

PIOPOD G

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

Abbreviated Prescribing information for **Piopod G** [Pioglitazone hydrochloride 15mg and glimepiride 1mg Tablets and Pioglitazone hydrochloride 15mg and glimepiride 2mg 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.

INDICATION: As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are already treated with a thiazolidinedione and a sulfonylurea or who have inadequate glycemic control on a thiazolidinedione alone or a sulfonylurea alone. The drug should not be used as first line of therapy for diabetes.

DOSAGE AND ADMINISTRATION: Starting dose for patients currently on **pioglitazone** monotherapy; usual starting doses of glimepiride (1 mg or 2 mg once daily), and pioglitazone 15 mg or 30 mg. PIOPOD G may be initiated at once daily, and adjusted after assessing adequacy of therapeutic response. The total daily doses of Piopod G should not exceed the maximum recommended total daily doses of pioglitazone (45mg) or glimepiride (8 mg).

CONTRAINDICATION: In patients with symptomatic heart failure, established New York Heart Association (NYHA) Class III or IV heart failure, hypersensitivity to any of its components and sulfonamide derivatives and diabetic ketoacidosis with and without coma.**WARNINGS &**

PRECAUTIONS: Use cautiously or stop the **pioglitazone** in patients with cardiac failure and other cardiac effects, type 2 diabetes combined with systolic heart failure (NYHA Class II), type 1 diabetes, hypoglycemia, patients with New York Heart Association (NYHA) class III and IV cardiac status, congestive heart failure, edema, weight gain, premenopausal anovulatory women, decreases in hemoglobin and hematocrit and macular edema. Periodic monitoring of liver enzymes required. Use cautiously or stop the glimepiride in patients with hypoglycemia, hypersensitivity reactions, hemolytic anemia, increased risk of cardiovascular mortality with sulfonylureas and macrovascular outcomes.

DRUG INTERACTIONS: **Glimepiride:** Oral anti-diabetic medications, pramlintide acetate, insulin, ACE inhibitors, H₂ receptor antagonists, fibrates, propoxyphene, pentoxifylline, somatostatin analogs, anabolic steroids and androgens, cyclophosphamide, phenyramidol, guanethidine, fluconazole, sulfipyrazone, tetracyclines, clarithromycin, disopyramide, quinolones, fluoxetine, NSAIDs, salicylates, sulfonamides, chloramphenicol, coumarins, probenecid and MAOI,

danazol, glucagon, somatropin, protease inhibitors, atypical antipsychotic medications (e.g., olanzapine and clozapine), barbiturates, diazoxide, laxatives, rifampin, thiazides and other diuretics, corticosteroids, phenothiazines, thyroid hormones, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics (e.g., epinephrine, albuterol, terbutaline), isoniazid, beta-blockers, clonidine, and reserpine, alcohol, miconazole, inhibitors (e.g., fluconazole) and inducers (e.g., rifampin) of cytochrome P450 2C9 and colestevorol. **Pioglitazone:** Oral contraceptives, cyclosporin, calcium channel blockers, and HMG-CoA reductase inhibitors, rifampicin, gemfibrozil and inducible cytochrome P450, 1A, 2C8/9 and 3A4.

ADVERSE REACTIONS: Visual disturbance, upper respiratory tract infection, sinusitis, weight increased, hypoesthesia, insomnia, vertigo, visual disturbance, flatulence, fatigue, increased lactic dehydrogenase, appetite increased, hypoglycaemia, dizziness, headache, glycosuria, proteinuria, sweating, macular edema, hemolytic anemia, headache, accidental injury, flu syndrome, nausea, allergic reactions, elevated ALT, serious hypersensitivity reactions, hemolytic anemia, Porphyria cutanea tarda, photosensitivity reactions, leukopenia, agranulocytosis, aplastic anemia, and pancytopenia, thrombocytopenia, hepatic porphyria reactions, hyponatremia and SIADH.

MARKETED BY:



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In/ Piopod G 15,1,2mg/Aug-15/01/Abpi

(Additional information is available on request)