

Only for the use of medical professionals

# Politor<sup>®</sup>

Pioglitazone + Metformin

## Description

Politor<sup>®</sup> contains two oral antihyperglycemic agents (Pioglitazone Hydrochloride and Metformin Hydrochloride) with different mechanisms of action to improve glycemic control in patients with type II diabetes mellitus. Pioglitazone is a member of the thiazolidinedion class decreases insulin resistance in the periphery and in the liver resulting in increased insulin dependent glucose disposal and decreased hepatic glucose output. Metformin is a member of biguanide class, improve glucose tolerance in patients with type II diabetes, lowering both basal and postprandial plasma glucose. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity by increasing peripheral glucose uptake and utilization.

## Indication

Politor<sup>®</sup> is indicated as an adjunct to diet and exercise.

1. To improve glycemic control in patients type II diabetes mellitus, or
2. For patients who are already treated with a separate combination of Pioglitazone and Metformin, or
3. For patients whose diabetes is not adequately controlled with Metformin alone, or
4. For those patients whose diabetes is not adequately controlled with Metformin alone' or
5. For those patients who have initially responded to Pioglitazone alone and require additional glycemic control.

## Dosage and administration

### Recommended dose

Use of antihyperglycemic agents in the management of type II diabetes should be individualized on the basis of effectiveness and tolerability. Politor<sup>®</sup> should be given with meals; the initial starting dose is either the 15mg/500mg or 15mg / 800mg tablet strength once or twice daily and gradually titrated after assessing adequacy of therapeutic response, while not exceeding the maximum recommended daily dose of Pioglitazone 45mg and Metformin 2550mg.

### Starting dose for patients who initially responded to Pioglitazone monotherapy and require additional glycemic control:

Based on the usual starting doses of Metformin (500mg twice daily or 850mg daily, Politor<sup>®</sup> may be initiated at either the 15mg/850mg once daily, and gradually titrated after assessing adequacy of therapeutic response.

### Starting dose for patients inadequately controlled on Metformin monotherapy:

Based on the usual starting dose of Pioglitazone (15-30mg daily Politor<sup>®</sup> may be initiated at either the 15mg/500mg or 15mg/ 850mg once or daily and gradually titrated after assessing adequacy of therapeutic response.

### Starting dose for patients switching from combination therapy of Pioglitazone plus Metformin as separate tablets:

Politor<sup>®</sup> may be initiated with either the 15mg/500mg or 15mg/850mg tablet strengths based on the dose of Pioglitazone and Metformin already being taken.

### **Use in Pregnancy & lactation**

Politor<sup>®</sup> (Pioglitazone and Metformin) should not be used during pregnancy unless the potential benefit justifies the potential risk to the later. There are no adequate and well controlled studies in pregnant women with combination of Pioglitazone and Metformin or its individual components. It is not known whether Pioglitazone and/or Metformin are secreted in human milk. Because many drugs are excreted in human milk, Politor should not be administered to a breastfeeding woman.

### **Side effects**

The most common side-effects are upper respiratory infection. Diarrhea, combined edema/peripheral edema and headache, respectively. Most clinical adverse events were similar between groups treated with Pioglitazone in combination with Metformin and those treated with pioglitazone monotherapy.

### **Precautions**

Politor<sup>®</sup> (Pioglitazone and Metformin) should not be used in patients with type I diabetes or for the treatment of diabetic ketoacidosis and should used with caution in patients with edema. Serum ALT levels should be evaluated to the initiation of therapy with combination of Pioglitazone and Metformin in patient's and periodically thereafter per the clinical judgment of the health care professional.

### **Contraindications**

Politor<sup>®</sup> (Pioglitazone and Metformin) is contraindicated in patients with known hypersensitivity to any components of this combination. These combination also contraindicated in renal disease which may also result from conditions e.g., acute myocardial infarction, septicemia, acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma.

### **Drug Interactions**

Politor<sup>®</sup> (Pioglitazone and Metformin) may interact with furosemide, nifedipine, cationic drugs (e.g., amiloride, dioxin, morphines, procainamide, quinidine, quinine, ranitidine, triamterene, Irimethoprim, and vancon and certain drugs tend to produce hyperglycemia and may lead to loss of glycemic control (e.g., thiazides and either diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phentolamine, nicotinic acid, sympathomimetics, calcium channel blocking drugs, and isoniazid).

### **Presentation**

**Politor<sup>®</sup> 500 tablet:** A light blue colored, caplet shaped, film coated tablet. Each coated tablet contains Pioglitazone 15mg as Hydrochloride INN and Metformin Hydrochloride BP 500mg.

**Politor<sup>®</sup> 850 tablet:** A light green colored oval shaped, film coated tablet. Each coated tablet contains Pioglitazone 15mg as Hydrochloride INN and Metformin Hydrochloride BP 850mg.

### **Pharmaceutical precautions**

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

### **Package quantities -**

Politor<sup>®</sup> 500mg tablet: Carton of 30 tablets in Alu PVC blister.

Politor<sup>®</sup> 850mg tablet: Carton of 30 tablets in Alu- PVC blister.

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