PIOPOD

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

Abbreviated Prescribing information for **Piopod** [Pioglitazone hydrochloride 15mg and 30mg 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 agent. Pioglitazone is a potent agonist for peroxisome proliferator-activated receptor gamma. INDICATION: As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus in multiple clinical settings. The drug should not be used as first line of therapy for diabetes. DOSAGE AND **ADMINISTRATION:** Should be taken once daily without regard to meals. Initial dose: 15 or 30 mg once daily. It can be increased up to 45mg. Keep medicament out of reach of children. **CONTRAINDICATION:** In patients with symptomatic heart failure, established New York Heart Association (NYHA) Class III or IV heart failure, active bladder cancer, hypersensitivity to pioglitazone or any of its components. 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, bladder cancer, congestive heart failure, edema, weight gain, premenopausal anovulatory women, decreases in hemoglobin and hematocrit and macular edema. Periodic monitoring of liver enzymes required. DRUG INTERACTIONS: Oral contraceptives, fexofenadine, digoxin, warfarin, midazolam, ranitidine, nifedipine ER, ketoconazole, atorvastatin calcium and rifampin. ADVERSE REACTIONS: Upper respiratory tract, infection, headache, sinusitis, myalgia, tooth disorder, diabetes mellitus aggravated, pharyngitis, dyspnea, decreases in hemoglobin and hematocrit, ALT values ≥ 3 times the upper limit of normal, bilirubin, AST, ALT, alkaline phosphatase, and GGT decreased

MARKETED BY:



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IN/ PIOPOD 15,30mg/Aug-2015/01/ABPI

(Additional information is available on request)