

Composition : Piozena - 15 Tablet : Each Film Coated Tablet Contains Pioglitazone Hydrochloride USP 15 mg.

Pharmacology : Pioglitazone is a member of the newest class of oral antidiabetic agents called thiazolidinediones which 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 PPAR- γ receptor.

Indications : It is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type II diabetes (NIDDM). It also indicated for monotherapy and also indicated for use in combination with a sulfonylurea, metformin or insulin when diet and exercise plus the single agent does not result in adequate glycemic control.

Dosage and administration : Pioglitazone 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 at 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. Or, as directed by the registered physicians.

Contraindication : It is contraindicated in patients having serious hypersensitivity reaction to the Pioglitazone or any other component of this product.

Precautions : Pioglitazone exerts its hypoglycemic effect only in the presence of insulin. Therefore it should not be used in patients with type I diabetes or for the treatment of diabetic ketoacidosis. Pioglitazone should be used with caution in

Piozena-15 Tablet



in case of combination therapy, hepatic insufficiency & heart diseases.

Side effects : Most Commonly reported adverse effects are- Upper respiratory tract infections 13.2%, headache 9.1%, sinusitis 6.3%, myalgia 5.4%, tooth disorder 5.3%, pharyngitis 5.1%.

Use in pregnancy & lactation : Pregnancy- There are no adequate and well controlled studies 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. Because many drugs are excreted in human milk, it should not be administered to a breast feeding women.

Use in Child : It is not recommended for patients under 18 years of age.

Drug interactions : Administration of another thiazolidinedione with an oral contraceptive containing ethinyl estradiol and norethindrone reduces the plasma concentrations of both hormones by approximately 30%, which could result in loss of contraception.

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

Storage : Store below 30°C in a dry place.

Packing : Piozena -15 Tablet : Each box contains 28's, tablets in blister pack.