

SPINE SAFETY WARNING:

**Information for Healthcare Professionals:
Voltaren Gel (diclofenac sodium topical gel) –
Hepatic Effects Labeling Change: Cases of Drug-Induced Hepatotoxicity Reported**

According to MedWatch, Endo, Novartis and FDA notified healthcare professionals of revisions to the Hepatic Effects section of the Prescribing Information to add new warnings and precautions about the potential for elevation in liver function tests during treatment with all products containing diclofenac sodium.

In postmarketing reports, cases of drug-induced hepatotoxicity have been reported in the first month but can occur at any time during treatment with diclofenac. Postmarketing surveillance has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. Some of these reported cases resulted in fatalities or liver transplantation.

Physicians should measure transaminases periodically in patients receiving long-term therapy with diclofenac. The optimum times for making the first and subsequent transaminase measurement are not known. Based on clinical trial data and postmarketing experiences, transaminases should be monitored within 4 to 8 weeks after initiating treatment with diclofenac.

Read the complete MedWatch 2009 Safety summary, including links to the Dear Healthcare Professional letter and revised Prescribing Information, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicinalProducts/ucm193047.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.