

## **FDA Warns of Meningitis Linked to Lamotrigine**

By John Gever, Senior Editor, MedPage Today August 12, 2010

The antiepileptic drug lamotrigine (Lamictal), also approved for maintenance therapy in bipolar disorder, can cause aseptic meningitis, the FDA warned. The agency said it had identified 40 cases in children and adults taking the drug from 1994 to 2009.

It recommended that healthcare professionals consider discontinuing lamotrigine in patients showing signs of meningitis, though patients should first be evaluated for other potential causes.

Symptoms in the 40 cases included headache, fever, nausea, vomiting, nuchal rigidity, rash, photophobia, and myalgias, starting from one to 42 days after initiating lamotrigine therapy (mean 16 days). In 35 cases, the patients had to be hospitalized.

Symptoms resolved in most cases after the drug was stopped. In 15 patients, restarting the drug led to a return of symptoms within one day, the FDA said. A causal mechanism has not been established. Findings in cerebrospinal fluid collected from 25 patients included mild to moderate pleocytosis, normal glucose levels, and mild to moderate increase in protein, according to the FDA.

"In addition, cerebrospinal fluid white blood cell count differentials showed a predominance of neutrophils in a majority of the cases, although a predominance of lymphocytes was reported in approximately one-third of the cases," the agency's announcement said.

Some cases involved patients with autoimmune diseases, notably systemic lupus erythematosus. Also, some patients developed abnormalities in the liver and kidneys, suggesting hypersensitivity or a generalized drug reaction, the FDA indicated.

The agency said it was working with the drug's manufacturer, GlaxoSmithKline, to update the product's label and patient medication guide to include information on the meningitis risk.

The drug is sold in several forms: a conventional oral pill, an orally disintegrating tablet, and a chewable tablet. It also comes in an extended release pill.