Zoltero®

Zoledronic acid INN 5 mg infusion

Description: Zoltero® solution for infusion: One bottle with 100 ml solution contains Zoledronic acid INN 5 mg.

Indication and Usage: Zoltero® is indicated for the treatment of osteoporosis in postmenopausal women to reduce the incidence of hip, vertebral and non-vertebral fractures; prevention of clinical fractures after a hip fracture; treatment and prevention of glucocorticoid-induced osteoporosis; treatment of osteoporosis in men and for the treatment of paget's disease of bone. Treatment should be restricted to three annual doses.

Dosage and Administration: Treatment of postmenopausal osteoporosis: Recommended dose is a single intravenous infusion of 5 mg Zoltero® administered once a year. Adequate supplemental Calcium and Vitamin-D intake is important in women with osteoporosis if dietary intake is inadequate. Prevention of clinical fractures after a hip fracture: Recommended dose is a single intravenous infusion of 5 mg Zoltero® administered once a year. In patients with a recent low-trauma hip fracture, it is recommended to give the first Zoltero® solution for infusion two or more weeks after hip fracture repairs. It is also recommended to have a loading dose of 50,000 to 125,000 IU of Vitamin-D given orally or via intramuscular route prior to the first administration of Zoltero® solution for infusion. Supplemental Calcium and Vitamin-D intake is recommended for patients treated to prevent clinical fractures after a hip fracture. Treatment of osteoporosis in men: Recommended dose is a single intravenous infusion of 5 mg Zoltero® administered once a year. Adequate supplemental Calcium and Vitamin-D intake is important in men with osteoporosis if dietary intake is inadequate. Treatment and prevention of glucocorticoid-induced osteoporosis: Recommended dose is a single intravenous infusion of 5 mg Zoltero® administered once a year. Adequate supplemental Calcium and Vitamin-D intake is important in patients with osteoporosis if dietary intake is inadequate. Treatment of paget's disease of bone: Recommended dose is a single intravenous infusion of 5 mg Zoltero®. Re-treatment with Zoltero® may be considered in patients who have relapsed, based on increases in serum alkaline phosphatase, in patients who failed to achieve normalization of serum alkaline phosphatase, or in patients with symptoms, as dictated by medical practice 12 months after the initial dose. In patients with paget's disease, adequate Vitamin-D intake is recommended in association with Zoltero® administration. In addition, it is strongly advised that adequate supplemental Calcium corresponding to at least 500 mg elemental Calcium twice daily is ensured in patients with paget's disease for at least 10 days following Zoltero® administration. Zoltero® should be administered intravenously via a infusion line, given at a constant infusion rate. The infusion time must not be less than 15 minutes. Patients with renal impairment: The use of Zoltero® in patients with creatinine clearance <35 ml/min is not recommended due to limited clinical safety data in such patients. No dose adjustment is necessary in patients with creatinine clearance >35 ml/min.

Patients with Hepatic Impairment: No dose adjustment is required for patients with hepatic impairment. Elderly Patients: No dose adjustment is required. However, because decreased renal function occurs more commonly in the elderly, special care should be taken to monitor renal function. Zoltero® must not be mixed or given intravenously with any other medication and must be given through a separate infusion line at a constant infusion rate. If refrigerated, allow the refrigerated solution to reach room temperature before administration. Aseptic techniques must be followed during the preparation of the infusion. Any unused solution should be discarded. Only clear solution free from particles and discoloration should be used. After opening, the solution is chemically and physically stable for at least 24 hours at 2°C to 8°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C. Zoltero® solution for infusion must not be allowed to come into contact with any Calcium or other divalent cation-containing solutions. The dose of 5 mg Zoledronic acid must be administered over at least 15 minutes.

Precautions: Patients must be appropriately hydrated prior to administration of Zoltero®. This is especially important in the elderly and for patients receiving diuretic therapy. Adequate hydration can be achieved by the patient drinking two glasses of fluid (such as water) before and after the infusion. Pre-existing hypocalcaemia must be treated by adequate intake of Calcium and Vitamin-D before initiating therapy with Zoltero®. Other disturbances of mineral metabolism must also be effectively treated (e.g. diminished parathyroid reserve, thyroid surgery, parathyroid surgery, intestinal Calcium malabsorption). Physicians should consider clinical monitoring for these patients.

Contraindications: The drug is contraindicated if patients have hypersensitivity to the active substance or to any of the excipients or to any bisphosphonates, hypocalcaemia, renal impairment (creatinine clearance <35 ml/min), current or recent uveitis, or a history of bisphosphonate-associated uveitis, pregnancy and lactation.

Adverse Effects: The post-dose side-effects are fever, myalgia, flu-like symptoms, arthralgia and headache, the majority of which occur within the first 3 days following Zoltero® administration. The majority of these symptoms were mild to moderate in nature and resolved within 3 days of the event onset. The incidence of these symptoms occurring within the first 3 days after administration of Zoltero®, can be reduced with the administration of Paracetamol or Ibuprofen shortly following Zoltero® administration. Severe and occasionally incapacitating bone, joint, and/or muscle pain have been infrequently reported in patients taking Zoltero®.

Use in Pregnancy and Lactation: Zoltero® is contraindicated during pregnancy and in breast-feeding women. It is also not recommended for use in children and adolescents below 18 years of age.

Drug Interaction: Specific drug-drug interaction studies have not been conducted with Zoledronic acid. Zoledronic acid is eliminated by renal excretion. Caution is indicated when Zoltero® is administered in conjunction with drugs

that can significantly impact renal function (e.g. aminoglycosides or diuretics that may cause dehydration).

Pharmaceutical Precaution: Zoltero® must be kept out of the reach and sight of children. Protect from light.

Commercial Pack: Zoltero® Solution for IV Infusion: Each pack contains a single 100 ml COC (Cyclo Olefinic Co-Polymer) vial containing Zoledronic acid INN 5 mg.

Manufactured by
BEXIMCO PHARMACEUTICALS LTD.
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