SPINE SAFETY CAUTIONARY NOTICE:

Information for Healthcare Professionals:
Zmax (azithromycin extended release) for oral suspension:
Labeling Changes

According to MedWatch, FDA notified healthcare professionals of labeling changes for Zmax (azithromycin extended release) for oral suspension. The following has been added to the labeling:

CONTRAINDICATIONS

Cholestatic jaundice/hepatic dysfunction

- Zmax is contraindicated in patients with a history of cholestatic jaundice/hepatic dysfunction associated with prior use of azithromycin.

WARNINGS

Hepatotoxicity

- Abnormal liver function, hepatitis, cholestatic jaundice, hepatic necrosis, and hepatic failure have been reported, some of which have resulted in death. Discontinue azithromycin immediately if signs and symptoms of hepatitis occur.

ADVERSE REACTIONS

Postmarketing Experience

- Liver/Biliary: Adverse reactions related to hepatic dysfunction have been reported in postmarketing experience with azithromycin.

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.