

SPINE SAFETY CAUTIONARY NOTICE:

Information for Healthcare Professionals: Drug Safety Labeling Changes - Boniva (ibandronate sodium) tablets

According to MedWatch, FDA notified healthcare professionals that the CONTRAINDICATIONS and WARNINGS AND PRECAUTIONS text for Boniva have been updated. The following sentences have been added to the labeling:

CONTRAINDICATIONS

- Abnormalities of the esophagus which delay esophageal emptying such as stricture or achalasia.

WARNINGS AND PRECAUTIONS

Upper Gastrointestinal Adverse Reactions

- Boniva, like other bisphosphonates administered orally, may cause local irritation of the upper gastrointestinal mucosa. Because of these possible irritant effects and a potential for worsening of the underlying disease, caution should be used when BONIVA is given to patients with active upper gastrointestinal problems (such as known Barrett's esophagus, dysphagia, other esophageal diseases, gastritis duodenitis or ulcers).
- Esophageal adverse experiences, such as esophagitis, esophageal ulcers and esophageal erosions, occasionally with bleeding and rarely followed by esophageal stricture or perforation, have been reported in patients receiving treatment with oral bisphosphonates. In some cases, these have been severe and required hospitalization. Physicians should therefore be alert to any signs or symptoms signaling a possible esophageal reaction and patients should be instructed to discontinue BONIVA and seek medical attention if they develop dysphagia, odynophagia, retrosternal pain or new or worsening heartburn.
- The risk of severe esophageal adverse experiences appears to be greater in patients who lie down after taking oral bisphosphonates and/or who fail to swallow it with the recommended full glass (6-8 oz) of water, and/or who continue to take oral bisphosphonates after developing symptoms suggestive of esophageal irritation. Therefore, it is very important that the full dosing instructions are provided to, and understood by, the patient. In patients who cannot comply with dosing instructions due to mental disability, therapy with BONIVA should be used under appropriate supervision.
- There have been post-marketing reports of gastric and duodenal ulcers with oral bisphosphonate use, some severe and with complications, although no increased risk was observed in controlled clinical trials.

Read the complete summary of MedWatch safety labeling changes at:
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm200255.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.