Indian Health Service
National Pharmacy and Therapeutics Committee

Pharmacovigilance Drug Safety Communication

Lamotrigine (Lamictal®) *and possibly other sodium channel blockers*: Potential increased risk of arrhythmia in people with heart disease

The FDA issued a Drug Safety Communication to inform healthcare providers and patients of increased risks of arrhythmia when lamotrigine (Lamictal®) is used in patients who have heart disease. This risk may exist with other sodium channel blocking medications.

Lamotrigine is approved for the treatment of focal epilepsy, generalized epilepsy, Lennox-Gastaut syndrome, and bipolar disorder. It is theorized to work by blocking sodium channels on the nerve, prolonging the refractory period.

The FDA received reports of abnormal ECG findings and some other serious problems among patients treated with lamotrigine. In vitro studies of lamotrigine show Class 1B antiarrhythmic activity at therapeutically relevant concentrations. In October 2020, the FDA updated the package insert of lamotrigine to include a new warning: "Cardiac rhythm and conduction abnormalities: Avoid LAMICTAL in patients with certain underlying cardiac disorders or arrhythmias."

Other sodium channel blocking medications should not be considered safer alternatives to lamotrigine at this time due to absence of information. The FDA will evaluate the proarrhythmic effect of similar medications and provide additional information as it becomes available. Other sodium channel blocking medications include:

- Carbamazepine (Carbatrol, Carnexiv, Equetro, Tegretol®)
- Cenobamate (X®)
- Elicarbazepine (Aptiom®)
- Fosphenytoin (Cerebyx,Sesquient®)
- Lacosamide (Vimpant®)
- Oxcabazepine (Oxtellar, Trileptal®)
- Phenytoin (Dilantin®)
- Rufinamide (Banzel®)
- Topiramate (Qsymia, Quedexy, Topamax, Trokendi®)
- Zonisamide (Zonegran®)

Recommendations for Patients:

- Do NOT stop taking lamotrigine without first talking to your prescriber. Stopping lamotrigine can lead to uncontrolled seizures or worsening mental health problems.
- Contact a healthcare professional right away if you experience an abnormal heart rate, irregular rhythm, or symptoms such as a racing heartbeat, skipped or slow heartbeat, shortness of breath, dizziness or fainting.

Recommendations for health care professionals:

- Assess the benefits and risks of lamotrigine therapy.
- Avoid in patients with cardiac conduction disorders, ventricular arrhythmias, cardiac disease, or cardiac abnormality.
- Concomitant use of other sodium channel blockers may increase the risk of proarrhythmia.

The complete Drug Safety Communication can be viewed on the FDA website.

To help the FDA track safety issues with lamotrigine, please report adverse events involving this or other medicines to the MedWatch program as recommended in the Indian Health Manual and include "IHS" in the reporter section (section G).

Instructions for reporting can be found at the IHS Pharmacovigilance website.

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