

Information for Healthcare Professionals:

Coumadin® Tablets (warfarin sodium tablets, USP) Crystalline

Coumadin® for Injection (warfarin sodium for injection, USP)

Important revisions to the BOXED WARNING section of Prescribing Information

According to MedWatch, FDA and Bristol-Myers Squibb notified pharmacists and physicians of revisions to the labeling for Coumadin®, to include a new patient Medication Guide as well as a reorganization and highlighting of the current safety information to better inform providers and patients. The new BOXED WARNING section highlights that warfarin sodium can cause major or fatal bleeding. Bleeding is more likely to occur during the starting period and with a higher dose (resulting in a higher INR). Risk factors for bleeding include high intensity of anticoagulation (INR >4.0), age ≥65, highly variable INRs, history of gastrointestinal bleeding, hypertension, cerebrovascular disease, serious heart disease, anemia, malignancy, trauma, renal insufficiency, concomitant drugs, and long duration of warfarin therapy. Regular monitoring of INR should be performed on all treated patients. Those at high risk of bleeding may benefit from more frequent INR monitoring, careful dose adjustment to desired INR, and a shorter duration of therapy. Patients should be instructed about prevention measures to minimize risk of bleeding and to report immediately to physicians any signs and symptoms of bleeding.

The complete MedWatch Safety Labeling Changes, including links to prescribing information and the new medication guide for Coumadin®, are available at:

<http://www.fda.gov/medwatch/SAFETY/2006/oct06.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 Web site at http://www.spine.org/spine_safety_notices.cfm. This information is provided as a service for information and education only.