

PIOPOD GM

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

Abbreviated Prescribing information for **Piopod GM** [Metformin hydrochloride 500mg, pioglitazone hydrochloride 15mg, glimepiride 1mg bilayered tablets and Metformin hydrochloride 500mg, pioglitazone hydrochloride 15mg, glimepiride 2mg 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. **Glimepiride** in lowering blood glucose appears to be dependent on stimulating the release of insulin from functioning pancreatic beta cells. **Metformin** decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity by increasing peripheral glucose uptake and utilization.

INDICATION: Indicated 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 pioglitazone and sulfonylurea or who have inadequate glycemic control on pioglitazone alone or metformin or a sulfonylurea urea alone. The drug should not be used as first line of therapy for diabetes.

DOSAGE AND ADMINISTRATION: The total daily doses of Piopod GM should not exceed the maximum recommended total daily doses of pioglitazone (45mg) or metformin (2000mg for extended release metformin) or glimepiride (8 mg).

CONTRAINDICATION: Contraindicated 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. Use cautiously or stop the **glimepiride** in patient with hypoglycemia, loss of control of blood glucose and

hemolytic anemia. **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. **Glimepiride:** Sulfonylureas, NSAIDs, salicylates, sulfonamides, chloramphenicol, coumarins, probenecid, monoamine oxidase inhibitors and beta adrenergic blocking agents.

ADVERSE REACTIONS: Anaemia, visual disturbance, flatulence, weight increased, arthralgia, headache, haematuria, erectile dysfunction, taste disturbance, nausea, vomiting, diarrhea, abdominal pain, loss of appetite, liver function tests abnormalities, hypoglycemia, headache, dizziness, asthenia, pruritus, erythema, urticarial, hepatic porphyria reactions, disulfiram-like reactions, hyponatremia, Leukopenia, agranulocytosis, thrombocytopenia, hemolytic anemia, blurred vision, upper respiratory tract infection, combined edema/peripheral edema, insomnia, weight increased, myalgia and tooth disorder.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

IN/ PIOPOD GM 500,15,1,2mg/Aug-15/01/ABPI

(Additional information is available on request)