Reclast® (zoledronic acid) injection
5 mg/100 mL for infusion

Long-Term Care (LTC) Patient Selection and Administration Guide

Significant and sustained relative risk reduction at 3 years

- **70%**
  (ARR 7.6%) in vertebral fracture
- **41%**
  (ARR 11.1%) in hip fracture
- **25%**
  (ARR 2.7%) in nonvertebral fracture, a composite endpoint excluding fingers, toes, facial, and clinical thoracic and lumbar vertebral fractures

With annual dosing, BMD increased over 3 years:
- 6.7% at lumbar spine (P<0.001)
- 6.0% at hip (P<0.001)
- 5.1% at femoral neck (P<0.001)

ARR=Absolute Risk Reduction. BMD=Bone Mineral Density.

Reclast is indicated for treatment and prevention of osteoporosis in postmenopausal women. In patients with a recent low-trauma hip fracture, Reclast reduces the incidence of new clinical fractures. Reclast is indicated for treatment to increase bone mass in men with osteoporosis. Reclast is indicated for the treatment and prevention of glucocorticoid-induced osteoporosis in patients expected to be on glucocorticoid therapy for at least twelve months.

Important Safety Information
Reclast is contraindicated in patients with hypocalcemia or hypersensitivity to any component of this product. Reclast contains the same active ingredient found in Zometa® (zoledronic acid) Injection and patients receiving Zometa should not receive Reclast.

Please see accompanying full Prescribing Information.
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**Contraindications**

- Hypocalcemia
- Hypersensitivity to any component of Reclast
- Severe renal impairment (creatinine clearance <35 mL/min)

**Warnings**

- Use during pregnancy: Avoid if possible because of potential harm to the fetus.
- Osteonecrosis of the jaw has been reported rarely in postmenopausal osteoporosis patients treated with bisphosphonates. A routine oral exam should be performed by the prescriber prior to treatment. Consider patients with risk factors for osteoporotic fracture; ie, patients with any of the following:
  - A T-score of ≤−2.5 or lower
  - A prior hip fracture or vertebral fracture (clinical fracture confirmed by x-ray or MRI)
  - Low bone mass and 10-year probability of a hip fracture (≥2%) or a 10-year probability of a significant osteoporosis-related fracture (>20%)

**Precautions**

- Monitor serum creatinine before each dose and consider interim monitoring for at-risk patients.
- Use a separate vented infusion line.
- Do not allow solution to come in contact with any calcium or other divalent cation-containing solutions.
- Consider postmenopausal women, men with low bone mass, and men or women with glucocorticoid-induced osteoporosis.
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**Adverse Reactions**

- Among patients treated with bisphosphonates, there have been infrequent reports of severe and occasionally incapacitating bone, joint, and/or muscle pain. The most common side effects (>10%) were pyrexia, myalgia, headache, arthralgia and pain in extremity. Other clinically important adverse reactions were flu-like illness, nausea, vomiting, diarrhea, and eye inflammation.

**Administration**

- Administer Reclast (5 mg in a 100-mL ready-to-infuse solution) over no less than 15 minutes at a constant infusion rate.
- Confirm that patient does not have hypersensitivity to zoledronic acid or any components of Reclast.
- Confirm that patient does not have bone pain.
- Confirm that patient does not have severe renal impairment (creatinine clearance <35 mL/min).
- Confirm that serum calcium levels are within normal range to ensure that the patient does not have hypocalcemia.
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**Drug Interactions**

- X-ray, MRI, CT, PET, and bone densitometry cannot be performed in patients on bisphosphonates.
- Peak serum calcium occurs at 5 to 15 minutes after infusion.
- Biopsy or other bone destructive procedures should be performed prior to starting treatment.

**Patient Instructions**

- Do not discontinue Reclast for bone pain.
- Check bone pain before each dose.
- Consider interim monitoring for at-risk patients.
- Consider postmenopausal women, men with low bone mass, and men or women with glucocorticoid-induced osteoporosis.
- Consider patients with risk factors for osteoporotic fracture, ie, patients with any of the following:
  - A T-score of ≤−2.5 or lower
  - A prior hip fracture or vertebral fracture (clinical fracture confirmed by x-ray or MRI)

**Pharmacokinetics**

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RELY ON RECLAST

PRESCRIBE RECLAST INSTEAD OF ACTONEL OR BONIVA FOR YOUR POSTMENOPAUSAL OSTEOPOROSIS PATIENTS

- Guaranteed yearlong bisphosphonate compliance in a single dose
- The only bisphosphonate FDA approved to reduce risk at 3 key sites of fracture in postmenopausal osteoporosis
- The most common adverse events—transient postinfusion symptoms—can be reduced with acetaminophen
- No increased incidence of osteonecrosis of the jaw vs placebo in clinical trials
- Will not irritate the upper GI tract, a common concern with oral bisphosphonates
- No requirements to fast or remain upright
- Osteoporosis patients can get a single bisphosphonate treatment that lasts for a full year

Osteoporosis patients require an average of 1200 mg calcium and 800-1000 IU vitamin D daily.

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