

## SPINE SAFETY CAUTIONARY NOTICE:

### **Information for Healthcare Professionals: Cymbalta (duloxetine hydrochloride): Labeling Changes**

According to MedWatch, FDA notified healthcare professionals of labeling changes for Cymbalta (duloxetine hydrochloride). The following has been added to the labeling:

## **WARNINGS and PRECAUTIONS**

### ***Severe Skin Reactions***

- Severe skin reactions, including erythema multiforme and Stevens-Johnson Syndrome (SJS), can occur with Cymbalta. The reporting rate of SJS associated with Cymbalta use exceeds the general population background incidence rate for this serious skin reaction (1 to 2 cases per million person years). The reporting rate is generally accepted to be an underestimate due to underreporting.
- Cymbalta should be discontinued at the first appearance of blisters, peeling rash, mucosal erosions, or any other sign of hypersensitivity if no other etiology can be identified

## **MEDICATION GUIDE**

- add severe skin reactions language

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.