

SPINE SAFETY CAUTIONARY NOTICE:

**Information for Healthcare Professionals:  
Oral Osteoporosis Drugs (bisphosphonates):  
Drug Communication – Potential Increased Risk of Esophageal Cancer**

*Includes: Fosamax (alendronate), Actonel (risedronate), Boniva (ibandronate), Atelvia (risedronate delayed release), Didronel (etidronate), and Skelid (tiludronate)*

**AUDIENCE:** Geriatrics, Family Practice, Internal Medicine

**ISSUE:** FDA notified healthcare professionals and patients about its ongoing review of data from published studies to evaluate whether use of oral bisphosphonate drugs is associated with an increased risk of cancer of the esophagus. FDA has not concluded that taking an oral bisphosphonate drug increases the risk of esophageal cancer. There are insufficient data to recommend endoscopic screening of asymptomatic patients. FDA will continue to evaluate all available data supporting the safety and effectiveness of bisphosphonate drugs and will update the public when more information becomes available.

**BACKGROUND:** Oral bisphosphonates are commonly used for the prevention and treatment of osteoporosis as well as to treat other bone diseases such as Paget's disease. There have been conflicting findings from studies evaluating the risk of esophageal cancer. Esophagitis and other esophageal events have been reported, particularly in patients who do not follow the specific directions for use of oral bisphosphonates. See the Data Summary in the Drug Safety Communication for additional details.

**RECOMMENDATION:** Patients should talk with their healthcare professional about the benefits and risks of taking oral bisphosphonates and how long they should expect to take them. Patients should talk with their healthcare professional if they develop swallowing difficulties, chest pain, new or worsening heartburn, or have trouble or pain when swallowing. Patients should be instructed to carefully follow the directions for use of the oral bisphosphonate drug they are prescribed.

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](http://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 a link to the FDA Drug Safety Communication, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicinalProducts/ucm264087.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.