

# Diaglit®

(Pioglitazone Tablet )

## Description

Diaglit is a preparation of Pioglitazone which is a member of the newest class of oral antidiabetic agent called thiazolidinediones. It depends 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- $\gamma$ ).

## Indications

Diaglit is indicated as an adjunct to diet and exercise to improve glycaemic control in patients with type II diabetes (NIDDM). Diaglit is indicated for monotherapy and also indicated for use in combination with sulphonylurea, Metformin or Insulin when diet and exercise plus the single agent does not result in adequate glycaemic control.

## Dosage and Administration

Diaglit can be taken once daily without regard to meals. The management of antidiabetic therapy should be individualized. Diaglit monotherapy may be initiated at 15 mg or 30 mg once daily dosages in patients not adequately controlled with diet and exercise alone. 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.

Maximum recommended daily dose of Diaglit should not exceed 45 mg since doses higher than 45 mg have not been studied in placebo controlled clinical studies. Besides, no placebo controlled clinical studies of more than 30 mg once daily have been conducted in combination therapy.

## Contraindication

Diaglit is contraindicated in patients with known hypersensitivity to any of its components.

## **Precautions**

Pioglitazone exerts its antihyperglycaemic 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. Liver enzyme should be monitored regularly.

## **Drug Interactions**

Administration of thiazolidinediones with an oral contraceptive containing ethinyl oestradiol and norethindrone reduces the plasma concentration of both hormones by approximately 30% which could result in loss of contraception.

## **Side Effects**

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 tract infection (13.2%), headache (9.1%), sinusitis (6.3%), myalgia (5.4%), tooth disorder (5.3%), and pharyngitis (5.1%).

## **Use in Special Populations**

*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 foetus.

*Lactation* : 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 lactating women.

## **Commercial Packs**

Diaglit® 15 Tablet : Box containing 30 tablets in 3 x 10's blister strips, each tablet contains Pioglitazone Hydrochloride INN equivalent to Pioglitazone 15 mg.

Diaglit® 30 Tablet : Box containing 30 tablets in 3 x 10's blister strips, each tablet contains Pioglitazone Hydrochloride INN equivalent to Pioglitazone 30 mg.