



20 APR 2022

FDA ADVISORY
No. ~~2022-0941~~

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the following Verified Counterfeit Drug Products:

1. Mefenamic Acid (Dolfenal[®]) 500 mg Film-Coated Tablet
2. Aluminum Hydroxide / Magnesium Hydroxide / Simeticone (Kremil-S[®]) 178 mg / 233 mg / 30 mg Chewable Tablet
3. Naproxen Sodium (Flanax[®] Forte) 550 mg Tablet
4. Ibuprofen (Medicol[®] Advance) 200 mg Softgel Capsule

The Food and Drug Administration (FDA) advises the public against the purchase and use of the counterfeit version of the following products:

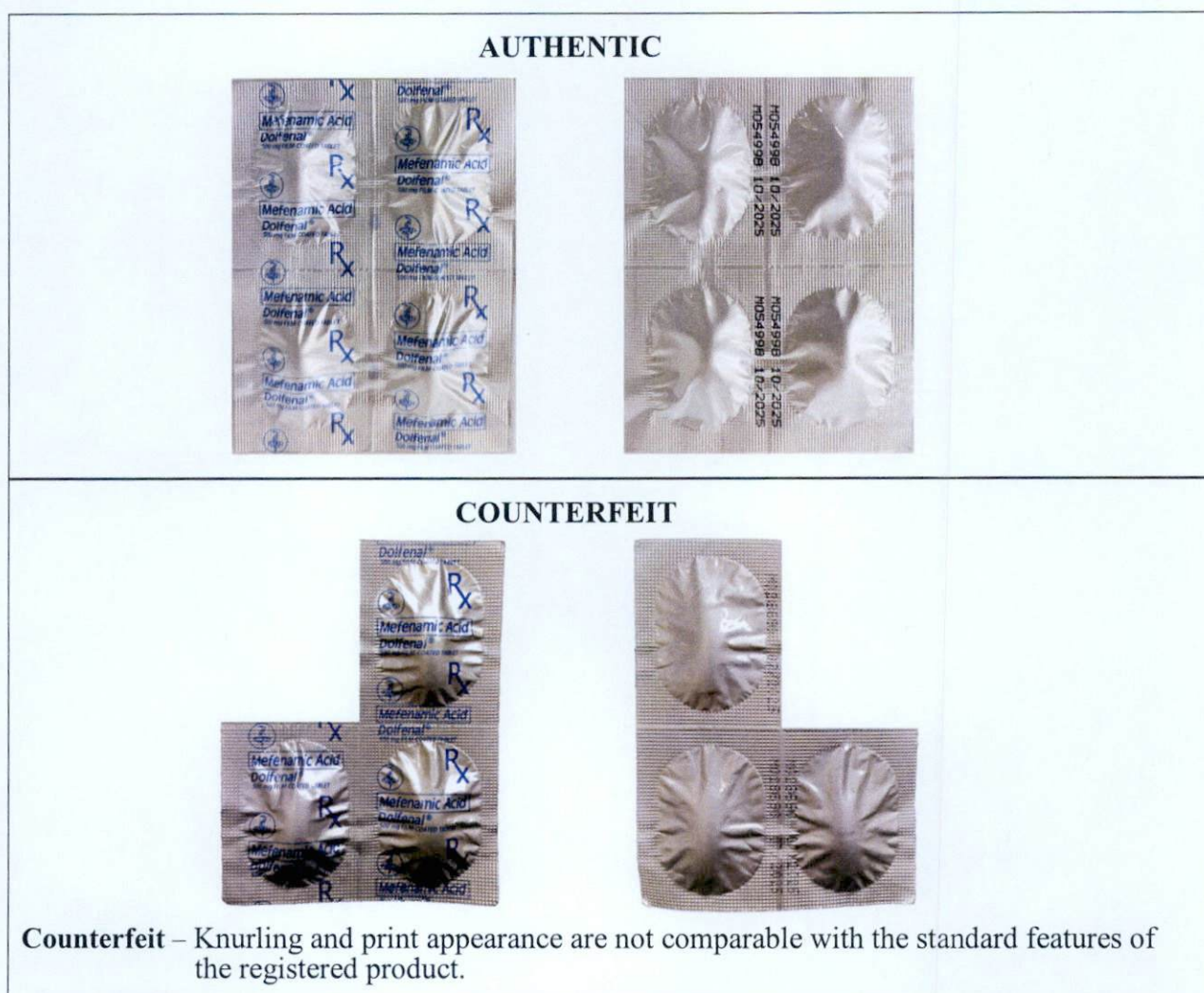


Figure 1. Comparison between the Authentic and Verified Counterfeit Mefenamic Acid (Dolfenal[®]) 500 mg Film-Coated Tablet (Lot No. M028690 Exp. 07/2025)



AUTHENTIC



COUNTERFEIT



Counterfeit – Knurling, security mark and print appearance are not comparable with the standard features of the registered product.

Figure 2. Comparison between the Authentic and Verified Counterfeit Aluminum Hydroxide / Magnesium Hydroxide / Simeticone (Kremil-S®) 178 mg / 233 mg / 30 mg Chewable Tablet (Lot No. U022972 Exp. APR 2024)

AUTHENTIC



COUNTERFEIT



Counterfeit – Batch no. was not manufactured by the Marketing Authorization Holder (MAH) Taisho Pharmaceuticals Philippines, Inc.

Figure 3. Comparison between the Authentic and Verified Counterfeit Naproxen Sodium (Flanax® Forte) 550 mg Tablet (Lot No. TFF9K780 Exp. JUN 2024)

AUTHENTIC



COUNTERFEIT



Counterfeit – The capsule, knurling and print appearance of the strip are not comparable with the standard features of the registered product.

Figure 4. Comparison between the Authentic and Verified Counterfeit Ibuprofen (Medical[®] Advance) 200 mg Softgel Capsule (Lot No. M044640 Exp. 08/2023)

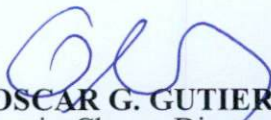
All healthcare professionals and the general public are hereby warned as to the availability of these counterfeit drug products in the market which pose potential danger or injury to consumers. Consumers are also reminded to purchase drug products only from FDA-licensed establishments.

Likewise, all establishments and outlets are hereby warned against selling and/or dispensing of the said counterfeit products with the abovementioned features. 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 products will be penalized.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are 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 unregistered health products, kindly e-mail us via ereport@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.


DR. OSCAR G. GUTIERREZ, JR.
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