December 2009: Voltaren Gel And Other Products Containing Diclofenc Sodium Linked To Liver Problems

"Dear Doctor" Letter From Endo And Novartis Offers Information About Prevention And Diagnosis Of Drug-Induced Liver Injury (DILI)

(Posted by Tom Lamb at www.DrugInjuryWatch.com on December 11, 2009; see http://bit.ly/5x4t0P)

On December 4, 2009 the FDA issued this MedWatch alert, "Voltaren Gel (diclofenac sodium topical gel) 1% - Hepatic Effects Labeling Changes", which provided news about an emerging drug safety issue concerning all products containing diclofenac sodium, including Voltaren Gel. From the FDA MedWatch alert, in relevant part:

> 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.

This December 2009 FDA MedWatch alert also provided links to: (1) "Prescribing Information" -- also known as the package insert or label -- for Voltaren Gel; and, (2) a "Dear Healthcare Professional Letter" -- commonly called a "Dear Doctor" letter -- from Endo Pharmaceuticals Inc. and Novartis Consumer Health, Inc., the companies responsible for Voltaren Gel in the U.S.

On December 5, 2009 *Medscape* published an article, "Diclofenac Linked to Liver Failure, Death", about these developments which included a summary of the Voltaren Gel Dear Doctor letter:

> Physicians should discontinue diclofenac treatment immediately if patients continue to have abnormal or worsening liver test results, if liver disease symptoms develop, or if systemic manifestations occur, such as eosinophilia, rash, abdominal pain, diarrhea, or dark urine, according to a letter from Endo and Novartis to healthcare professionals.
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> The companies also recommend that physicians advise their patients receiving diclofenac of the signs and symptoms of hepatotoxicity, including nausea, fatigue, lethargy, diarrhea, pruritus, jaundice, right upper quadrant tenderness, and flulike symptoms, and what to do if these signs and symptoms appear.
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> To reduce the risk for hepatotoxicity in patients receiving diclofenac sodium, the lowest effective dose should be used for the shortest time possible.

To supplement this "Dear Doctor" letter information from Endo and Novartis, for those who are interested in learning more, we offer a relatively recent article from the medical journal *Gut*, "Diagnosis, management and prevention of drug-induced liver injury".

If you are aware of a case of drug-induced liver injury involving any product containing diclofenac sodium, including Voltaren Gel, you are encouraged to report that adverse event to the FDA through its MedWatch program. Your report can be made by the following means:

- by telephone at 1-800-FDA-1088;
- by fax at 1-800-FDA-0178;
- online at http://www.fda.gov/medwatch; or,
- by mail to 5600 Fishers Lane, Rockville, MD 20852-9787.

We will continue to monitor this emerging drug safety issue involving Voltaren Gel and other diclofenac products.

Attorney Tom Lamb represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
http://www.DrugInjuryWatch.com