Diatag®

Pioglitazone

Description

Diatag® is a preparation of Pioglitazone Hydrochloride.It is a thiazolidinedione oral antidiabetic agent. Diatag® decreases insulin resistance in the periphery and in the liver resulting in increased insulin-dependent glucose disposal and decreased hepatic glucose output. Pioglitazone is a potent agonist for peroxisome proliferator-activated receptor-gamma (PPARγ). PPAR receptors are found in tissues important for insulin action such as adipose tissue, skeletal muscle and liver. Activation of PPARγ nuclear receptors modulates the transcription of a number of insulin responsive genes involved in the control of glucose and lipid metabolism. Activation of PPARγ nuclear receptors modulates the transcription of a number of insulin responsive genes involved in the control of glucose and lipid metabolism. The decreased insulin resistance produced by **Diatag®** results in lower glucose concentrations,lower plasma insulin levels and lower HbA_1c values. Fasting and postprandial glycaemic controls are improved in patients with type 2 diabetes mellitus.

Indications

Diatag® is indicated for the treatment of type 2 diabetes mellitus inadequately controlled by diet. **Diatag®** is effective as a single agent and may also be used in combination with sulfonylureas, metformin or insulin when diet plus the single agent does not result in adequate glycaemic control.

Dosage and administration

Monotherapy

The recommended dosage of **Diatag®** is 15 mg or 30 mg once daily regardless to meals, increasing after four weeks, if greater therapeutic effect is needed, to 45 mg once daily.

Combination Therapy

The recommended dose of **Diatag®** is 30 mg once daily in combination with sulfonylureas, insulin or metformin. It may be possible to achieve metabolic control at a reduced dose of the sulfonylurea, insulin or metformin. If there is a particular risk of hypoglycaemia, Pioglitazone can be introduced at a dose of 15 mg. For patients already on insulin, Pioglitazone should be introduced at a dose of 15 mg once daily. Dosage can then be increased cautiously.

Maximum Recommended Dose

The dose of Pioglitazone should not exceed 45mg/daily in monotherapy or in combination with sulfonylurea, metformin, or insulin. Dose adjustment in patients with renal insufficiency is not recommended.

Use in pregnancy and lactation

There are no adequate and well-controlled studies in pregnant women. **Diatag®** should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether Pioglitazone is secreted in human milk. As many drugs are excreted in human milk, **Diatag®** should not be administered to a lactating woman.

Use in children

Safety and effectiveness of **Diatag®** in children have not been established.

Pecaution

Pioglitazone should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis and should be used with caution in patients with edema and hepatic insufficiency. Patients receiving Pioglitazone in combination with insulin or oral hypoglycaemic agents may be at risk for hypoglycaemia and a reduction in the dose of the concomitant agent may be necessary.

Side –effects

Major side effects of Pioglitazone monotherapy at doses of 7.5mg, 15mg, 30mg, and 45mg are upper respiratory tract infection and headache. The other side effects are sinusitis, myalgia, tooth disorder and pharyngitis.

Contraindications

Pioglitazone is contraindicated in patients with known hypersensitivity or allergy to Pioglitazone or any of its components. Initiation of Pioglitazone in patients with New York Heart Association Class III or IV heart failure is also contraindicated.

Drug interaction

Administration of thiazolidinedione with an oral contraceptive containing ethinyl oestradiol and norethindrone reduced the plasma concentrations of both hormones by approximately 30%.This could result in loss of contraception. Gemfibrozil may significantly increase the AUC of Pioglitazone where as Rifampin significantly decrease in the AUC of Pioglitazone.

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

Presentation

Diatag® 15 mg tablet: Each coated tablet contains Pioglitazone 15mg as Hydrochloride INN
Diatag® 30 mg tablet: Each coated tablet contains Pioglitazone 30mg as Hydrochloride INN
Diatag® 45 mg tablet: Each coated tablet contains Pioglitazone 15mg as Hydrochloride INN

Package quantities

Diatag® 15 mg tablet: Carton of thirty tablets in Alu-PVC blister.
Diatag® 30 mg tablet: Carton of thirty tablets in Alu-PVC blister.
Diatag® 45 mg tablet: Carton of thirty tablets in Alu-PVC blister.

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