



Tos[®]
Pioglitazone
Oral Antidiabetic

COMPOSITION

Tos[®] 15 : Each tablet contains Pioglitazone INN 15 mg.

PHARMACOLOGY

Tos[®] is a member of the newest class of oral antidiabetic agent called thiazolidinediones that depend on the presence of insulin for its mechanism of action. Pioglitazone decreases insulin resistance in the periphery and in the liver resulting in increased insulin-dependent glucose disposal and decreased hepatic glucose output. It also improves abnormality in lipid metabolism by activating Peroxisome Proliferator Activated Receptor-gamma (PPAR γ).

INDICATION

Tos[®] is indicated as an adjunct to diet and exercise to improve glycemic control in patients with NIDDM. It is indicated for monotherapy and also in combination with sulfonylurea, metformin or insulin when diet and exercise plus the single agent does not result in adequate glycemic control.

DOSAGE AND ADMINISTRATION

Tos[®] can be taken once daily without regard to meals. The management of antidiabetic therapy should be individualized. Pioglitazone monotherapy, in patients not adequately controlled with diet and exercise, may be initiated with 15 mg or 30 mg once daily. For patients who respond inadequately to the initial dose of Pioglitazone, the dose can be increased up to 45 mg once daily. For patients not responding adequately to monotherapy, combination therapy should be considered.

CONTRAINDICATION AND PRECAUTION

Pioglitazone is contraindicated in patients with known hypersensitivity to this product or any of its components.

Pioglitazone exerts its antihyperglycemic effect only in the presence of insulin. Therefore, it should not be used in type 1 diabetes or for the treatment of diabetic ketoacidosis. Pioglitazone should be used with caution in case of combination antidiabetic therapy and hepatic insufficiency.

SIDE EFFECT

The overall incidence and types of adverse events reported in placebo controlled clinical trials of Pioglitazone monotherapy at doses of 7.5 mg, 15 mg, 30 mg or 45 mg once daily are upper respiratory infection (13.2%) and

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headache (9.1%). The other side effects are sinusitis, myalgia, edema, tooth disorder, pharyngitis, etc.

DRUG INTERACTION

Administration of thiazolidinediones with an oral contraceptive containing ethinyl estradiol and norethindrone reduce the plasma concentration of both the hormones by approximately 30%, which could result failure in contraception.

USE IN PREGNANCY AND LACTATION

Pregnancy: There is no adequate and well controlled study in pregnant women. Pioglitazone should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing mothers: It is not known whether Pioglitazone is secreted in human milk. As many drugs are excreted in human milk, it should not be administered to a breast feeding woman.

OVERDOSAGE

In the event of overdosage, appropriate supportive treatment should be initiated according to patient's clinical signs and symptoms.

STORAGE CONDITION

Keep in a cool and dry place, away from direct sunlight.

HOW SUPPLIED

Tos[®] 15 : Box containing 5 x 6 tablets in blister pack.

