Generic Name:
Zoledronic acid
Trade Name:
Reclast
Company:
Novartis
Notes:

FDA has updated the labeling for zoledronic acid to better educate health providers about the risk of renal failure with this agent. The revised label states that zoledronic acid is contraindicated in patients with a creatinine clearance < 35 mL/min or in those with evidence of acute renal impairment. In addition, the label recommends that health providers screen patients before administering zoledronic acid to identify at-risk patients and monitor renal function in patients who are receiving the drug. At-risk patients include those with underlying moderate-to-severe renal impairment, use of nephrotoxic or diuretic medications at the same time as zoledronic acid, or severe dehydration occurring before or after zoledronic acid is given.

This labeling change was prompted by new reports of renal adverse events in patients receiving zoledronic acid. In January 2009, a FDA postmarketing safety review identified 5 deaths from acute renal failure, and the Warning and Precautions section of the label was updated in March 2009. An additional 11 cases of fatal acute renal failure and 9 cases of renal injury requiring dialysis after zoledronic acid infusion have been reported to the Agency's Adverse Event Reporting System.

The current changes were only made to the Reclast label and not to the label of zoledronic acid marketed under the trade name Zometa; renal toxicity is already addressed in the Warnings and Precautions section of this medication.

Medication Monitor Categories:
Alerts and Recalls