

SPINE SAFETY WARNING:

**Information for Healthcare Professionals:  
Zoledronic Acid (Marketed as Reclast®):  
Renal Impairment and Acute Renal Failure**

Reclast® (zoledronic acid) is an FDA-approved bisphosphonate administered as a once-yearly intravenous infusion for the treatment of osteoporosis in postmenopausal women and men, Paget's disease of bone, and prevention and treatment of glucocorticoid-induced osteoporosis in patients expected to be on glucocorticoids for at least 12 months. FDA's Adverse Event Reporting System (AERS) has received 24 cases of renal impairment and some cases of acute renal failure associated with the use of Reclast®. As the label indicates, Reclast® is not recommended for use in patients with severe renal impairment (creatinine clearance  $\leq$  35 mL/min). Physicians should monitor serum creatinine in patients with pre-existing renal compromise or other risk factors, including concomitant nephrotoxic medications or diuretic therapy, or severe dehydration, before and after each infusion. Based on new postmarket reports, the manufacturer has recently updated Warnings and Precautions, Post-Marketing Experience, and Drug Interactions sections of the Reclast® label to include data on acute renal failure.

Read the complete article from the *FDA Drug Safety Newsletter*, at:

<http://www.fda.gov/Drugs/DrugSafety/DrugSafetyNewsletter/ucm167883.htm#ZoledronicAcidMarketedasReclast:RenalImpairmentandAcuteLiverFailure>.

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.