COMMUNICATION

COM-2023-074

4 DECEMBER 2023

URGENT PLEASE REVIEW

Safety Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug safety information.

U.S. Food & Drug Administration Publication Date:

11/28/2023

Drug Indication:

Seizures

Safety Topic:

FDA updating warning that the antiseizures medicines can cause a rare but serious reaction that can be life- threatening if not diagnosed and treated quickly.

Antiseizure Drugs Causing Rare Reaction

It is for this reason that we are notifying you that on 11/28/2023 the U.S. Food and Drug Administration (FDA) published a safety communication for the following antiseizure product(s): levetiracetam and clobazam.

Reason for Communication:

The FDA is warning that the antiseizure medicines levetiracetam (Keppra™, Keppra XR™, Elepsia XR™, Spritam™) and clobazam (Onfi™, Sympazan™), can cause a rare but serious reaction that can be life-threatening if not diagnosed and treated quickly. This reaction is called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). It may start as a rash but can quickly progress, resulting in injury to internal organs, the need for hospitalization, and even death.

This hypersensitivity reaction to these medicines is serious but rare. DRESS can include fever, rash, swollen lymph nodes, or injury to organs including the liver, kidneys, lungs, heart, or pancreas.

Pharmacy Required Action:

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients should seek immediate medical attention if unexplained rash, fever, or swollen lymph nodes develop.

Assess whether the potential benefits of continuing the drug outweigh the potential risks highlighted in this safety communication.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

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.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252 ext. 219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

REFERENCES:

1. U.S. Food and Drug Administration. (2023). FDA updating warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions. https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-rare-serious-drug-reaction-antiseizure-medicines-levetiracetam-keppra-keppra-xr-elepsia-xr
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

2 Street 1, Suite 500
Guaynabo, PR 00968

Tel. 787.522.5252
Fax 866.912.2830

www.pharmpix.com
FRM-CL-000127-001