

Lamictal (lamotrigine): Label Change - Risk of Aseptic Meningitis

ISSUE: FDA notified healthcare professionals and patients that Lamictal (lamotrigine), a medication commonly used for seizures in children two years and older, and bipolar disorder in adults, can cause aseptic meningitis. 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.

BACKGROUND: The decision to revise the Lamictal label is based on FDA's identification of 40 cases of aseptic meningitis in patients taking Lamictal (from December 1994 to November 2009). See the Data Summary section of the Drug Safety Communication for additional information.

RECOMMENDATION: Patients should be advised to contact their healthcare professional immediately if they experience signs and symptoms of meningitis while taking Lamictal. If meningitis is suspected, patients should be evaluated for other causes of meningitis and treated as indicated. Discontinuation of Lamictal should be considered if no other clear cause of meningitis is identified.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of this product to the FDA's MedWatch Safety Information and Adverse Event Reporting Program: