Proven protection of annual reinfusion in postmenopausal osteoporosis (PMO)

Annual reinfusion data from the **HORIZON Pivotal Fracture Trial (PFT)** have shown that Reclast® (zoledronic acid) Injection (5 mg/100 mL for infusion) offers consistent vertebral fracture reduction for 3 years.[1,2]

Annual reinfusion data from the HORIZON PFT trial confirm:

➢ **Consistent vertebral fracture reduction with Reclast for 3 years**[1,2]

➢ **Safety profile of Reclast for long-term use**[1-3]

Scroll below for more details.

Reclast offers consistent vertebral fracture reduction for 3 years[1,2]

Study design: The HORIZON PFT was a 3-year, multinational, randomized, double-blind, placebo-controlled study of 7736 postmenopausal women with osteoporosis 65 to 89 years of age from 240 clinical centers in 27 countries. Women received a 15-minute infusion of Reclast or placebo once a year for 3 years. All women received 1000 mg to 1500 mg elemental calcium plus 400 IU to 1200 IU vitamin D supplementation per day.[1-3]

In the same study, Reclast increased patients' BMD over 3 years versus placebo[2]:

- **6.7% increase at lumbar spine in 3 years (*P*<.001)**
- **6.0% increase at hip in 3 years (*P*<.001)**
- **5.1% increase at femoral neck in 3 years (*P*<.001)**

Important Safety Information
Reclast is contraindicated in patients with hypocalcemia, creatinine clearance <35 mL/min, evidence of acute renal impairment, 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.

Click here to view additional Important Safety Information for Reclast.

The incidence of post-treatment symptoms declines markedly after the first Reclast treatment[1,3]:

RECLAST SmartSite—RECLAST information and other resources for healthcare professionals:

— To view the SmartSite on your desktop, please click here.
— To view the SmartSite on your mobile desktop, please click here.

Results from the HORIZON Extension Trial confirm safety profile during long-term use[4]—Reclast has a proven long-term safety profile[4]

Overall incidence of AEs was similar in patients receiving 6 years of Reclast therapy compared with those who received 3 years of Reclast followed by 3 years of placebo

- No long-term effect on renal function was observed with Reclast versus placebo

- No difference in osteonecrosis of the jaw (ONJ) events was observed with Reclast versus placebo after 6 years

Common adverse events

- In the HORIZON PFT, the majority of adverse events occurred within 3 days of infusion[1-3]

— Most resolved within 3 days of onset; others may last up to 14 days

- Post-treatment symptoms can be reduced with acetaminophen taken for up to 3 days following infusion[1-3,5]

- Patients previously treated with bisphosphonate therapy experienced a lower incidence of post-treatment symptoms compared with treatment-naïve patients[6]

Prescribing considerations

- The infusion time must not be less than 15 minutes given over a constant infusion rate, using a separate vented line[1]

- The infusion should be followed by a 10 mL normal saline flush

- Confirm creatinine clearance ≥35 mL/min; monitor serum creatinine before each dose[1]

- Confirm serum calcium is within normal range[1]

- Patients must be appropriately hydrated prior to administration of Reclast[1]

- Acetaminophen given up to 3 days after Reclast administration may reduce the incidence of post-infusion symptoms[1-3,5]

- Osteoporosis patients require an average of 1200 mg calcium and 800 IU to 1000 IU vitamin D daily[1]

Reinfusion is made easy with the *Reclast & You* program.

For more information about the efficacy and safety profile of Reclast, please click here.

For information on live reimbursement support and additional patient assistance services, **contact your Reclast representative at 1-866-Reclast.**

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.

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Disturbances of mineral metabolism must be treated before starting therapy. Patients must be adequately supplemented with calcium and vitamin D. Patients should be appropriately hydrated prior to infusion. A single dose of Reclast should not exceed 5 mg, and infusion time should be no less than 15 minutes. The IV infusion should be followed by a 10 mL normal saline flush of the intravenous line.

Acute renal impairment has been observed, especially in patients with pre-existing renal compromise, advanced age, concomitant diuretic therapy, or severe dehydration occurring before or after Reclast administration. Rarely, hospitalization and/or dialysis or fatal outcomes have been reported. Monitor serum creatinine before each dose and consider interim monitoring for at-risk patients.

Atypical, low-energy, or low trauma fractures of the femoral shaft have been reported in bisphosphonate treated patients. Any patient with a history of bisphosphonate exposure who presents with thigh or groin pain should be suspected of having an atypical fracture and should be evaluated to rule out an incomplete femur fracture.

Interruption of bisphosphonate therapy should be considered, pending a risk/benefit assessment, on an individual basis.

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.

Reclast should not be used during pregnancy, and women should be advised to avoid becoming pregnant because of potential harm to the fetus.

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. Acetaminophen taken following Reclast administration may reduce these symptoms.

The safety and effectiveness of Reclast for the treatment of osteoporosis is based on clinical data of three years' duration. The optimal duration of use has not been determined. All patients on bisphosphonate therapy should have the need for continued therapy re-evaluated on a periodic basis.

Please see full Prescribing Information.

Zometa is a registered trademark of Novartis Pharmaceuticals Corporation.

REFERENCES

1. Reclast Injection [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2011.

2. Black DM, Delmas PD, Eastell R, et al; for the HORIZON Pivotal Fracture Trial. Once-yearly zoledronic acid for treatment of postmenopausal osteoporosis. *N Engl J Med.* 2007;356:1809-1822.

3. Clinical Study Report ZOL446H2301. Data on file; Novartis Pharmaceuticals Corporation;2006.

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5. Lyles KW, Colón-Emeric CS, Magaziner JS, et al; for the HORIZON Recurrent Fracture Trial. Zoledronic acid and clinical fractures and mortality after hip fracture. *N Engl J Med.* 2007;357:1799-1809.

6. McClung M, Recker R, Miller P, et al. Intravenous zoledronic acid 5 mg in the treatment of postmenopausal women with low bone density previously treated with alendronate. *Bone.* 2007;41:122-128.

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