Studies show increased risk of heart rhythm problems with seizure and mental health medicine lamotrigine (Lamictal) in patients with heart disease

FDA now requiring studies to evaluate heart risk across the drug class

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Safety Announcement

A U.S. Food and Drug Administration (FDA) review of study findings showed a potential increased risk of heart rhythm problems, called arrhythmias, in patients with heart disease who are taking the seizure and mental health medicine lamotrigine (Lamictal). We want to evaluate whether other medicines in the same drug class have similar effects on the heart and are requiring safety studies on those also. We will update the public when additional information from these studies becomes available.

FDA required these studies, called *in vitro* studies, to further investigate Lamictal's effects on the heart after we received reports of abnormal electrocardiographic (ECG) findings and some other serious problems. In some cases, problems including chest pain, loss of consciousness, and cardiac arrest occurred. *In vitro* studies are studies done in test tubes or petri dishes and not in people or animals. We first added information about this risk to the lamotrigine prescribing information and Medication Guides in October 2020, which we have updated.

Lamotrigine is used alone or with other medicines to treat seizures in patients 2 years and older. It may also be used as maintenance treatment in patients with the mental health condition bipolar disorder to help delay the occurrence of mood episodes such as depression, mania, or hypomania. Lamotrigine has been approved and on the market for more than 25 years and is available under the brand name Lamictal and as generics.

Patients should not stop taking your medicine without first talking to your prescriber because stopping lamotrigine can lead to uncontrolled seizures, or new or worsening mental health problems. Contact your health care professional right away or go to an emergency room if you experience an abnormal heart rate or irregular rhythm, or symptoms such as a racing heartbeat, skipped or slow heartbeat, shortness of breath, dizziness, or fainting.

Health care professionals should assess whether the potential benefits of lamotrigine outweigh the potential risk of arrhythmias for each patient. Laboratory testing performed at therapeutically relevant concentrations has shown that lamotrigine can increase the risk of serious arrhythmias, which can be life-threatening, in patients with clinically important structural or functional heart disorders. Clinically important structural and functional heart disorders include heart failure, valvular heart disease, congenital heart disease, conduction system disease, ventricular arrhythmias, cardiac channelopathies such as Brugada syndrome, clinically important ischemic heart disease, or multiple risk factors for coronary artery disease. The risk of arrhythmias may increase further if used in combination with other medicines that block sodium channels in the heart. Other sodium channel blockers approved for epilepsy, bipolar disorder, and other indications should not be considered safer alternatives to lamotrigine in the absence of additional information (see List of Sodium Channel Blockers Required to Conduct Postmarket Studies).

We previously communicated safety information associated with lamotrigine in April 2018 (serious immune system reaction), August 2010 (aseptic meningitis warning), and September 2006 (possible association between Lamictal exposure during pregnancy and oral clefts in newborns). Lamotrigine was also covered as part of a May 2009 safety alert concerning suicidal thoughts and behavior with the entire class of anti-seizure medicines.

All medicines have side effects even when used correctly as prescribed. It is important to know that people respond differently to all medicines depending on their health, the diseases they have, genetic factors, other medicines they are taking, and many other factors. As a result, we cannot determine how likely it is that someone will experience these side effects when taking lamotrigine. Your health care professionals know you best, so talk to them if you have questions or concerns.

To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving lamotrigine or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

Health care professionals, patients, and consumers can sign up for email alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

List of Sodium Channel Blockers Required to Conduct Postmarket Studies

Generic Name	Brand Name
Carbamazepine	Carbatrol, Carnexiv, Equetro, Tegretol, Tegretol XR
Cenobamate	Xcopri
Eslicarbazepine	Aptiom
Fosphenytoin	Cerebyx, Sesquient
Lacosamide	Vimpat
Oxcarbazepine	Oxtellar XR, Trileptal
Phenytoin	Dilantin-125
Rufinamide	Banzel
Topiramate	Qsymia, Qudexy XR, Topamax, Trokendi XR
Zonisamide	Zonegran

Related Information

- Arrhythmia
- Seizures
- The Facts on Bipolar Disorder and FDA-approved Treatments
- The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective
- Think It Through: Managing the Benefits and Risks of Medicines