



FDA ADVISORY
No. **2021-0833**

23 APR 2021

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the Counterfeit Dermovate™ Ointment (Clobetasol) 20 grams

The Food and Drug Administration (FDA) advises the public against the purchase and use of the counterfeit Dermovate™ Ointment (Clobetasol) 20 grams:

Authentic	Counterfeit
 <p>The authentic product consists of a 5g ointment tube and a box. The tube is white with a yellow and white patterned band and contains the text: "Clobetasol propionate 5g", "Dermovate 500mcg/g Ointment", "Steroidal Anti-inflammatory/Antipruritic For external use only", and a large "Rx" symbol. The box is white with a yellow and white patterned band and contains the text: "5 Grams", "Clobetasol propionate", "Dermovate 500mcg/g Ointment", "Steroidal Anti-inflammatory/Antipruritic For external use only", and a large "Rx" symbol. The box also features the GSK logo and manufacturer information.</p>	 <p>The counterfeit product consists of a 20g ointment tube and a box. The tube is white with a brown and white patterned band and contains the text: "FOR EXTERNAL USE ONLY", "GSK Specifications", "GlaxoSmithKline Pakistan Limited", "35-Dockyard Road, West Wharf, Karachi", "Dermovate™ Ointment", and "20g". The box is white with a brown and white patterned band and contains the text: "Dermovate™ Ointment (Clobetasol) 20 grams", "GlaxoSmithKline", and Urdu text: "ڈرمووایٹ کریم ۲۰ گرام". The box also features the GSK logo.</p>

Figure 1. Comparison between the Authentic and Verified Counterfeit Dermovate™ Ointment (Clobetasol)



The FDA together with the Marketing Authorization Holder (MAH), GlaxoSmithKline Philippines Inc., have verified that the above-mentioned sample drug product is counterfeit. The comparison of the collected counterfeit drug product and the distinguishing feature of the authentic are as follows:

Authentic	Counterfeit
1. Manufacturing Site: Glaxo Operations UK Ltd. Harmire Road, Barnard Castle Durham, UK	1. Manufacturing Site: GlaxoSmithKline Pakitsan Limited West Wharf, Karachi Pakistan
2. Pack size: 5g, registered in the Philippines	2. Pack size: 20g, not registered in the Philippines
3. Compliant to generic labelling requirements	3. Not compliant to generic labelling requirements

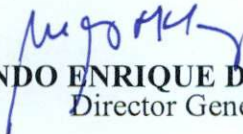
All healthcare professionals and the general public are hereby warned as to the availability of this counterfeit drug product in the market which poses potential danger or injury to consumers. Consumers are also reminded to purchase drug products only from FDA-licensed establishments.

Likewise, all establishments and outlets are hereby warned against selling and/or dispensing of this drug product with the abovementioned features of a counterfeit drug product. The importation, selling or offering for sale of such is in direct violation of Republic Act No. 9711 or the Food and Drug Administration Act of 2009, and Republic Act No. 8203 or the Special Law on Counterfeit Drugs. Anyone found selling the said counterfeit drug product will be penalized.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this counterfeit product is not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at info@fda.gov.ph. To report continuous sale or distribution of counterfeit health products, kindly e-mail us via report@fda.gov.ph, or through the online reporting facility, **eReport**, at www.fda.gov.ph/ereport. You may also call the Center for Drug Regulation and Research at telephone number **(02) 8809-5596**. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> and fill out all the required fields.

Dissemination of the information to all concerned is requested.


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