

SPINE SAFETY CAUTIONARY NOTICE:

**Information for Healthcare Professionals:
Voltaren (diclofenac sodium enteric-coated) Tablets
Voltaren-XR (diclofenac sodium extended release) Tablets
Cataflam (diclofenac potassium immediate-release) Tablets:
Precautions – Labeling Changes**

According to MedWatch, FDA notified healthcare professionals that the PRECAUTIONS and ADVERSE REACTIONS text for Voltaren (diclofenac sodium enteric-coated), Voltaren-XR (diclofenac sodium extended release) and Cataflam (diclofenac potassium immediate-release) Tablets has been updated. The following sentences have been added to the labeling:

PRECAUTIONS

Drug Interactions

- CYP2C9 Inhibitors or Inducers: Diclofenac is metabolized by cytochrome P450 enzymes, predominantly by CYP2C9. Co-administration of diclofenac with CYP2C9 inhibitors (e.g. voriconazole) may enhance the exposure and toxicity of diclofenac whereas co-administration with CYP2C9 inducers (e.g. rifampin) may lead to compromised efficacy of diclofenac. Use caution when dosing diclofenac with CYP2C9 inhibitors or inducers, a dosage adjustment may be warranted

ADVERSE REACTIONS

- Digestive System: ... fulminant hepatitis with and without jaundice, liver necrosis

Read the complete summary of MedWatch safety labeling changes at:

Voltaren: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm247149.htm>

Cataflam: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm247150.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.