

SPINE SAFETY CAUTIONARY NOTICE:

Information for Healthcare Professionals:

Reclast (zoledronic acid):

Drug Safety Communication - New Contraindication and Updated Warning on Kidney Impairment

SOURCE: FDA MedWatch

AUDIENCE: Endocrinology, Pharmacy, Patient

ISSUE: FDA notified healthcare professionals and patients of an update to the drug label for Reclast (zoledronic acid) regarding the risk of kidney failure. Cases of acute renal failure requiring dialysis or having a fatal outcome following Reclast use have been reported to FDA. The revised label states that Reclast is contraindicated in patients with creatinine clearance less than 35 mL/min or in patients with evidence of acute renal impairment. The label also recommends that healthcare professionals screen patients prior to administering Reclast in order to identify at-risk patients.

The Reclast Medication Guide for patients is being updated to contain information about the risk of severe kidney problems. In addition, the manufacturer of Reclast will issue a Dear Healthcare Provider letter to inform healthcare professionals about this risk.

BACKGROUND: Risk factors for developing renal failure include underlying moderate to severe renal impairment, use of kidney-damaging (nephrotoxic) or diuretic medications at the same time as Reclast, or severe dehydration occurring before or after Reclast is given. The risk of developing renal failure in patients with underlying renal impairment also increases with age.

These labeling changes are being made to the Reclast label only, although zoledronic acid, also sold as Zometa, is approved for treatment of cancer-related indications. Renal toxicity is already addressed in the Warnings and Precautions section of the Zometa label. Dose reductions for Zometa are provided for patients with renal impairment.

RECOMMENDATIONS: Reclast is contraindicated in patients with creatinine clearance less than 35 mL/min, or in patients with evidence of acute renal impairment. Healthcare professionals should screen patients prior to administering Reclast in order to identify at-risk patients. Healthcare professionals should also monitor renal function in patients who are receiving Reclast.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including links to the Drug Safety Communication, including a Data Summary, and prescribing information, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm270464.htm>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members.

Information from these notices is also archived on the NASS website at

<http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.