

## SPINE SAFETY CAUTIONARY NOTICE:

### Information for Healthcare Professionals:

#### Drug Safety Labeling Changes -

#### Tramadol hydrochloride tablets:

- Ultracet (tramadol HCl/acetaminophen) tablets
- Ultram (tramadol hydrochloride) tablets

According to MedWatch, FDA notified healthcare professionals that WARNINGS and PRECAUTIONS text for Ultracet and Ultram have been updated to address serotonin syndrome risk. The revised WARNINGS and PRECAUTIONS indicate the following:

### WARNINGS

#### *Serotonin Syndrome Risk*

- The development of a potentially life-threatening serotonin syndrome may occur with the use of tramadol products...

### PRECAUTIONS

#### *Information for Patients*

- Patients should be informed that tramadol may cause seizures and/or serotonin syndrome with concomitant use of serotonergic agents (including SSRIs, SNRIs, and triptans) or drugs that significantly reduce the metabolic clearance of tramadol.

Read the complete summary of MedWatch safety labeling changes at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm186456.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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