

SPINE SAFETY CAUTIONARY NOTICE:

**Information for Healthcare Professionals:  
Warfarin Sodium Tablets (Jantoven), 3mg  
Recall - Mislabeled Bottles Containing Higher Dosage**

**SOURCE:** FDA MedWatch

**AUDIENCE:** Pharmacy, Family Practice, Consumer

**ISSUE:** Upsher-Smith Laboratories and FDA notified healthcare professionals of the recall of one lot of Jantoven Warfarin Sodium, USP, 3mg Tablets, an anticoagulant, after a single bottle labeled as Jantoven Warfarin Sodium, USP, 3mg Tablets was found to contain tablets at a higher 10mg strength. To date, the company has identified no additional mislabeled bottles.

**BACKGROUND:** The recalled lot is numbered as #284081, with an expiration date of September 2012. The product lot was distributed to wholesalers, retail chains and independent pharmacies throughout the United States. The primary risk of substituting 10mg warfarin for 3mg warfarin is overdosing more than 3 times the labeled amount which leads to excessive anticoagulation that could be expected to result in life-threatening hemorrhage in patients.

**RECOMMENDATION:** The two Jantoven tablets (see photo at link below) can be readily identified by color: the 3mg tablet is tan and the 10mg tablet is white. In addition, the 3mg tablet is imprinted with the letters WRF, a line, and the number 3 below the line. The reverse side of the 3mg tablet carries the number 832. The 10mg tablet is imprinted with the letters WRF, a line, and the number 10 below the line. The reverse side of the 10mg tablet carries the number 832. Consumers and pharmacists can call the Upsher-Smith medical information line at 1-888-650-3789 for more information and to access product details, Monday-Friday between 8:00 a.m. and 5:00 p.m. (CST).

Healthcare professionals and patients are encouraged to report adverse events, side effects, or product quality problems 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 links to the company press release and product photos, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm243850.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.