Abridged Prescribing Information

ZOBILAN™ (Zoledronic Acid)

Composition: Zoledronic acid injection is available as vial of 4 mg/5 mL (0.8 mg/mL) Intravenous (IV) only. **Indications:** Patients with Multiple Myeloma (MM) and patients with documented bone metastases from solid tumors, in conjunction with standard anti-neoplastic therapy. Prostate cancer should have progressed after treatment with at least one hormonal therapy and Hypercalcemia of Malignancy (HCM). **Dosage and Administration:** MM and patients with documented bone metastases from solid tumors, in conjunction with standard anti-neoplastic therapy**:** Adults and elderly: The recommended dose is 4 mg zoledronic acid. The concentrate must be further diluted with 100 mL 0.9% w/v sodium chloride or 5% w/v glucose solution and given as an intravenous infusion lasting no less than 15 minutes every 3 to 4 weeks. HCM: Adults and elderly Patients: In hypercalcemia, 4 mg zoledronic acid. The concentrate must be further diluted with 100 mL 0.9% w/v sodium chloride or 5% w/v glucose solution, given as a single intravenous infusion of no less than 15 minutes. Patients must be maintained well hydrated prior to and following administration of zoledronic acid. Retreatment with zoledronic acid 4 mg may be considered if serum calcium does not return to normal or remain normal after initial treatment. Renal impairment: Zoledronic acid treatment in patients with HCM and who have severe renal impairment should be considered only after evaluating the risks and benefits of treatment. MM and Bone metastases from solid tumors, in conjunction with standard therapy: Dose of zoledronic acid is calculated based on the creatinine clearance. **Contraindications**: Zoledronic acid concentrate is contraindicated, in breast-feeding women, patients with clinically significant hypersensitivity to zoledronic acid or other bisphosphonates or any of the excipients in the formulation of zoledronic acid**. Warnings and Precautions:** Pediatric use: The safety and efficacy have not been established in pediatrics. Renal Insufficiency: Patients with HCM with evidence of deterioration in renal function should be appropriately evaluated with consideration given as to whether the potential benefit of continued treatment with zoledronic acid outweighs the possible risk. Asthma: There have been reports of bronchoconstriction in aspirin sensitive patients receiving bisphosphonates. Hypocalcaemia: Hypocalcaemia has been reported in patients treated with zoledronic acid. Cardiac arrhythmias and neurologic adverse events (seizures, tetany and numbness) have been reported secondary to cases of severe hypocalcaemia. Hepatic insufficiency: As only limited clinical data are available in patients with severe hepatic insufficiency, no specific recommendations can be given for this patient population. **Adverse reactions:** Anemia, thrombocytopenia, leukopenia, pancytopenia, hypersensitivity reaction, angioneurotic edema, anxiety, sleep disturbance, confusion, headache, dizziness, paresthesia, dysgeusia, hypoesthesia, hyperesthesia, tremor, somnolence. **Overdosage:** Clinical experience with acute overdosage of zoledronic acid is limited. Patients who have received doses higher than those recommended should be carefully monitored, since renal function impairment (including renal failure) and serum electrolyte (including calcium, phosphorus and magnesium) abnormalities have been observed. In the event of hypocalcemia, calcium gluconate infusions should be administered as clinically indicated**. Special population:** Pregnancy: There are no adequate data on the use of zoledronic acid in pregnant women. Women of child-bearing potential should be advised to avoid becoming pregnant. Lactation: It is not known whether zoledronic acid is excreted into human milk. Zoledronic acid should not be used by breast-feeding women. **Storage:** Store below 30°C.

Dated: 06th September 2017

For more details and information, please refer the pack insert or full prescribing information.