

PIOPOD MF

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for **Piopod MF** [Metformin hydrochloride (extended release) 500mg and pioglitazone hydrochloride (extended release) 15mg bilayered tablets and Metformin hydrochloride 500mg and pioglitazone hydrochloride 30mg bilayered tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

Advice for healthcare professionals:

- Patients with active bladder cancer or with a history of bladder cancer, and those with uninvestigated haematuria, should not receive pioglitazone
- Prescribers should review the safety and efficacy of pioglitazone in individuals after 3–6 months of treatment to ensure that only patients who are deriving benefit continue to be treated. Pioglitazone should be stopped in patients who do not respond adequately to treatment (eg, reduction in glycosylated haemoglobin, HbA1c).
- Before starting pioglitazone, the following known risk factors for development of bladder cancer should be assessed in individuals: age; current or past history of smoking; exposure to some occupational or chemotherapy agents such as cyclophosphamide; or previous irradiation of the pelvic region.
- Use in elderly patients should be considered carefully before and during treatment because the risk of bladder cancer increases with age. Elderly patients should start on the lowest possible dose and be regularly monitored because of the risks of bladder cancer and heart failure associated with pioglitazone.

PHARMACOLOGICAL PROPERTIES: Oral anti diabetic agents. **Pioglitazone** is a potent agonist for peroxisome proliferator-activated receptor gamma. **Metformin** decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity by increasing peripheral glucose uptake and utilization. **INDICATION:** As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are already treated with pioglitazone and Metformin or who have inadequate glycemic control on pioglitazone alone or metformin alone. The drug should not be used as first line of therapy for diabetes. **DOSAGE AND ADMINISTRATION:** The Piopod MF administered once daily with evening meal. The total daily doses of Piopod MF should not exceed the maximum recommended total daily doses of pioglitazone (45mg) or metformin (2000mg for extended release metformin). **CONTRAINDICATION:** In patients with hypersensitivity to the active substances or to any of the excipients, established NYHA class III or IV heart failure, acute or chronic disease which may cause tissue hypoxia such as cardiac or respiratory failure, recent myocardial infarction, shock, hepatic impairment, acute alcohol intoxication, alcoholism, diabetic ketoacidosis or diabetic pre-coma, renal failure or renal dysfunction, acute conditions with the potential to alter renal function such as: dehydration, severe infection, shock, intravascular administration of iodinated contrast agents and lactation. **WARNINGS & PRECAUTIONS:** Use cautiously or stop the metformin in patient with lactic acidosis and increased risk of cardiovascular mortality. Use cautiously or stop the **pioglitazone** in patients with cardiac failure and other cardiac effects, type 1 diabetes or for the treatment of diabetic ketoacidosis, hypoglycemia, with NYHA Class III or IV cardiac status, edema, weight gain, ovulation, hematologic disturbance, hepatic effects, macular edema and fractures. Use cautiously or stop the **metformin** in patient with impairment of renal function, hypoxic states, surgical procedures, alcohol intake, impaired hepatic function, vitamin b12 levels, change in clinical status of patients with previously controlled type 2 diabetes, hypoglycemia and loss of control of blood glucose. **DRUG INTERACTIONS:** **Pioglitazone:** Oral contraceptives, midazolam, nifedipine er, rifampin and gemfibrozil. **Metformin:** Glyburide, furosemide, nifedipine, cationic drugs (e.g., amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, and vancomycin), thiazides and other

diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs, and isoniazid.

ADVERSE REACTIONS: Anaemia, visual disturbance, flatulence, weight increased, arthralgia, headache, haematuria, erectile dysfunction, lactic acidosis, taste disturbance, nausea, vomiting, diarrhea, abdominal pain, loss of appetite, liver function tests abnormalities or hepatitis resolving upon metformin discontinuation and skin reactions such as erythema, pruritis and urticaria.

MARKETED BY:



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IN/ PIOPOD MF500,15,30mg/Aug-15/01/ABPI

(Additional information is available on request)