

SPINE SAFETY CAUTIONARY NOTICE:

**Information for Healthcare Professionals:  
Drug Safety Labeling Changes -  
Coumadin (warfarin sodium) tablets and injection**

According to MedWatch, FDA notified healthcare professionals that the DOSAGE AND ADMINISTRATION text for Coumadin have been updated. The following sentences have been added to the labeling:

## **DOSAGE AND ADMINISTRATION**

### ***Initial Dosage***

The dose of Coumadin must be individualized by monitoring the PT/INR. Not all factors causing warfarin dose variability are known. The maintenance dose needed to achieve a target PT/INR is influenced by:

- Clinical factors including age, race, body weight, sex, concomitant medications, and comorbidities and
- Genetic factors (CYP2C9 and VKORC1 genotypes).
- Select the starting dose based on the expected maintenance dose, taking into account the above factors. Routine use of loading doses is not recommended as this may increase hemorrhagic and other complications and does not offer more rapid protection against clot formation...
- The patient's CYP2C9 and VKORC1 genotype information, when available, can assist in selection of the starting dose...
- Table 5: Range of Expected Therapeutic Warfarin Doses Based on CYP2C9 and VKORC1 Genotypes (new table)

Read the complete summary of MedWatch safety labeling changes at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm201100.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>.

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