

SPINE SAFETY CAUTIONARY NOTICE:

**Information for Healthcare Professionals:**

**Drug Safety Labeling Changes -**

**Flector Patch (diclofenac epolamine) 1.3% topical patch**

**Voltaren Gel (diclofenac sodium) 1 % topical gel**

According to MedWatch, FDA notified healthcare professionals that WARNINGS text for Flector Patch and Voltaren Gel have been updated to address hepatic effects. The revised WARNING indicates the following:

**WARNINGS**

***Hepatic Effects***

- Elevations of one or more liver tests may occur during therapy with Flector Patch/diclofenac sodium. These...
- In clinical trials, meaningful elevations (i.e., more than 3 times the ULN) of AST (GOT) (ALT was not measured in all studies) occurred in about 2% of approximately 5,700 patients...
- Almost all meaningful elevations in transaminases were detected before patients became symptomatic. Abnormal tests occurred during the first 2 months of therapy with diclofenac...
- In postmarketing reports, cases of drug-induced hepatotoxicity have been reported in the first month, and in some cases, the first 2 months of therapy, but can occur at any time...
- Physicians should measure transaminases periodically in patients receiving long-term therapy with diclofenac, because severe hepatotoxicity may develop without a prodrome of...
- If abnormal liver tests persist or worsen, if clinical signs and/or symptoms consistent with...
- To minimize the potential risk for an adverse liver related event in patients treated with Flector Patch/diclofenac sodium, the lowest effective dose should be used for the shortest duration possible...

Read the complete summary of MedWatch safety labeling changes at:

Flector Patch:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm186427.htm>

Voltaren Gel:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm186449.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.