

**F. No. 12-03/19-DC (Safety-004)**  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(New Drugs Division)

FDA Bhawan, Kotla Road,  
New Delhi-110002.

Dated 6 DEC 2019

To,

All State/UT Drugs Controllers,

**Sub: Serious immune system reaction with the drug lamotrigine - Reg.**

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Sir,

Lamotrigine is approved by CDSCO and marketed in the country in various dosage forms.

USFDA has released drug safety communication dated 25.04.2018, that the drug lamotrigine for seizures and bipolar disorder can cause a rare but very serious reaction that excessively activates the body's infection-fighting 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 per USFDA, the immune system reaction, called hemophagocytic lymphohistiocytosis (HLH), causes an uncontrolled response by the immune system. HLH typically presents as a persistent fever, usually greater than 101°F. and it can lead to severe problems with blood cells and organs throughout the body such as the liver, kidney, and lungs.

Various lamotrigine formulations are approved and marketed in the country.

The above safety issue on lamotrigine was deliberated in the Subject Expert Committee (Neurology & Psychiatry) meeting held on 27.11.2019.

After detailed deliberation, the committee recommended that the warning of immune system reaction called hemophagocytic lymphohistiocytosis (HLH) should be mentioned in the package insert of the drug lamotrigine marketed in the country.

The recommendation of the SEC has been considered by this office. Accordingly, you are requested to direct the manufacturers of lamotrigine formulations under your jurisdiction to mention the warning of hemophagocytic lymphohistiocytosis (HLH) in the Package insert / Promotional Literature of the drug.

Action taken in this regard may be intimated to this office.

Yours faithfully,



**Dr. V. G. Somani**  
**Drugs Controller General (India)**

1. Copy for information & follow-up: -  
All Zonal / Sub Zonal Offices of CDSCO.
2. Copy for information to: -  
JS(R), Nirman Bhawan, MoHFW, New Delhi-110002.