

**FDA ADVISORY**  
No. 2024-0197

31 JAN 2024

**TO: ALL HEALTHCARE PROFESSIONALS AND GENERAL PUBLIC**

**SUBJECT: Safety Information: Topical Corticosteroids and increased risk of misuse and abuse**

Topical corticosteroids are used to treat the symptoms of many skin disorders, such as eczema, dermatitis, and psoriasis. These drug products play a major role in the treatment of many dermatologic conditions. These are usually recommended for once to twice daily use. However, misuse, abuse, and abrupt stop of topical corticosteroids result in **Topical Steroids Withdrawal** ("**Topical Steroid Addiction**" or "**Red Skin Syndrome**"). this includes prolonged, frequent, and inappropriate use of moderate to high potency topical corticosteroids, especially on the face and genital area. Several different medical conditions resulting from excessive use are *atrophy*, *rosacea*, *acne*, *perioral dermatitis* and symptoms includes redness of the skin, burning sensation, followed by skin peeling, which appears to be distinct from a flare-up of the underlying condition. The signs and symptoms occur within days to weeks after discontinuation.

The Food and Drug Administration (FDA) conducted literature review to assess the safety of topical corticosteroids considering regulatory actions made by other countries and the risks of abuse and misuse. In the interest of public health and safety, the FDA classifies all topical corticosteroid products as prescription drug.

**Safety Information for Healthcare Professionals:**

1. Healthcare professionals should inform their patients on the risk of topical steroids withdrawal, provide instruction on the correct, safe and effective use and should advise them to regularly check their skin for new marks or growths and any changes to existing marks.
2. Pharmacists should advise the patients correctly about the safety of topical corticosteroids and not to dispense the product without a written prescription from dermatologists or treating physicians. Upon presentation of prescription, patients should undergo counseling on the proper use of the product to avoid serious health risks and worsening of their conditions.
3. Healthcare professionals are also encouraged to report any serious adverse reactions, including topical steroids withdrawal, related to prolonged use of topical corticosteroids, to the FDA.



**Safety Information for the General Public:**

1. Avoid prescription sharing from friends and relatives. Not all skin problems require the same management.
2. Avoid searching through the internet to address skin problems. Consult with your physician or nearest pharmacist for proper recommendations.
3. Report to your healthcare professional or FDA for any adverse reactions after using a drug product.

For more information, visit us at <https://www.fda.gov.ph/pharmacovigilance/> and you may report any adverse drug reaction to <https://bit.ly/FDAPHReportSideEffect>, or send us an email at [pharmacovigilance@fda.gov.ph](mailto:pharmacovigilance@fda.gov.ph).



**DR. SAMUEL A. ZACATE**  
Director General



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