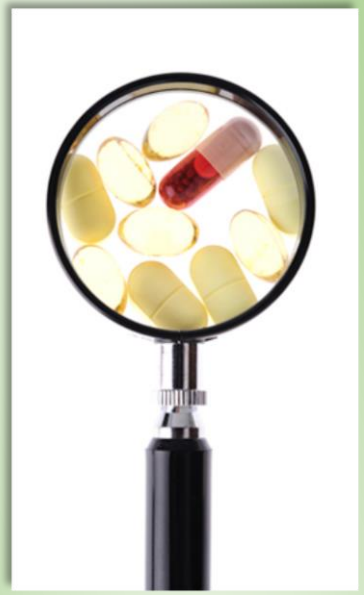
May 11, 2021 **COM-2021-026**

DRUG SAFETY NOTIFICATION



DATE: MARCH 31, 2021

DRUG NAME: LAMICTAL (LAMOTRIGINE)

DRUG INDICATION: SEIZURES, BIPOLAR DISORDER

SAFETY TOPIC: STUDIES SHOW INCREASED RISK OF HEART RHYTHM PROBLEMS IN PATIENTS WITH HEART DISEASE

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate with you with the latest up-to-date information on drug safety. For this reason, we are notifying you that the U.S. Food and Drug Administration (FDA) published a drug safety communication notifying that studies have shown a potential increased risk of heart rhythm problems, called arrhythmias, in patients with heart disease who are taking the seizure and mental health medicine Lamictal (lamotrigine).

The FDA is requiring safety studies for other drugs in the same drug class to evaluate if they have similar effects on the heart.

Recommendations for healthcare professionals:

- Advise patient to not stop taking their medications without first talking to their prescriber because stopping lamotrigine can lead to uncontrolled seizures, or new or worsening mental health problems.
- Advise patients to talk with their healthcare provider if they have any questions or concerns.
- Assess whether the potential benefits of lamotrigine outweigh the potential risk of arrhythmias for each patient.
- Report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

2 Street 1, Suite 500 Guaynabo, PR 00968 | Tel. 787.522.5252 | Fax 1.866.912.2830 | www.pharmpix.com

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at MedWatch: The FDA Safety Information and Adverse Event Reporting Program and FDA's Drug Safety and Availability portal.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

- Lamictal (lamotrigine): Drug Safety Communication. U.S. Food and Drug Administration. (2021). Retrieved April 2021, from https://www.fda.gov/safety/medical-product-safety-information/lamictal-lamotrigine-drug-safety-communication-studies-show-increased-risk-heart-rhythm-problems.
- Increased heart risk with lamotrigine in patients with heart disease. U.S. Food and Drug Administration. (2021). Retrieved April 2021, from https://www.fda.gov/drugs/studies-show-increased-risk-heart-rhythm-problems-seizure-and-mental-health-medicine-lamotrigine?utm_medium=email&utm_source=govdelivery.

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