



21 MAR 2022

FDA ADVISORY
No. 2022-0617

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. Carbocisteine (Solmux[®]) 500 mg Capsule
3. Dextromethorphan HBr / Phenylephrine HCl / Paracetamol (Tuseran[®] Forte) 15 mg / 25 mg / 325 mg Capsule

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

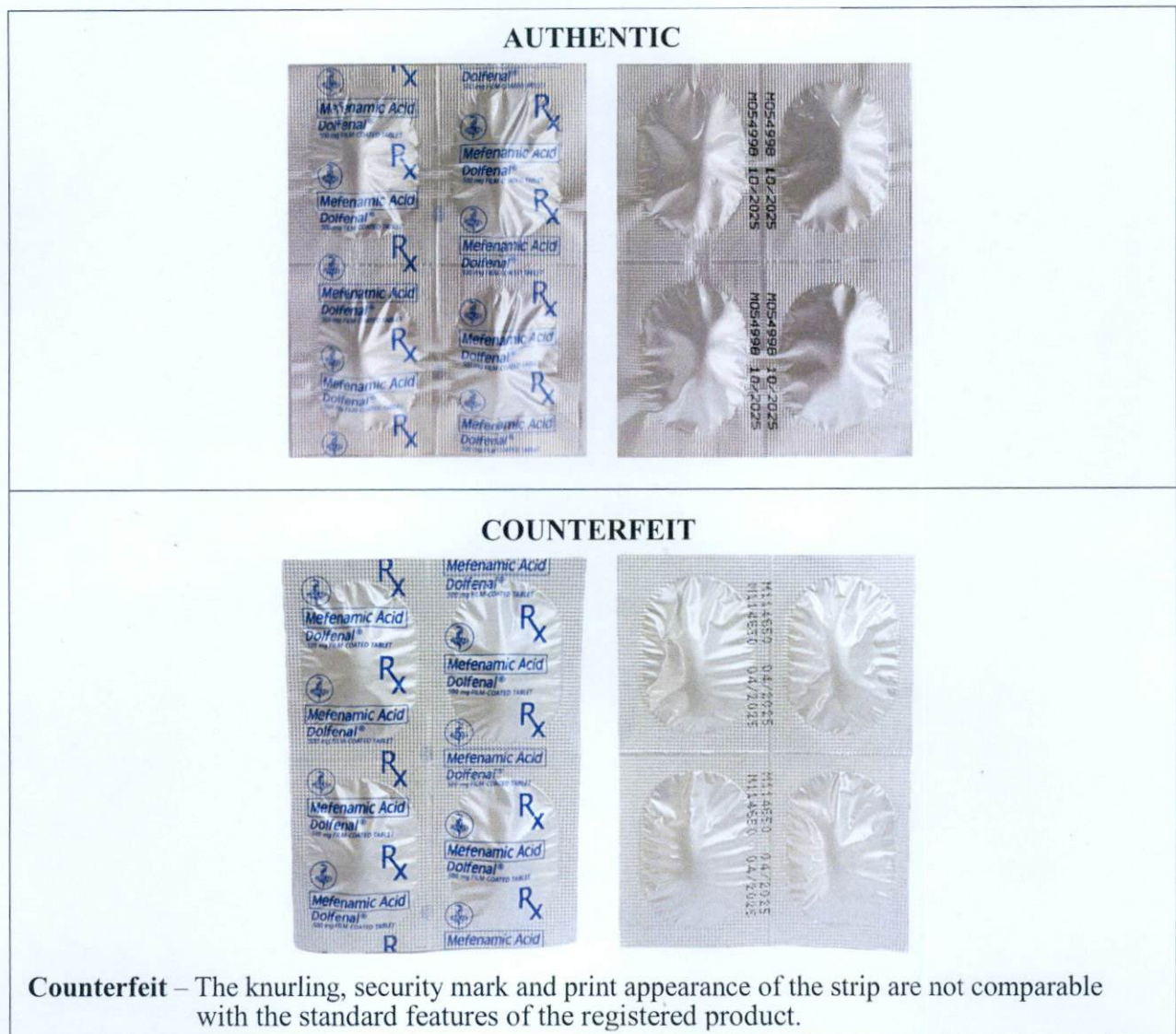


Figure 1. Comparison between the Authentic and Counterfeit Mefenamic Acid (Dolfenal[®]) 500 mg Film-Coated tablet (Lot No. M114650 Exp. 04/2025)



AUTHENTIC



COUNTERFEIT



Counterfeit – The print appearance of the box is not comparable with the standard features of the registered product.

Figure 2. Comparison between the secondary packaging (box) of the Authentic and Counterfeit Carbocisteine (Solmux®) 500 mg Capsule (Lot No. U281600 Exp. AUG 2026)

AUTHENTIC



COUNTERFEIT



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

Figure 3. Comparison between the Authentic and Counterfeit Carbocisteine (Solmux[®]) 500 mg Capsule (Lot No. U281600 Exp. AUG 2026)

AUTHENTIC



COUNTERFEIT



Counterfeit – The print appearance of the box is not comparable with the standard features of the registered product.

Figure 4. Comparison between the secondary packaging (box) of the Authentic and Verified Counterfeit Dextromethorphan HBr/ Phenylpropanolamine HCl/ Paracetamol (Tuseran® Forte 15 mg/ 25 mg/ 325 mg Capsule (Lot No. U021060 Exp. SEP 2024))

AUTHENTIC



COUNTERFEIT



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

Figure 5. Comparison between the Authentic and Verified Counterfeit Dextromethorphan HBr/ Phenylpropanolamine HCl/ Paracetamol (Tuseran[®] Forte 15 mg/ 25 mg/ 325 mg Capsule (Lot No. U021060 Exp. SEP 2024)

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 concerned establishments and/or entities are warned not to distribute the above-identified violative drug product until it has been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product is registered with the FDA by using the **FDA Verification Portal feature** accessible at <http://verification.fda.gov.ph>.

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.
Officer-in-Charge, Director General

DTN:



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