

# Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2022U478

0 8 MAR 2022

TO

ALL HEALTHCARE PROFESSIONALS AND

GENERAL PUBLIC

SUBJECT

Public Health Warning Against the Purchase and Use of the

following Verified Counterfeit Drug Products:

1. Dextromethorpan HBr / Phenylephrine HCl / Paracetamol (Tuseran® Forte) 15 mg / 10 mg / 325 mg Capsule

2. Carbocisteine (Solmux®) 500 mg Capsule

3. Loperamide (Diatabs®) 2 mg Capsule

4. Naproxen Sodium (Flanax®Forte) 550 mg Tablet

5. Paracetamol (Biogesic®) 500 mg Tablet

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

### AUTHENTIC





### COUNTERFEIT





Counterfeit - The knurling and print appearance are different from standard.

Figure 1. Comparison between the Authentic and Counterfeit Dextromethorpan HBr / Phenylephrine HCl / Paracetamol (Tuseran®Forte) 15 mg / 10 mg / 325 mg Capsule (Lot No. U011218 Exp. OCT 2022)







# Solonux Sol



### COUNTERFEIT









Counterfeit - The knurling and print appearance are different from standard.

Figure 2. Comparison between the Authentic and Counterfeit Carbocisteine (Solmux<sup>®</sup>) 2 mg Capsule (Lot No. U089515 Exp. MAR 2026) and (Lot No. Not Indicated Exp. Not Indicated)

# **AUTHENTIC**





# COUNTERFEIT



Counterfeit - The knurling, security mark, and print appearance are different from standard.

Figure 3. Comparison between the Authentic and Counterfeit Loperamide (Diatabs®) 2 mg Capsule (Lot No. U038725 Exp. DEC 2025) and (Lot No. U021606 Exp. APR 2026)

# **AUTHENTIC**





# COUNTERFEIT





Counterfeit - The Lot/batch no. was not manufactured by the Marketing Authorization Holder

Figure 4. Comparison between the Authentic and Counterfeit Naproxen Sodium (Flanax®Forte) 550 mg Tablet (Lot No. TFFUK465 Exp. NOV 23)

# **AUTHENTIC**





# **COUNTERFEIT**





Counterfeit - The tablet, knurling, security mark, and print appearance are different from standard.

Figure 5. Comparison between the Authentic and Counterfeit Paracetamol (Biogesic ) 500 mg Tablet (Lot No. 19188563 Exp. MAR 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 <a href="http://verification.fda.gov.ph">http://verification.fda.gov.ph</a>.

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 <a href="mailto:info@fda.gov.ph">info@fda.gov.ph</a>. To report continuous sale or distribution of unregistered health products, kindly e-mail us via <a href="mailto:ereport@fda.gov.ph">ereport@fda.gov.ph</a>, or through the online reporting facility, eReport, at <a href="mailto:www.fda.gov.ph/ereport">www.fda.gov.ph/ereport</a>. 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: <a href="https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH">https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH</a> 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

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