

[Zithromax Label Adds Warning About Drug-Induced Liver Injury In February 2011](#)

Adverse Reactions And Warnings Sections Now Include Hepatotoxicity, From Hepatic Dysfunction To Liver Failure

(Posted by Tom Lamb at www.DrugInjuryWatch.com on March 3, 2011; see <http://bit.ly/fLoNXu>)

The association between the antibiotic Zithromax (azithromycin) and drug-induced liver failure first received some real attention in 2010.

Here, we wrote a couple of article about this emerging drug-safety issue last year:

>> [Zithromax-Induced Liver Injury Case Report Where There Was No History Of Liver Problems](#) (5/20/10)

>> [Zithromax \(Azithromycin\) And Zmax Associated With Liver Failure And Pyloric Stenosis, Respectively](#) (7/1/10)

On February 1, 2011 the FDA was still evaluating the liver failure side effect "link" for Zithromax to determine whether there was a need for any regulatory action. See: ["Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System \(AERS\) between January – March 2010"](#) (Quarterly Report issued by FDA on or about 2/1/11).

In late February 2011, however, we learned that the FDA had decided the Zithromax package insert, or label, would be changed to include warnings about liver failure and other hepatic / liver side effects.

From the FDA document, ["Zithromax \(azithromycin\) tablet, single-dose packet, IV for injection, and oral suspension -- Detailed View: Safety Labeling Changes Approved By FDA Center for Drug Evaluation and Research \(CDER\)"](#), first posted online February 24, 2011:

CONTRAINDICATIONS

- Zithromax is contraindicated in patients with a history of cholestatic jaundice/hepatic dysfunction associated with prior use of azithromycin.

WARNINGS

Hepatotoxicity

- Abnormal liver function, hepatitis, cholestatic jaundice, hepatic necrosis, and hepatic failure have been reported, some of which have resulted in death. Discontinue azithromycin immediately if signs and symptoms of hepatitis occur.

ADVERSE REACTIONS

Post-Marketing Experience/Biliary

- Adverse reactions related to hepatic dysfunction have been reported in postmarketing experience with azithromycin. (See WARNINGS, Hepatotoxicity.)

We will continue to monitor Zithromax for side effects such as liver failure, hepatic necrosis, hepatitis, and hepatotoxicity.

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>