

## Lamictal® (lamotrigine) – New Warning

- The [FDA approved](#) an update to the *Warnings and Precautions* section of the [Lamictal \(lamotrigine\)](#) drug label regarding the risk of hemophagocytic lymphohistiocytosis (HLH).
  - The update applies to Lamictal tablets and chewable dispersible tablets, Lamictal ODT orally disintegrating tablets, and Lamictal XR extended-release tablets.
- Lamotrigine is generically available and is an anticonvulsant indicated for the treatment of epilepsy and bipolar disorder. Lamotrigine can be used as monotherapy in adults (aged 16 years and older) or adjunctive therapy to treat epilepsy in patients aged 2 years and older. Lamotrigine is also used as maintenance treatment in patients with bipolar disorder to help delay the occurrence of mood episodes such as depression, mania, or hypomania.
- The immune system reaction HLH has occurred in pediatric and adult patients taking Lamictal for various indications. HLH is a life-threatening syndrome of pathologic immune activation characterized by clinical signs and symptoms of extreme systemic inflammation. It is associated with high mortality rates if not recognized early and treated. HLH symptoms include fever greater than 101 °F, hepatosplenomegaly, rash, lymphadenopathy, neurologic symptoms, cytopenias, high serum ferritin, and liver function and coagulation abnormalities.
  - In reported cases of HLH with Lamictal, patients have presented with signs of systemic inflammation and blood dyscrasias. Symptoms have been reported to occur within 8 to 24 days following the initiation of treatment.
  - Patients who develop early manifestations of pathologic immune activation should be evaluated immediately, and a diagnosis of HLH should be considered. Lamictal should be discontinued if an alternative etiology for the signs or symptoms cannot be established.
  - Patients should not stop taking lamotrigine without first talking to their health care professional. Stopping it suddenly can potentially cause uncontrolled seizures, or new or worsening mental health problems.
- The FDA has been closely monitoring the risk of HLH and [previously communicated](#) this risk before.