



HEALTH ALERT

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The Office of Developmental Programs is sharing this important information about levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan) from the U.S. Food and Drug Administration. FDA warns of rare but serious drug reaction to the antiseizure medicines. Full details available at link at bottom of page

FDA Drug Safety Communication

What safety concern is FDA announcing?

The U.S. Food and Drug Administration (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.

What should patients and caregivers do?

Do not stop taking levetiracetam or clobazam without talking with your health care professional.

Stopping these medicines suddenly can lead to uncontrolled seizures.

Patients who develop any unusual symptoms or reactions, including a rash, at any time while taking levetiracetam or clobazam should go to an emergency room immediately.

Fever with a rash and swollen lymph nodes or swelling in the face are common with DRESS, but some patients may not develop a rash.

Symptoms of DRESS generally start 2 weeks to 8 weeks after starting on the medicine, but these symptoms may occur earlier or later. A physical examination, laboratory blood tests, and other evaluations are used to diagnose DRESS.

A link to the full FDA Safety Communication can be found here: [FDA warns of rare but serious drug reaction to the antiseizure medicines levetiracetam \(Keppra, Keppra XR, Elepsia XR, Spritam\) and clobazam \(Onfi, Sympazan\) | FDA](#)