Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20220479

08 MAR 2022

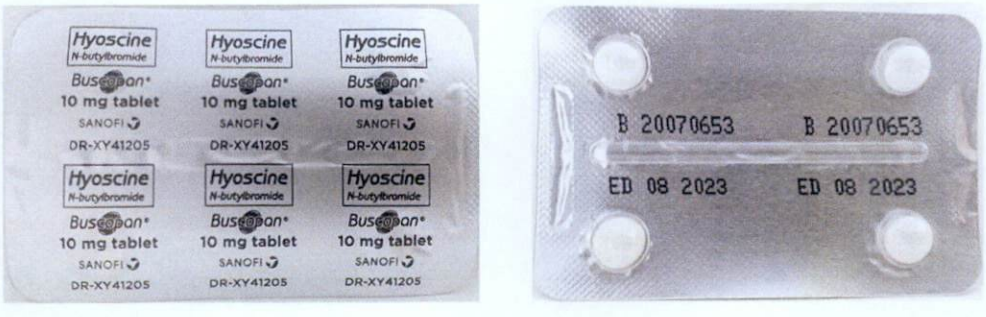
TO : **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

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

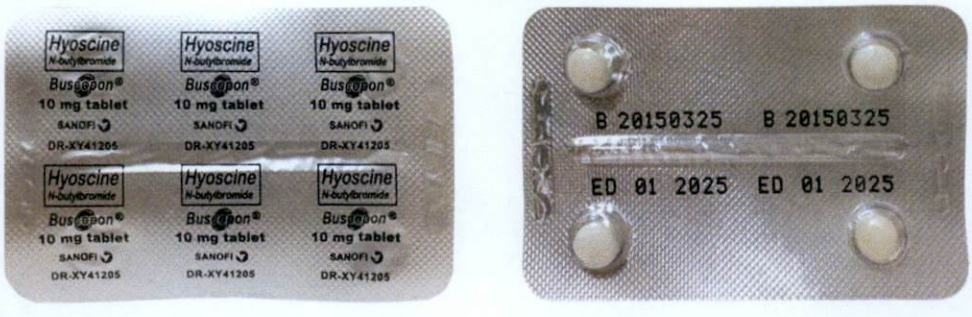
1. **Hyoscine N-butylbromide (Buscopan®) 10 mg Capsule**
2. **Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Neozep® Forte) 10 mg / 2 mg / 500 mg Tablet**
3. **Paracetamol (Biogesic®) 500 mg Tablet**
4. **Ibuprofen (Medicol®Advance) 200 mg Softgel Capsule**
5. **Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Bioflu®) 10 mg / 2 mg / 500 mg Film-Coated Tablet**
6. **Dextromethorphan HBr / Phenylephrine HCl / Paracetamol (Tuseran® Forte) 15 mg / 10 mg / 325 mg Capsule**
7. **Naproxen Sodium (Flanax®Forte) 550 mg Tablet**
8. **Loperamide (Diatabs®) 2 mg Capsule**

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

AUTHENTIC



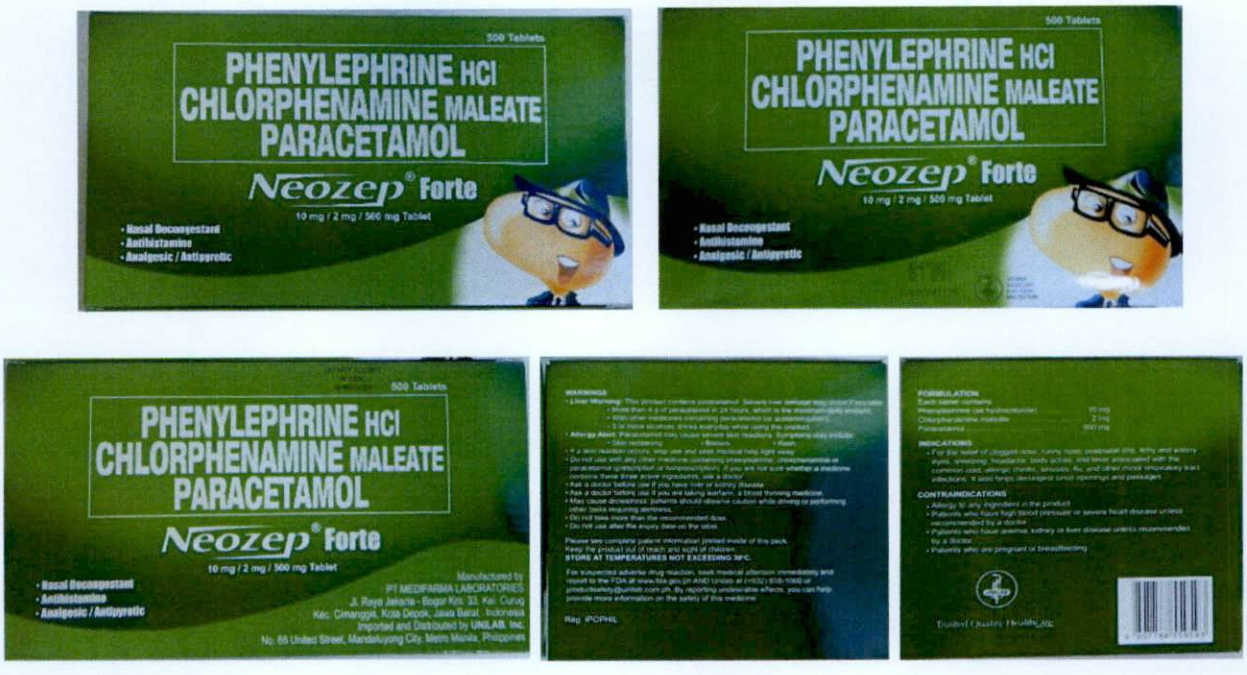
COUNTERFEIT



Counterfeit – Batch number and expiry date are not valid. Wrong Spelling of brand name. Quality of print of bird logo is not comparable to standard.

Figure 1. Comparison between the Authentic and Counterfeit Hyoscine N-butylbromide (Buscopan®) 10 mg Capsule (Lot No. 20150325 Exp. 1 2025)

AUTHENTIC

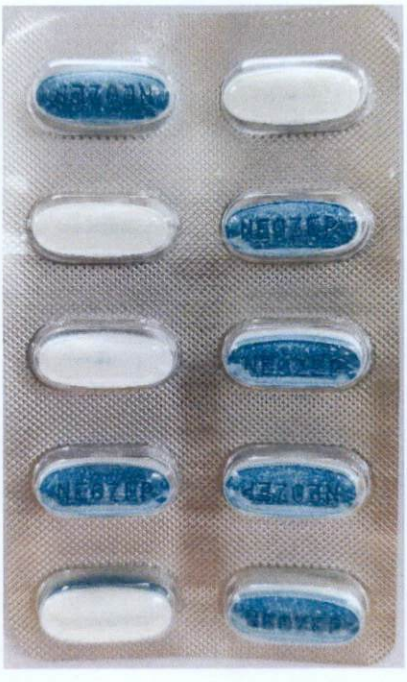


COUNTERFEIT

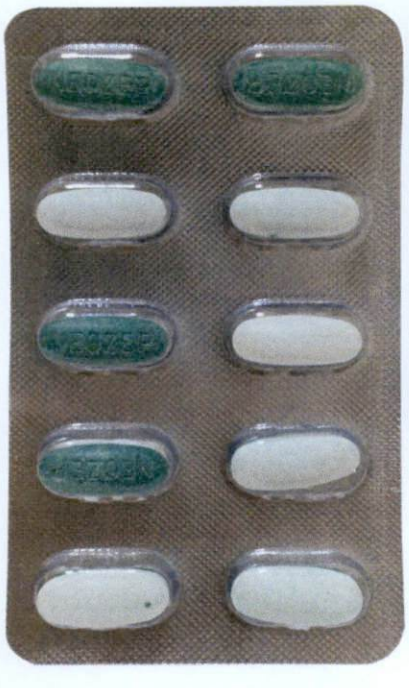
Counterfeit – The print appearance of the box is not comparable with the standard features of the registered product.

Figure 2. Comparison between the secondary packaging (box) of the Authentic and Counterfeit Phenylephrine HCl/ Chlorphenamine Maleate/ Paracetamol (Neozep®Forte) 10 mg/ 2 mg/ 500 mg Tablet (Lot No. 13121158 Exp. OCT 2023)

AUTHENTIC



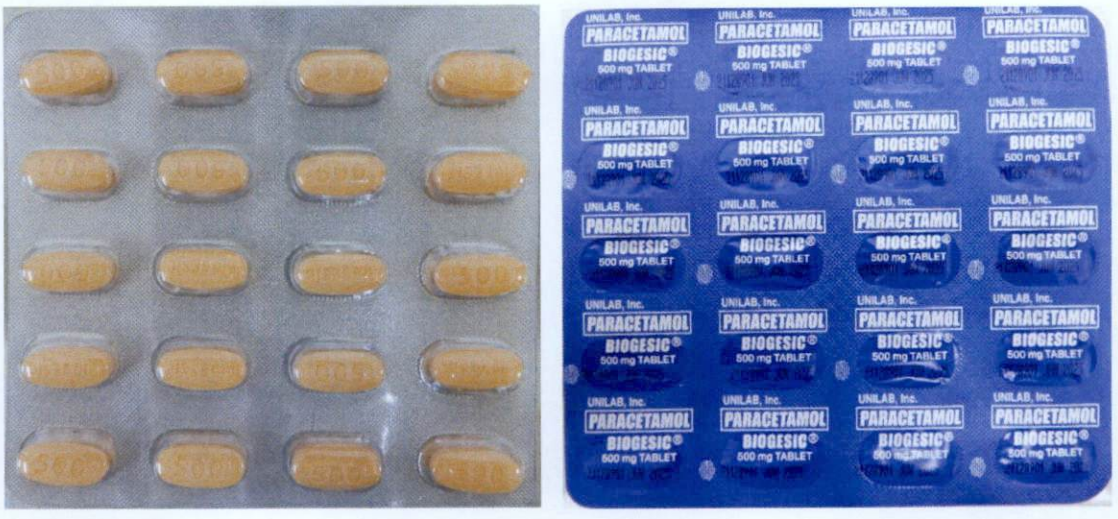
COUNTERFEIT



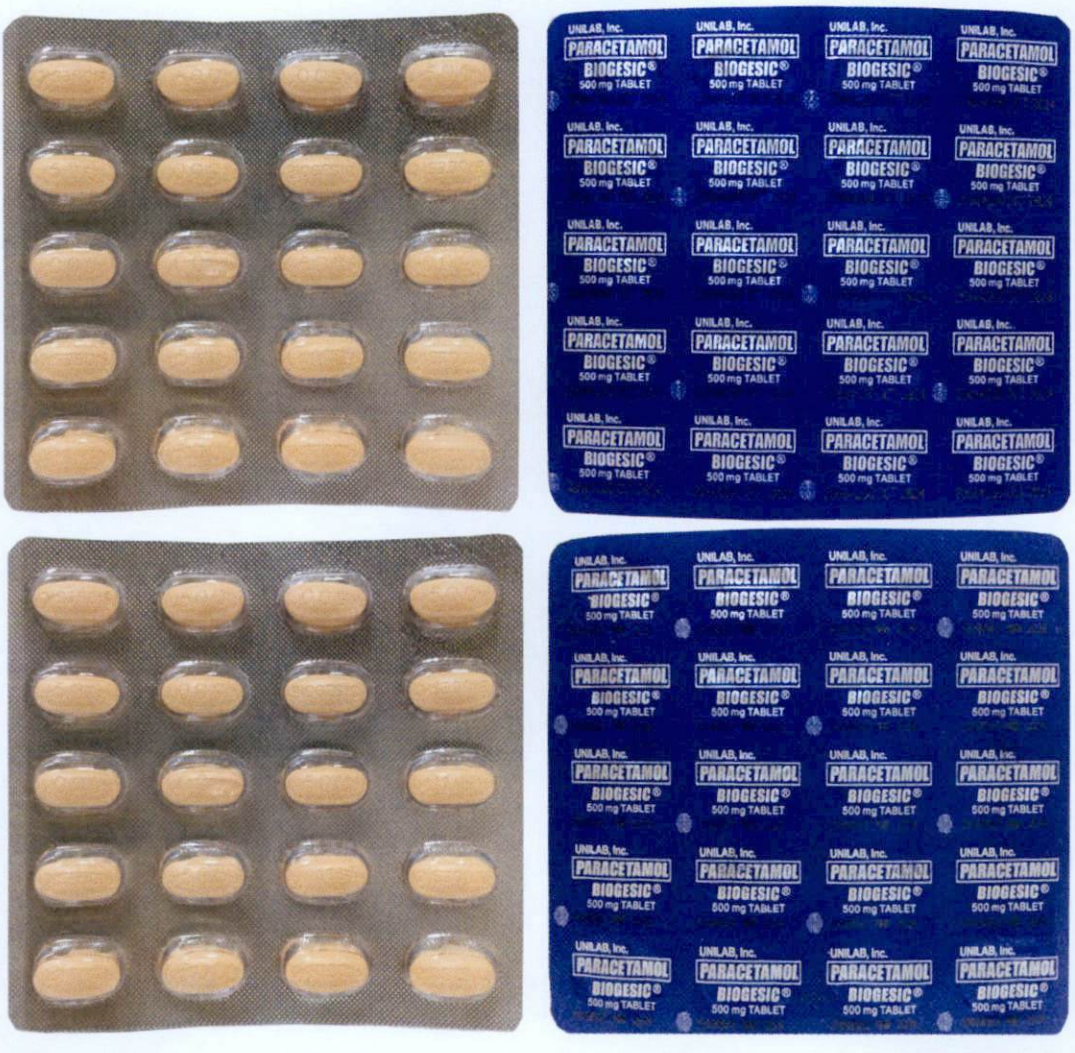
Counterfeit – The tablet, knurling, and print appearance of the strip are not comparable with standard.

Figure 3. Comparison between the Authentic and Verified Counterfeit Phenylephrine HCl/ Chlorphenamine Maleate/ Paracetamol (Neozep®Forte) 10 mg/ 2 mg/ 500 mg Tablet (Lot No. 13121158 Exp. OCT 2023)

AUTHENTIC



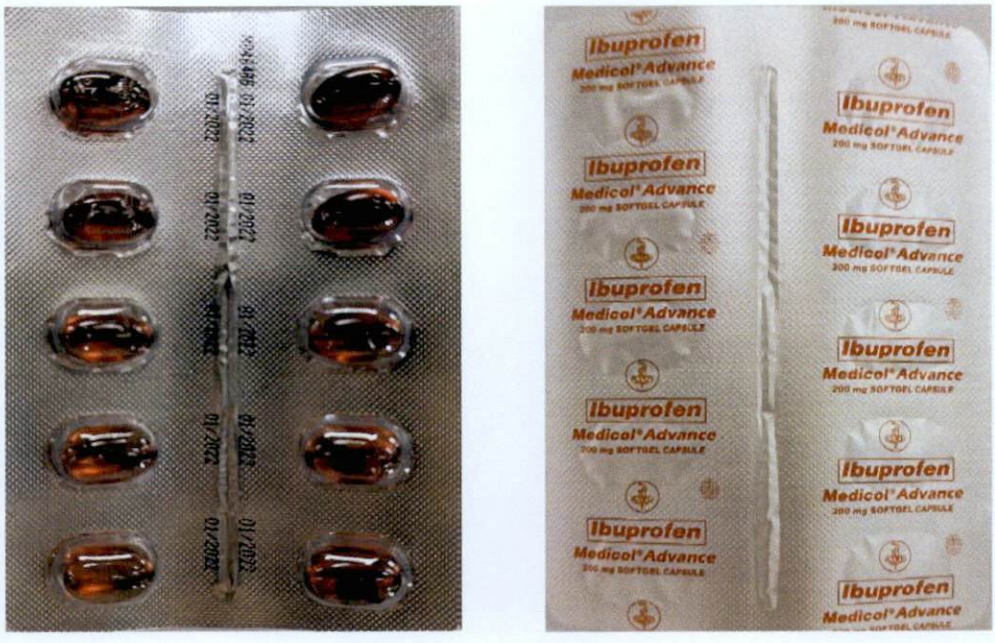
COUNTERFEIT



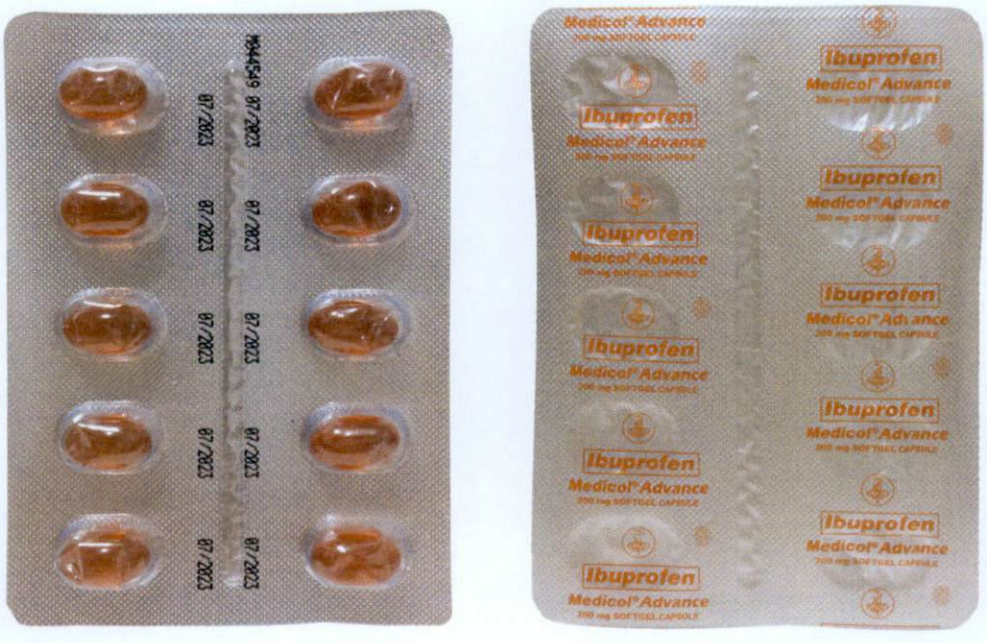
Counterfeit – The tablet, knurling, security mark, and print appearance are not comparable with standard.

Figure 4. Comparison between the Authentic and Counterfeit Paracetamol (Biogesic®) 500 mg Tablet (Lot No. 20664260 Exp. OCT 2024) and (Lot No. 19188563 Exp. MAR 2024)

AUTHENTIC



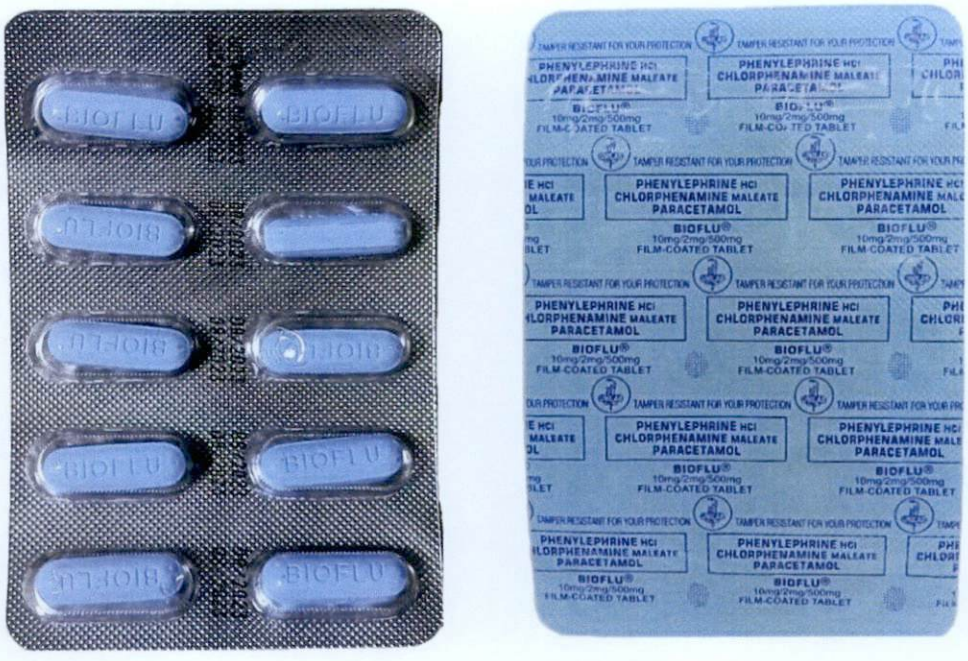
COUNTERFEIT



Counterfeit – The capsule and print appearance are not comparable with standard.

Figure 5. Comparison between the Authentic and Counterfeit Ibuprofen (Medicol® Advance) 200 mg Softgel Capsule (Lot No. M044549 Exp. 07/2023)

AUTHENTIC



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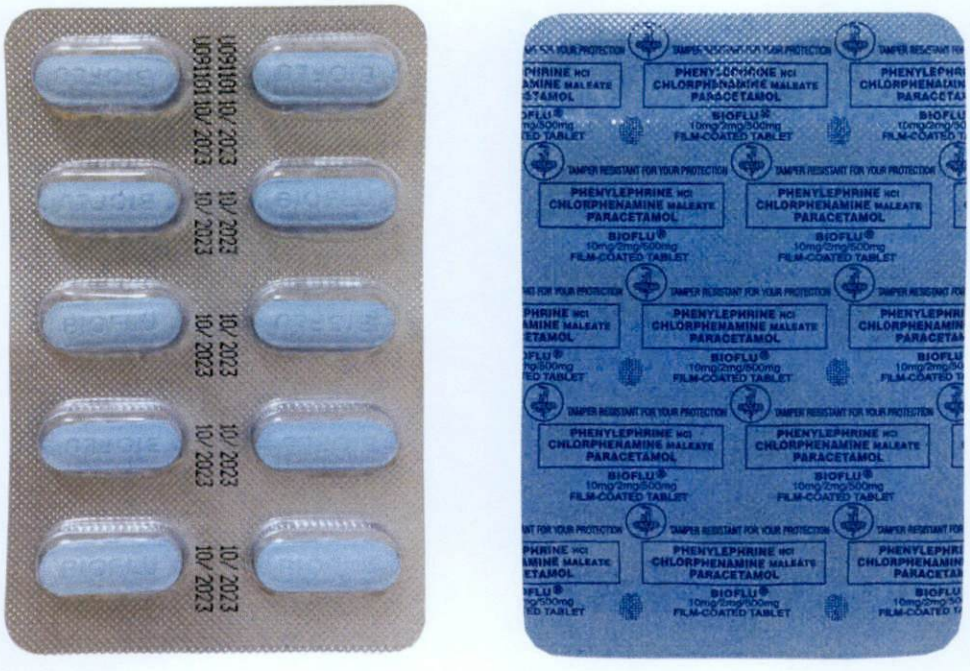
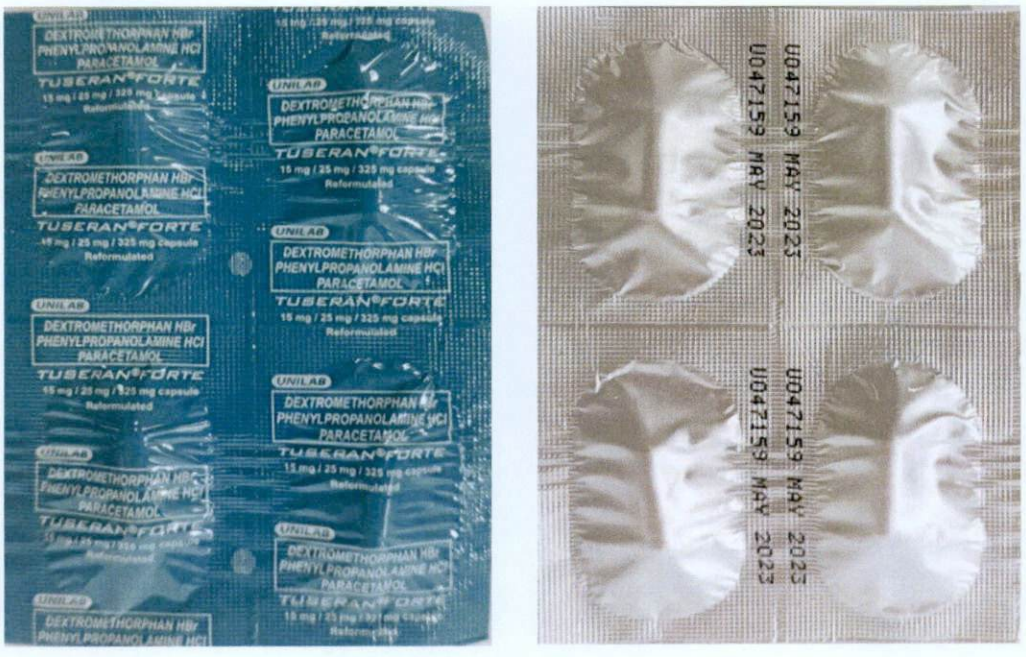


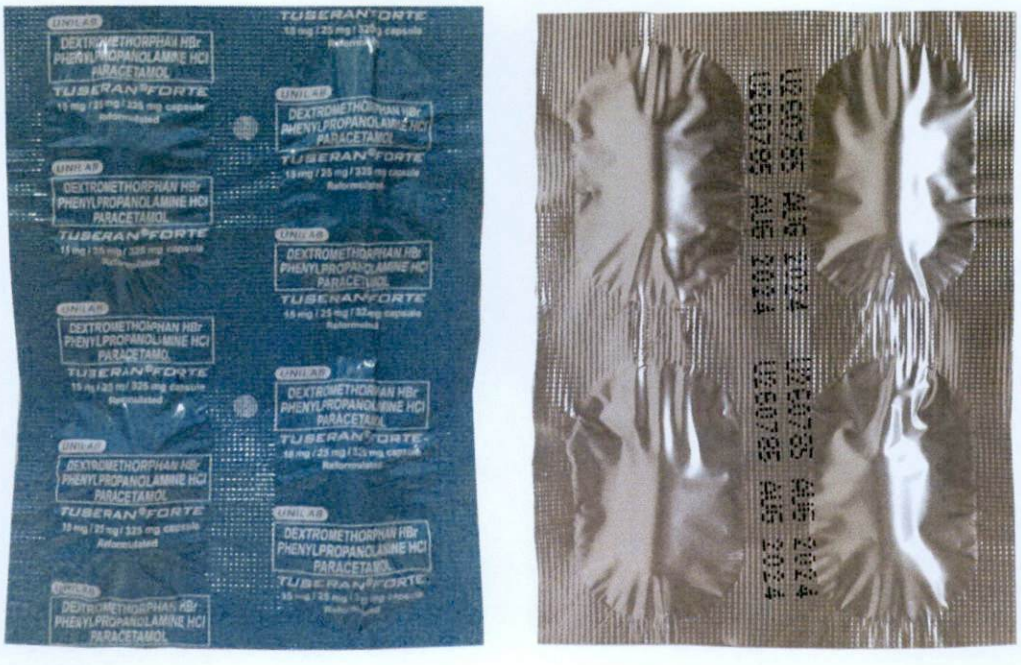
Counterfeit – The tablet and print appearance are not comparable with standard.

Figure 6. Comparison between the Authentic and Counterfeit Counterfeit Phenylephrine HCl/ Chlorphenamine Maleate/ Paracetamol (Bioflu®) 10 mg/ 2 mg/ 500 mg Film-Coated Tablet (Lot No. U091101 Exp. 10/2023)

AUTHENTIC



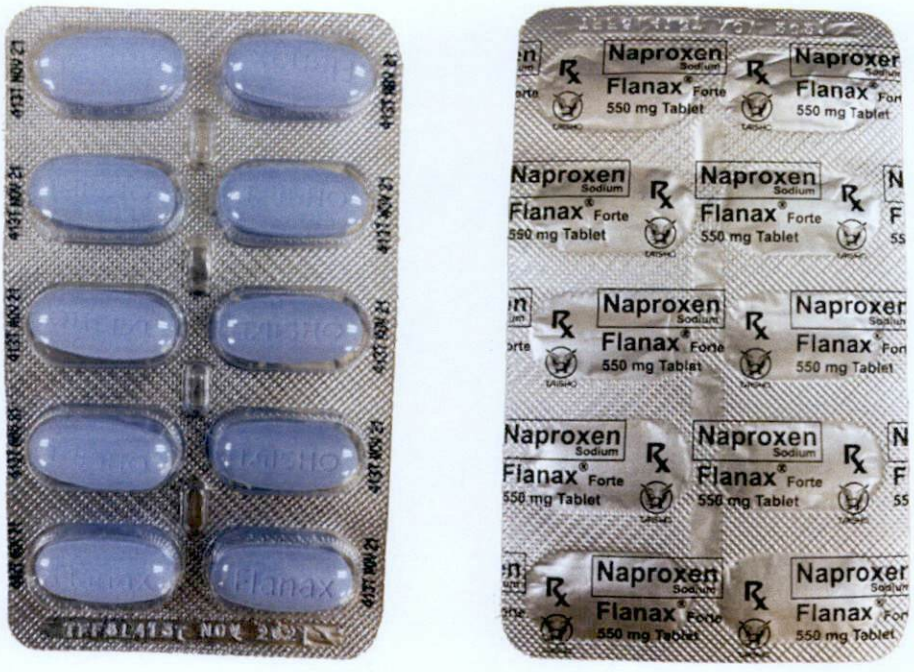
COUNTERFEIT



Counterfeit – The knurling, security mark, and print appearance are not comparable with standard.

Figure 7. Comparison between the Authentic and Counterfeit Dextromethorphan HBr/ Phenylpropanolamine HCl/ Paracetamol (Tuseran®Forte) 15 mg/ 25 mg/ 325 mg Capsule (Lot No. U260785 Exp. AUG 2024)

AUTHENTIC



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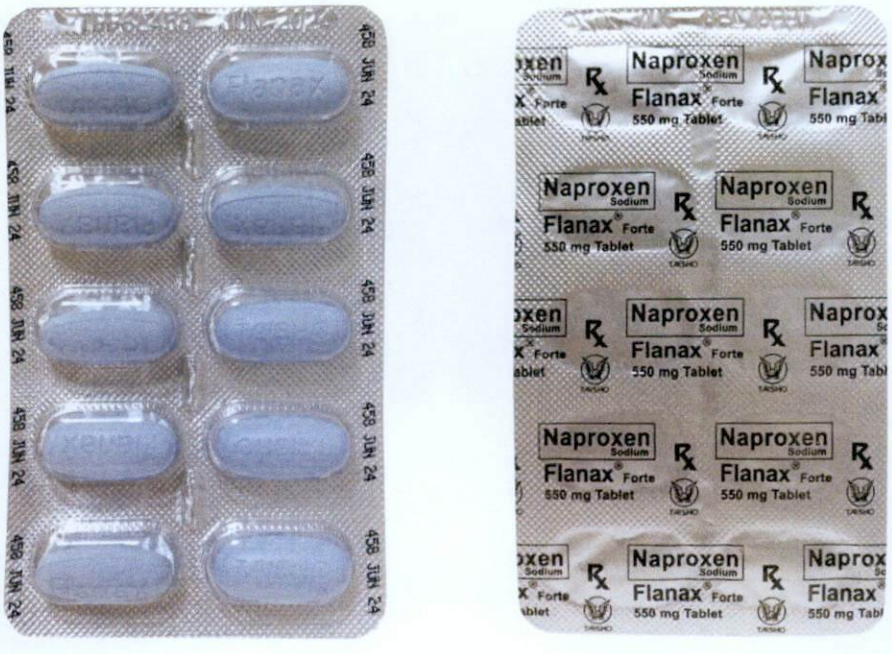
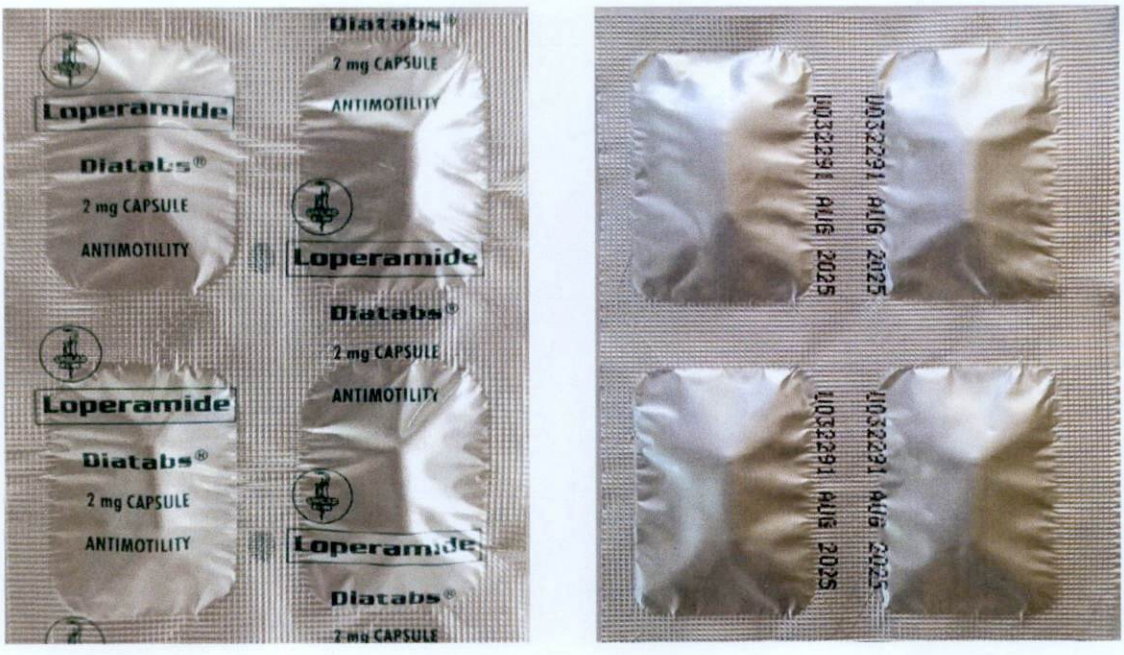


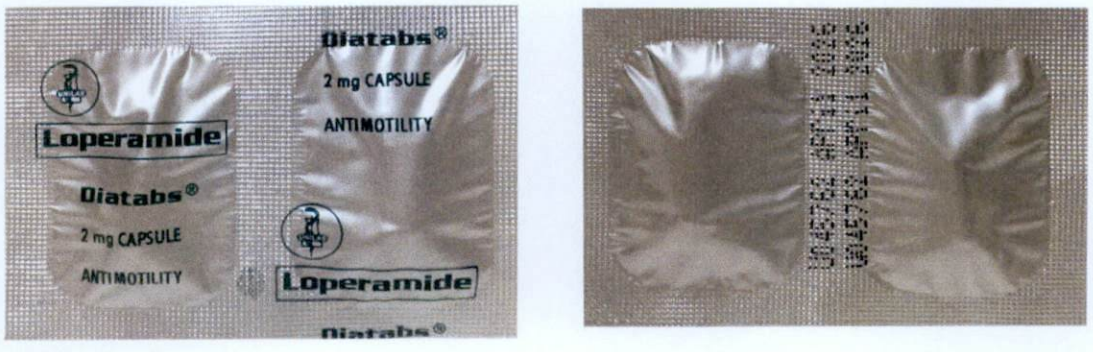
Counterfeit – This lot no. was not manufactured by Marketing Authorization Holder of Flanax®Forte.

Figure 8. Comparison between the Authentic and Counterfeit Naproxen Sodium (Flanax®Forte) 550 mg Tablet (Lot No. TFF6L458 Exp. JUN 24)

AUTHENTIC



COUNTERFEIT



Counterfeit – The knurling and print appearance are are not comparable with standard.

Figure 9. Comparison between the Authentic and Counterfeit Loperamide (Diatabs®) 2 mg Capsule (Lot No. U045762 Exp. APR 2026)

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.

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Dissemination of the information to all concerned is requested.

DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge, Director General

DTN: 20220221144031