FDA Flags Liver Damage Risks With Diclofenac

BY ELIZABETH MECHCATIE

Warnings about the potential risk of hepatotoxicity associated with the use of diclofenac have been added to the labels of all products containing the nonsteroidal anti-inflammatory drug, the Food and Drug Administration announced.

A notice on the FDA's MedWatch site said that the manufacturers—Endo Pharmaceuticals Inc. and Novartis Consumer Health Inc.— had revised the "hepatic effects" section of the diclofenac topical gel label to include new warnings and precautions about the potential for elevated liver function tests during treatment with diclofenac products, including the formulation marketed as Voltaren Gel 1%.

There have been postmarketing reports of severe hepatic reactions including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure in patients treated with diclofenac, according to the FDA. Some cases have been fatal or have resulted in liver transplantation.

Because severe hepatoxicity may be asymptomatic, the FDA and the revised label both recommend that clinicians periodically measure transaminase levels in patients taking diclofenac long term. Levels should be monitored within 4-8 weeks after initiating treatment, according to the FDA notice.

The labeling changes are summarized in a Dear Health Care Professional letter issued by the manufacturers. ■

For more information, call 800-452-0051. The MedWatch notice and letter can be viewed at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm193047.htm.