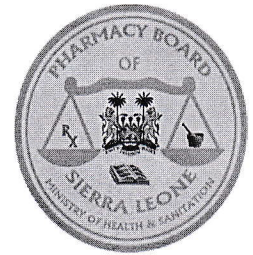




PHARMACY BOARD OF SIERRA LEONE
MINISTRY OF HEALTH AND SANITATION



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**PHARMACY BOARD OF SIERRA LEONE PRESS RELEASE ON THE TOXIC
EPIDERMAL NECROLYSIS LINKED TO SINOMAL (Sulphadoxine and Pyrimethamine)
Tablets 525mg USP (500/25)**

The Pharmacy Board of Sierra Leone (PBSL) has received a suspected adverse drug reaction report of Toxic Epidermal Necrolysis (TEN) linked to Sulphadoxine and Pyrimethamine 525mg tablets (500/25). This case report includes an adult female that took an OVERDOSE (six tablets) as a single dose of Sulphadoxine-Pyrimethamine 525mg (500/25) instead of three tablets, which is the recommended dose as stipulated in the summary of product characteristic (SmPC) and patient information leaflet (PIL) of the product. The clinical team at the hospital where the patient is admitted has been providing all medical care required, and the patient is on the way to recovery. As a result of this, PBSL did a preliminary causality assessment and risk-benefit analysis on this case and concluded that the Toxic epidermal necrolysis is not as a result of a DRUG QUALITY PROBLEM but probable/likely related to the medicine due to the OVERDOSE, the intrinsic pharmacology of the medicine and its sulpha chemical moiety which can all contribute to the risk of hypersensitivity reactions. It is important to note that dermatologic reactions like TEN are RARE. Therefore all healthcare professionals and the general public are advised that if sulphadoxine-pyrimethamine is prescribed, it is essential to inquire about allergy to any of the active ingredients or excipients. Another option should be prescribed if the patient is intolerant to any of these. Patients should be warned that at the first appearance of a skin rash, they should stop using the medicine and seek medical attention immediately.

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