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FDA/HPT/VVC/SMD/VGU/24/0045

29th January 2024

Dear Healthcare Professional,

POTENTIALLY LETHAL REACTION TO ANTI-SEIZURE MEDICATIONS (LEVETIRACETAM AND CLOBAZAM)

The Food and Drugs Authority (FDA) wishes to inform you about the potential of the antiseizure medications (levetiracetam and clobazam) to cause a rare but serious drug hypersensitivity reaction, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), which can be life-threatening if not detected and treated promptly.

Levetiracetam is an antiseizure medicine approved by the Food and Drugs Authority for use alone or with other medicines to control certain types of seizures in adults and children such as partial seizures, myoclonic seizures or tonic-clonic seizures. Registered brands include Keppra and other generic brands.

Clobazam is currently not registered in Ghana. It is a benzodiazepine indicated for use in combination with other medicines to control seizures in adults and children 2 years and older who have a specific severe form of epilepsy called Lennox-Gastaut syndrome.

DRESS may start as a rash but can quickly progress and cause injury to internal organs leading to hospitalization and possibly death. Patients with DRESS can have a broad range of symptoms, which can include fever, rash, facial swelling, enlarged lymph nodes and kidney or liver injury.

According to the United States Food and Drugs Administration, a search in its Adverse Event Reporting System and medical literature showed that there were 32 identified cases of DRESS worldwide associated with levetiracetam use from the time of product launch to March 2023 and 10 serious cases identified for clobazam from the time of product launch to July 2023. The Ghana Food and Drugs Authority has not received any report of DRESS through its spontaneous reporting system.

Advice to patients

- Do not stop taking levetiracetam or clobazam without talking with your health care professional. Stopping these medicines suddenly can lead to uncontrolled seizures.
- Patients should look out for symptoms of DRESS when taking Levetiracetam or Clobazam. Immediately stop taking these medications and seek medical attention if DRESS is suspected.

Advice to healthcare professionals

The FDA wishes to advice all healthcare professionals to:

- Be aware of the signs and symptoms of DRESS to enable prompt diagnosis and early treatment.
    - DRESS may develop 2-8 weeks after starting levetiracetam or clobazam. The symptoms and intensity may vary widely and could be confused with other serious skin reactions like Stevens-Johnson syndrome and toxic epidermal necrolysis.

- Advise patients on these medications to immediately stop them when symptoms of DRESS occur.

Patients and healthcare professionals may call the FDA on Mobile No: 024 431 0297/ 055 111 2224 or email to drug.safety@fda.gov.gh for enquiries or further guidance.

Meanwhile, you are reminded to report adverse reactions to all medicinal products including **lack of therapeutic effect, medication errors, suspected product quality, and substandard or falsified medicinal products through the following modes:**

- Download and complete the Med Safety App(Google Play Store or App Store)
- Complete and submit the report online at http:adr.fdaghana.gov.gh/
- Download and complete the Adverse Reaction reporting form and submit it at the nearest health facility.

Yours faithfully,

SETH K. SEANEKE (MR.)
DCEO, HEALTH PRODUCTS AND TECHNOLOGIES DIVISION
FOR: CHIEF EXECUTIVE OFFICER