

## ZORRENT 4

### For the use of Oncologist or a Hospital or a Laboratory only

Abbreviated Prescribing information for Zorrent 4 (Zoledronic Acid Injection I.P. Lyophilized) [Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

**PHARMACOLOGICAL PROPERTIES:** Zoledronic acid belongs to the class of bisphosphonates and acts primarily on bone by inhibition of bone resorption.

**INDICATION:** It is indicated for prevention of skeletal-related events like pathological fracture, spinal cord compression, radiation to bone or surgery to bone in patients with advanced malignancies involving bone and in treatment of tumour-induced hypercalcaemia.

**DOSAGE AND ADMINISTRATION:** Zorrent 4 should be reconstitute to 5 ml by adding Sterile Water for injections I.P. and use immediately after preparation. The recommended dose for adults and elderly patients in the prevention of skeletal related events in patients with advanced malignancies involving bone is 4 mg zoledronic acid. It should be given in 15-minute intravenous infusion every 3 to 4 weeks. *For treatment of tumour-induced hypercalcaemia:* The recommended dose for adults and elderly patients in hypercalcaemia is 4 mg zoledronic acid.

**CONTRAINDICATION:** Hypersensitivity reactions including rare cases of urticaria and angioedema, and very rare cases of anaphylactic reaction/shock have been reported with Zorrent 4.

**WARNINGS & PRECAUTIONS:** Patients with hypercalcemia of malignancy must be adequately rehydrated prior to administration of Zoledronic Acid. It should be used with caution with other nephrotoxic drugs. Zoledronic acid is excreted intact primarily via the kidney. In a view of limited data available of renal impaired patients, caution should be exercised. Cancer patients should maintain good oral hygiene and should have a dental examination with preventive dentistry prior to treatment with bisphosphonates. It occurrence of bronchoconstriction in aspirin sensitive patients receiving bisphosphonates have been reported.

**DRUG INTERACTIONS:** Aminoglycosides may cause an additive effect resulting in a lower serum calcium level for prolonged periods. Zoledronic acid with loop diuretics may increase the risk of hypocalcaemia.

**ADVERSE REACTIONS:** Osteonecrosis of the jaw, incapacitating bone, joint and/or muscle pain, atypical sub-trochanteric and diaphyseal femoral fractures, hypocalcemia, anaemia, headache, anxiety, conjunctivitis, nausea, vomiting, anorexia, bone pain, myalgia, arthralgia, generalised pain, skeletal pain, renal impairment, uveitis, scleritis, episcleritis, iritis, and orbital inflammation including orbital edema, fever, flu-like syndrome and hypophosphataemia.

### MARKETED BY:



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(Additional information is available on request)