

[Popular Seizure And Bipolar Disorder Medication Lamictal Associated With Aseptic Meningitis In August 2010](#)

FDA Working With GlaxoSmithKline To Update Label, Or Package Insert, And Patient Medication Guide To Warn About This Side Effect

(Posted by Tom Lamb at www.DrugInjuryWatch.com on August 19, 2010; see <http://bit.ly/cEMMDo>)

On August 12, 2010 the FDA announced that Lamictal (lamotrigine), a medication commonly used for seizures in children two years and older as well as for bipolar disorder in adults, can cause aseptic meningitis. Lamictal is also sold as Lamictal ODT (an orally disintegrating tablet), Lamictal CD (a chewable, dispersible tablet), and as Lamictal XR (an extended release product). GlaxoSmithKline -- commonly known as Glaxo and GSK -- is the drug company that manufactures and markets these several Lamictal products.

From the August 2010 ["FDA Drug Safety Communication: Aseptic meningitis associated with use of Lamictal \(lamotrigine\)":](#)

Meningitis is an inflammation of the protective membranes (the meninges) that cover the brain and spinal cord. Aseptic meningitis is generally diagnosed when tests of a patient with signs and symptoms of meningitis do not detect bacteria. Causes of aseptic meningitis include viruses and other non-bacterial infections, toxic agents, some vaccines, malignancy, and certain medications, including Lamictal.

Symptoms of meningitis may include headache, fever, stiff neck, nausea, vomiting, rash, and sensitivity to light. In cases of meningitis, it is important to rapidly diagnose the underlying cause so that treatment can be promptly initiated.

From the related August 12 press release, ["FDA: Aseptic Meningitis Risk with Use of Seizure Drug Lamictal":](#)

"Aseptic meningitis is a rare but serious side effect of Lamictal use," said Russell Katz, M.D., director of the Division of Neurology Products in the FDA's Center for Drug Evaluation and Research. "Patients that experience symptoms should consult their health care professional immediately."

The FDA became aware of the association between Lamictal and aseptic meningitis through routine adverse event monitoring and communications with the drug's manufacturer [GSK]....

The Data Summary section of this August 2010 FDA Drug Safety Communication about Lamictal provides more information about how this link with aseptic meningitis was found:

The decision to revise the Warnings and Precautions section of the Lamictal label and patient Medication Guide is based on FDA's review of adverse event reports submitted to the agency from December 1994 (when the drug was approved) through November 2009. A total of 40 cases of aseptic meningitis occurring in pediatric and adult patients taking Lamictal were identified.

In the 40 cases, headache, fever, nausea, vomiting, nuchal rigidity, rash, photophobia and myalgias were noted. Symptoms occurred 1 to 42 days after starting Lamictal (mean of 16 days). There was one reported death, although the death was not thought to be the result of aseptic meningitis. Thirty-five of the 40 patients required hospitalization. In the majority of cases, symptoms resolved after Lamictal was discontinued. Fifteen cases reported a rapid return of symptoms following re-initiation of Lamictal; symptoms recurred within 30 minutes to 24 hours following re-initiation of Lamictal (mean of 5 hours). In these rechallenge cases, symptoms were frequently more severe after re-exposure.

In addition to the items referenced above, the agency has issued an ["FDA Drug Safety Podcast for Healthcare Professionals: Aseptic meningitis associated with use of Lamictal \(lamotrigine\)"](#), which includes a written transcript.

It remains to be seen whether Glaxo will be sending a so-called "Dear Doctor" letter out to warn about the apparent link between Lamictal and aseptic meningitis.

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.

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