

SPINE SAFETY CAUTIONARY NOTICE:

**Information for Healthcare Professionals:
Expansion of Voluntary Nationwide Recall –
Affected Products Include Amantadine, Amlodipine, Androxy, Baclofen, Bethanechol,
Jantoven® and Oxybutynin**

SOURCE: FDA MedWatch

AUDIENCE: Pharmacy, Family Practice, Consumer

ISSUE: Upsher-Smith Laboratories, Inc., of Maple Grove, Minnesota is voluntarily expanding its previously announced recall of Jantoven® Warfarin Sodium, USP, 3 mg Tablets to include additional products that were packaged on the same packaging line between May 17, 2010 and November 17, 2010. The company is initiating the recall as a precautionary measure after a bottle labeled as Jantoven® Warfarin Sodium, USP, 3 mg Tablets was found by a retail pharmacy to contain tablets at a higher, 10 mg strength.

The list of products included in this expanded recall is available at:

<http://www.fda.gov/Safety/Recalls/ucm244111.htm>

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
- [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/SafetyAlertsforHumanMedicinalProducts/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.