Clastoz® 5
Zoledronic Acid
Solution for Intravenous Infusion, 5 mg/100 mL

One Year of **Steel** Bones

Dosage Form and Strength:

Clastoz® 5 mg/100 mL solution for infusion.

Mechanism of Action:

Clastoz® (zoledronic acid) is a bisphosphonate which inhibits bone resorption via actions on osteoclasts or on osteoclast precursors; it inhibits osteoclastic activity and skeletal calcium release induced by tumors, decreases serum calcium and phosphorus, and increases their elimination. In osteoporosis, zoledronic acid inhibits osteoclast-mediated resorption, therefore reducing bone turnover.

Indications:

Glucocorticoid-induced osteoporosis: Treatment and prevention of glucocorticoid-induced osteoporosis in men and women with low BMD (-2.5 <T-scores<-1) who are expected to receive systemic glucocorticoid therapy for at least 3 months at a daily prednisone dose of ≥7.5 mg (or its equivalent) or in any patient whose baseline risk of fracture is high and is receiving a glucocorticoid at any dose or duration.

Osteoporosis in men: To increase bone mass in men with osteoporosis.

Osteoporosis in postmenopausal women: Treatment and prevention of osteoporosis in postmenopausal women.

Osteoporosis in pediatrics: Primary or secondary

Paget disease of bone: Treatment of Paget disease of bone.

Dosage and administration:

Osteoporosis, glucocorticoid-induced, treatment and prevention: Females or males: IV: 5mg once a year.

Osteoporosis, prevention: Postmenopausal females: IV: 5 mg once every 2 years or 5 mg as a single (one-time) dose.

Osteoporosis, treatment: Males or postmenopausal females: IV: 5 mg once a year.

Osteoporosis, pediatric:

• Children <2 years: First dose: IV: 0.0125 mg/kg/dose. Maintenance (3 months after first dose): IV: 0.025 mg/kg/dose every 3 months.

• Children ≥2 years and Adolescents: First dose: IV: 0.0125 mg/kg/dose. Second dose (3 months after first dose): IV: 0.025 mg/kg/dose. Maintenance (6 months after first dose): IV: 0.05 mg/kg/dose every 6 months; maximum dose: 4 mg/dose.

Paget disease: IV: 5 mg as a single dose.

Administration:

IV, Infuse over at least 15 minutes in adults and over 30 minutes in children. Flush IV line with 10 mL NS flush following infusion. Infuse in a line separate from other medications. Patients must be appropriately hydrated prior to treatment. Acetaminophen after administration may reduce the incidence of acute reaction (eg, arthralgia, fever, flu-like symptoms, and myalgia).

Adverse Reactions

>10%:

Cardiovascular: Hypertension (5% to 13%)

Nervous system: Pain (2% to 24%), headache (4% to 20%), chills (2% to 18%), fatigue (2% to 18%)

Endocrine & metabolic: Hypocalcemia (Osteoporosis: <1%; Paget disease: 3% to 21%)

Gastrointestinal: Nausea (12% to 18%)

Neuromuscular & skeletal: Arthralgia (9% to 27%), myalgia (5% to 23%), back pain (4% to 18%), limb pain (3% to 16%), musculoskeletal pain (3% to 12%)

Respiratory: Flu-like symptoms (≤11%)

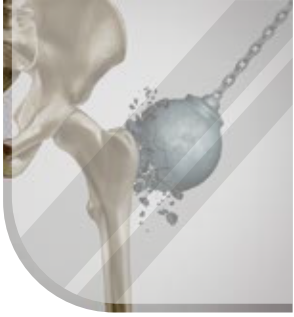
Hypersensitivity: Acute phase reaction-like symptoms (4% to 25%)

Miscellaneous: Fever (9% to 22%)

1% to 10%:

Cardiovascular: Chest pain (1% to 8%), peripheral edema (3% to 6%), atrial fibrillation (≤3%), palpitations (≤3%)

Nervous system: Dizziness (6% to 9%), rigors (8%), malaise (1% to 7%), hypoesthesia (≤6%), lethargy (3% to 5%), paresthesia (2%), hyperthermia (≤2%), flank pain (≤2%)



Endocrine & metabolic: Dehydration (3%)
Dermatologic: Skin rash (2% to 3%), hyperhidrosis (≤3%)
Gastrointestinal: Abdominal pain (≤9%), diarrhea (6%), vomiting (2% to 8%), constipation (6% to 7%), dyspepsia (5% to 7%), abdominal distension (≤2%), abdominal distress (1% to 2%), anorexia (≤2%)
Hematologic & oncologic: Change in serum protein (C-reactive protein increased; ≤5%)
Neuromuscular & skeletal: Ostealgia (3% to 9%), arthritis (2% to 4%), neck pain (7%), shoulder pain (≤7%), muscle spasm (4% to 6%), stiffness (1% to 5%), jaw pain (2% to 4%), joint swelling (≤3%), osteoarthritis (6%), asthenia (2% to 6%)
Ophthalmic: Eye pain (≤2%), iritis (1%), uveitis (1%)
Renal: Increased serum creatinine (2%)
Respiratory: Dyspnea (5% to 7%)
Infection: Influenza (7%)
Local: Injection site reaction (3%)

Use in Pregnancy and Lactation:

Pregnancy: It is not known if bisphosphonates cross the placenta, but fetal exposure is expected. Bisphosphonates are incorporated into the bone matrix and gradually released over time. The amount available in the systemic circulation varies by dose and duration of therapy.

Theoretically, there may be a risk of fetal harm when pregnancy follows the completion of therapy; however, available data have not shown that exposure to bisphosphonates during pregnancy significantly increases the risk of adverse fetal events. Because hypocalcemia has been described following in utero bisphosphonate exposure, exposed infants should be monitored for hypocalcemia after birth.

Lactation: It is not known if zoledronic acid is present in breast milk. According to the manufacturer, the decision to breastfeed during therapy should consider the risk of infant exposure, the benefits of breastfeeding to the infant, and the benefits of treatment to the mother.

Contraindications:

US labeling:

Hypersensitivity to zoledronic acid or any component of the formulation; hypocalcemia; CrCl <35 mL/minute and in those with evidence of acute renal impairment.

Canadian labeling:

Additional contraindications: pregnancy, breast-feeding

Precautions/Warnings:

Concerns related to adverse effects: Bone fractures, hypersensitivity reactions, hypocalcemia, influenza-like illness, musculoskeletal pain, ocular effects, osteonecrosis of the jaw.

Storage and Handling:

Clastoz® 5 mg/100 mL solution for infusion, is supplied in single use bottles as a sterile, pyrogen-free, clear and colorless aqueous solution. Store between 15°C to 30°C (59°F-86°F). Protect from light. Retain in carton until time of use. After opening, it should be used promptly in order to avoid microbial contamination.

Reference: UpToDate Monograph [January 2023]

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Sky's the Limit

NANOALVAND

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