Diaset®

Miglitol

Description

Diaset® is a preparation of Miglitol which is a desoxynojirimycin derivative. Miglitol does not enhance insulin secretion. The antihyperglycemic action of Miglitol results from a reversible inhibition of membrane bound intestinal α-glucoside hydrolase enzymes. Membrane-bound intestinal α- glucosidases hydrolyze oligosaccharides and disaccharides to glucose and other monosaccharides in the brush border of the small intestine. In diabetic patients, this enzyme inhibition results in delayed glucose absorption and lowering of postprandial hyperglycemia. As a consequence of plasma glucose reduction, Miglitol reduce levels of glycosylated hemoglobin.

Indications

Diaset®, as monotherapy, are indicated as an adjunct to diet and exercise to improve glycemic control in patients with Type II Diabetes whose hyperglycemia cannot be managed with diet alone. Diaset® may also be used in combination with a sulfonylurea when diet plus either Diaset® or a sulfonylurea alone do not result in adequate glycemic control.

Dosage and administration

There is no fixed dosage regimen for the management of diabetes mellitus with Diaset® or any other pharmacologic agent. Dosage of Diaset® must be individualized on the basis of both effectiveness and tolerance.

Initial Dosage:

The recommended starting dosage of Diaset® is 25 mg, given orally three times daily at the start of each main meal. However, some patients may benefit by starting at 25 mg once daily to minimize gastrointestinal adverse effects, and gradually increasing the frequency of administration to 3 times daily.

Maintenance Dosage:

The usual maintenance dose of Diaset® is 50 mg 3 times daily, although some patients may benefit from increasing the dose to 100 mg 3 times daily. In order to allow adaptation to potential gastrointestinal adverse effects, it is recommended that Diaset® therapy be initiated at a dosage of 25 mg 3 times daily, the lowest effective dosage, and then gradually titrated upward to allow adaptation. After 4 - 8 weeks of the 25 mg 3 times daily regimen, the dosage should be increased to 50 mg 3 times daily for approximately three months, following which a glycosylated hemoglobin level should be measured to assess therapeutic response. If, at that time, the glycosylated hemoglobin level is not satisfactory, the dosage may be further increased to 100 mg 3 times daily, the maximum recommended dosage. If no further reduction in postprandial glucose or glycosylated hemoglobin levels is observed with titration to 100 mg 3 times daily, consideration should be given to lowering the dose. Once an effective and tolerated dosage is established, it should be maintained.

Maximum Dosage:

The maximum recommended dosage of Diaset® is 100 mg 3 times daily.

Children:

Safety and effectiveness of Diaset® in pediatric patients have not been established.

Use in pregnancy and lactation

Miglitol is pregnancy category B. The safety of Miglitol in pregnant women has not been established. As there are no adequate and well-controlled studies in pregnant women, this drug should be used during pregnancy only if clearly needed. Miglitol has been shown to be excreted in human milk to a very small degree. Although the levels of Miglitol reached in human milk are exceedingly low, it is recommended that Miglitol not be administered to a nursing woman.

Precautions

Miglitol given in combination with a sulfonylurea will cause a further lowering of blood glucose; it may increase the hypoglycemic potential of the sulfonylurea. When diabetic patients are exposed to stress such as fever, trauma, infection, or surgery, a temporary loss of control of blood glucose may occur. At such times, temporary insulin therapy may be necessary. Plasma concentrations of Miglitol in renal impaired patients were proportionally increased relative to the degree of renal dysfunction. As there are no adequate and well-controlled studies in diabetic patients with significant renal dysfunction, therefore, treatment of these patients with Miglitol is not recommended.

Side effects

Gastrointestinal symptoms like abdominal pain, diarrhea, and flatulence may develop in patients taking Miglitol. Dermatologic symptoms like skin rashes may develop in patients receiving Miglitol. Abnormal laboratory findings e.g., low serum iron occurred more often in patients treated with Miglitol but did not persist in the majority of cases and was not associated with reductions in hemoglobin or changes in other hematologic indices.

Contraindications

Miglitol is contraindicated in patients with hypersensitivity to the drug or any of its components. It is also contraindicated in patients with diabetic ketoacidosis; inflammatory bowel disease, colonic ulceration, or partial intestinal obstruction, and in patients predisposed to intestinal obstruction; chronic intestinal diseases associated with marked disorders of digestion or absorption, or with conditions that may deteriorate as a result of increased gas formation in the intestine.

Drug Interactions

The mean Cmax and AUC values for glyburide & metformin decrease when co-administered with Miglitol. Miglitol may significantly reduce the bioavailability of ranitidine and propranolol. Intestinal adsorbents (e.g.charcoal) and digestive enzyme preparations containing carbohydrate-splitting enzymes (e.g.amylase, pancreatin) may reduce the effect of Miglitol and should not be taken concomitantly.

Overdosage

Overdose of Miglitol will not result in hypoglycemia. An overdose may result in transient increases in flatulence, diarrhea, and abdominal discomfort. Because of the lack of extra-intestinal effects seen with Miglitol, no serious systemic reactions are expected in the event of an overdose.

Pharmaceutical precautions

Store in a cool and dry place. Protect from light.

Presentation

Diaset® 25: Each coated tablet contains Miglitol INN 25 mg.
Diaset® 50: Each coated tablet contains Miglitol INN 50 mg.

Package quantities

Diaset® 25: Carton of 30 tablets in blister.
Diaset® 50: Carton of 30 tablets in blister.

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