

Drug Injury Watch: Warnings About Significant Liver Injury Added To Tecfidera Drug Label

(Posted by Tom Lamb at www.DrugInjuryWatch.com on February 7, 2017)

In January 2017 liver injury was added to the Warnings and Precautions part of the Prescribing Information document, or drug label, for Tecfidera (dimethyl fumarate), which was approved by the FDA in 2013 as a treatment of patients with relapsing forms of multiple sclerosis (MS).

We get background information and some commentary from this February 1, 2017 *Medscape Medical News* article, "Dimethyl Fumarate for MS: Liver Injury Warning Strengthened":

The prescribing information for the oral multiple sclerosis (MS) medication dimethyl fumarate (Tecfidera, Biogen) has been updated to include a warning of potential liver injury that could require hospitalization.

The new information notes that clinically significant cases of liver injury have been reported in patients treated with the drug in the postmarketing setting. The onset has ranged from a few days to several months after initiation of treatment....

MS experts contacted by *Medscape Medical News* did not think the labeling change would make much difference to its use.

"The incidence of liver function abnormalities appears to be rare, but the new labeling informs prescribers that monitoring will be necessary," said Edward Fox, MD, MS Clinic of Central Texas, Round Rock. "I would expect that this will lead to more frequent laboratory testing early in the course of treatment, but would be very unlikely to affect prescribing patterns. Personally, it won't change what I have already been doing. Most disease-modifying treatments for MS, including all approved oral therapies, have labeling reflecting a risk of hepatic injury."...

But Mark S. Freedman, MD, Ottawa Hospital, Ontario, Canada, noted that this was another side effect to have shown up with the drug since it reached the market.

"Tecfidera is not the 'honey' it was reported to be from the clinical trials," he commented. "Progressive multifocal leukoencephalopathy and other opportunistic infections (herpes), hepatotoxicity, renal toxicity, and other issues have all surfaced since the trials were reported."

We will continue to monitor the medical literature and adverse event reports for significant cases of liver injury associated with the use of Tecfidera by MS patients.

[\[Read this article in full at original source\]](#)

Earlier articles by attorney Tom Lamb on the [Side Effects Blog](#):

- [Newer Hepatitis C Drugs Harvoni And Sovaldi Could Cause Liver Failure](#)
- [Leukemia Drug Iclusig Had More Safety Warnings Added In November 2016](#)
- [Is The Risk Of Liver Cancer Increased From Use Of Harvoni Or Sovaldi?](#)
- [Invokana Has New Warning About Risk Of Lower Limb Amputation In Canada](#)
- [December 2016: FDA Requires Safety Warnings Label Change For Jardiance](#)

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>