Sitagil M® ER Tablet

Sitagliptin + Metformin HCl

Presentation

Sitagil M® 50/500 ER: Each extended release tablet contains Sitagliptin Phosphate Monohydrate INN eq. to Sitagliptin 50 mg & Metformin HCl BP 500 mg.
Sitagil M® 50/1000 ER: Each extended release tablet contains Sitagliptin Phosphate Monohydrate INN eq. to Sitagliptin 50 mg & Metformin HCl BP 1000 mg.
Sitagil M® 100/1000 ER: Each extended release tablet contains Sitagliptin Phosphate Monohydrate INN eq. to Sitagliptin 100 mg & Metformin HCl BP 1000 mg.

Description

Sitagliptin is 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. The pharmacologic mechanism of action of Metformin is different from other classes of oral antihyperglycemic agents. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose, and increases peripheral glucose uptake and utilization.

Indications

Sitagliptin + Metformin extended release is a dipeptidyl peptidase-4 (DPP-4) inhibitor and biguanide combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both Sitagliptin and Metformin extended release is appropriate.

Dosage and administration

May adjust the dosing based on effectiveness and tolerability while not exceeding the maximum recommended daily dose of 100 mg Sitagliptin and 2000 mg Metformin extended release.
Administer once daily with a meal preferably in the evening. Gradually escalate the dose to reduce the gastrointestinal side effects due to Metformin. Maintain the same total daily dose of Sitagliptin and Metformin when changing between Sitagliptin + Metformin extended release, without exceeding the maximum recommended daily dose of 2000 mg Metformin extended release.
Swallow whole. Never split, crush or chew.

Adverse Reactions

- The most common adverse reactions reported in ≥5% of patients simultaneously started on Sitagliptin and Metformin and more commonly than in patients treated with placebo were diarrhea, upper respiratory tract infection, and headache.
- Adverse reactions reported in ≥5% of patients treated with Sitagliptin in combination with Sulfonylurea and Metformin and more commonly than in patients treated with placebo in combination with Sulfonylurea and Metformin were hypoglycemia and headache.
- Hypoglycemia was the only adverse reaction reported in ≥5% of patients treated with Sitagliptin in combination with insulin and Metformin and more commonly than in patients treated with placebo in combination with insulin and Metformin.

Contraindications

- Renal dysfunction, e.g., serum creatinine ≥1.5 mg/dL [male], ≥1.4 mg/dL [female] or abnormal creatinine clearance.
- Metabolic acidosis, including diabetic ketoacidosis.
- History of a serious hypersensitivity reaction (e.g., anaphylaxis or angioedema) to Sitagliptin + Metformin extended release or to one of its components.

Precautions

Do not use the combination of Sitagliptin & Metformin in patients with hepatic disease. Before initiating the combination and at least annually thereafter, assess renal function and verify as normal. May need to discontinue the combination and temporarily use insulin during periods of stress and decreased intake of fluids and food as may occur with fever, trauma, infection or surgery.

Use in Pregnancy and Lactation

- There are no adequate and well-controlled studies in pregnant women with Sitagliptin + Metformin extended release or its individual components; therefore, the safety of Sitagliptin + Metformin extended release in pregnant women is not known. Sitagliptin + Metformin extended release should be used during pregnancy only if clearly needed.
- It is not known whether Sitagliptin or Metformin are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Sitagliptin + Metformin extended release is administered to a nursing woman.

Drug interactions

Carbonic anhydrase inhibitors should be used with caution treated with Sitagliptin + Metformin extended release, as the risk of lactic acidosis may increase.
Careful patient monitoring and dose adjustment of Sitagliptin + Metformin extended release and/or the interfering drug is recommended in patients who are taking cationic medications that are excreted via the proximal renal tubular secretory system.

Overdose

There is no experience with doses above 800 mg in clinical studies. In the event of an overdose, it is reasonable to employ the usual supportive measures, e.g., remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring (including obtaining an electrocardiogram), and institute supportive therapy as indicated by the patient's clinical status.
Prolonged hemodialysis may be considered if clinically appropriate. It is not known if Sitagliptin is dialyzable by peritoneal dialysis.
Overdose of Metformin Hydrochloride has occurred, including ingestion of amounts greater than 50 grams. Hypoglycemia was reported in approximately 10% of cases, but no causal association with Metformin Hydrochloride has been established. Lactic acidosis has been reported in approximately 32% of Metformin overdose cases. Hemodialysis may be useful for removal of accumulated drug from patients in whom Metformin overdose is suspected.

Storage

Do not store above 30 ^{0}C. Keep away from light and out of the reach of children.

Commercial pack

Sitagil M® 50/500 ER: Each box contains 5 blister strips of 4 tablets.
Sitagil M® 50/1000 ER: Each box contains 3 blister strips of 6 tablets.
Sitagil M® 100/1000 ER: Each box contains 3 blister strips of 6 tablets.

Manufactured by
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