

SPINE SAFETY CAUTIONARY NOTICE:

**Information for Healthcare Professionals:
Promethazine Hydrochloride Injection -
Boxed Warning Describing Severe Tissue Injury, Including Gangrene,
After IV Administration of Drug**

According to MedWatch, FDA notified healthcare professionals that a Boxed Warning is being added to the prescribing information for Promethazine Hydrochloride products, describing the risks of severe tissue injury, including gangrene, requiring amputation following intravenous administration of promethazine. The Boxed Warning will remind practitioners that due to the risks of intravenous injection, the preferred route of administration is deep intramuscular injection and that subcutaneous injection is contraindicated.

Perivascular extravasation, unintentional intra-arterial injection and intraneuronal or perineuronal infiltration of the drug may result in irritation and tissue damage. Healthcare professionals should be alert for signs and symptoms of potential tissue injury including burning or pain at the site of injection, phlebitis, swelling, and blistering.

Read the complete MedWatch 2009 Safety summary including links to the Information for Healthcare Professionals sheet and News Release, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicinalProducts/ucm182500.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.