is suspected, sitagliptin should promptly be discontinued and appropriate management should be initiated.

Use in Patients with Renal Insufficiency: Dosage adjustment is recommended in patients with moderate or severe renal insufficiency and in patients with ESRD requiring hemodialysis or peritoneal dialysis.

Use with Medications Known to Cause Hypoglycemia: When Sitagliptin is used in combination therapy dosage adjustment of sulfonylurea or insulin may be required to reduce the risk of hypoglycemia.

Hypersensitivity Reactions: There have been postmarketing reports of serious hypersensitivity reactions in patients treated with sitagliptin. These reactions include anaphylaxis, angioedema, and exfoliative skin conditions including Stevens-Johnson syndrome. If a hypersensitivity reaction is suspected, discontinue sitagliptin, assess for other potential causes for the event, and institute alternative treatment for diabetes.

Pregnancy Category B: Reproduction studies have been performed in rats and rabbits. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: Sitagliptin is secreted in the milk of lactating rats at 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.

Pediatric Use: Safety and effectiveness of sitagliptin in pediatric patients under 18 years of age have not been established.

Geriatric Use: This drug is known to be substantially excreted by the kidney. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection in the elderly, and it may be useful to assess renal function in these patients prior to initiating dosing and periodically thereafter

Drug Interactions

Effects of Sitagliptin on Other Drugs: Sitagliptin did not meaningfully alter the pharmacokinetics of metformin, glyburide, simvastatin, rosiglitazone, warfarin, or oral contraceptives.

Digoxin: Sitagliptin slightly increases the mean peak of Digoxin concentration. However, no dose adjustment of either drug is required.

Storage Condition

Keep out of the reach of children. Store below 25oC in a dry place away from light.

Commercial Pack

Incrit 50mg Tablet: 2x10's tablet in alu-alu blister pack.

Incrit 100mg Tablet: 1x10's tablet in alu-alu blister pack.


Manufactured by:

Synovia Pharma PLC., Station Road, Tongi, Gazipur.

A Subsidiary of BEXIMCO PHARMACEUTICALS LTD.

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Direction Slip artwork legend

Product Name	:	Incrit
Code number	:	523929/3
CDCS Version	:	03
Dimension	:	L 10.25 x W 6.37 inches
Min. size of text	:	8 pt
Used Colors	:	Black C  Pantone 186 C 