Generic Name:
Lamotrigine
Trade Name:
Lamictal
Company:
GlaxoSmithKline
Notes:

FDA warned that use of lamotrigine for seizures and bipolar disorder can cause a rare but very serious reaction that excessively activates the body?s immune system. This can cause severe inflammation throughout the body and lead to hospitalization and death, especially if the reaction is not diagnosed and treated quickly. As a result, FDA is requiring a new warning that this risk be added to the prescribing information in the lamotrigine drug labels.

The immune system reaction, called hemophagocytic lymphohistiocytosis (HLH), typically presents as a persistent fever, usually greater than 101°F. HLH can lead to severe problems with blood cells and organs throughout the body, such as the liver, kidneys, and lungs.

Lamotrigine is used alone or with other medications to treat seizures in patients aged 2 years and older. It may also be used as maintenance treatment in patients with bipolar disorder.

Health professionals should be aware that prompt recognition and early treatment is important for improving HLH outcomes and decreasing mortality. Diagnosis is often complicated, as early signs and symptoms such as fever and rash are not specific.

HLH may also be confused with other serious immune-related adverse reactions. Evaluate patients who develop fever or rash promptly, and discontinue lamotrigine if HLH or another serious immune-related adverse reaction is suspected and an alternative etiology for the signs and symptoms cannot be established.

Since lamotrigine?s 1994 approval, FDA identified eight cases worldwide of confirmed or suspected HLH associated with the medication in children and adults. This number includes only reports submitted to FDA and found in the medical literature, so there are likely additional cases about FDA is unaware, according to the agency. FDA determined there was reasonable evidence that lamotrigine was the cause of HLH in these eight cases based on the timing of events and order in which they occurred. These patients required hospitalization and received drug and other medical treatments, with one dying.

A link to the full communication detailing specific information for health professionals and the complete Data Summary can be found at www.fda.gov/DrugSafetyCommunications.

Medication Monitor Categories:
Alerts and Recalls