



FDA ADVISORY  
No. **2022-0611**

16 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. Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Bioflu<sup>®</sup>) 10 mg / 2 mg / 500 mg Film-Coated Tablet
2. Ibuprofen / Paracetamol (Alaxan<sup>®</sup> FR) 200 mg / 325 mg Capsule
3. Ibuprofen (Medical<sup>®</sup> Advance) 200 mg Softgel Capsule
4. Phenylpropanolamine HCl / Chlorphenamine Maleate / Paracetamol (Decolgen<sup>®</sup> Forte) 25 mg / 2 mg / 500 mg Tablet
5. Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Neozep<sup>®</sup> Forte) 10 mg / 2 mg / 500 mg Tablet
6. Dextromethorphan HBr / Phenylephrine HCl / Paracetamol (Tuseran<sup>®</sup> Forte) 15 mg / 25 mg / 325 mg Capsule
7. Naproxen Sodium (Flanax<sup>®</sup> Forte) 550 mg Tablet
8. Mefenamic Acid (Dolfenal<sup>®</sup>) 500 mg Film-Coated Tablet
9. Mefenamic Acid (Gardan<sup>®</sup>) 500 mg Tablet
10. Loperamide (Diatabs<sup>®</sup>) 2 mg Capsule
11. Loperamide (Imodium<sup>®</sup>) 2 mg Capsule
12. D-Alpha Tocopherol (Vitamin E) (Myra E) 400 IU Capsule
13. Aluminum Hydroxide / Magnesium Hydroxide / Simeticone (Kremil-S<sup>®</sup>) 178 mg / 233 mg / 30 mg Chewable 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 print appearance of the box is not comparable with the standard features of the registered product.

Figure 1. Comparison between the secondary packaging (box) of the Authentic and Verified Counterfeit Phenylephrine HCl, Chlorphenamine Maleate/ Paracetamol (Bioflu<sup>®</sup>) 10 mg/ 2 mg/ 500 mg Film-Coated Tablet (Lot No. U066300 Exp. OCT 2023) and (Lot No.U2350770 Exp. JUL 2024)

**AUTHENTIC**



**COUNTERFEIT**



**Counterfeit** – The tablet, 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 Phenylephrine HCl, Chlorphenamine Maleate/ Paracetamol (Bioflu<sup>®</sup>) 10 mg/ 2 mg/ 500 mg Film-Coated Tablet (Lot No. U066300 Exp. OCT 2023) and (Lot No. U2350770 Exp. JUL 2024)

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**COUNTERFEIT**



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

Figure 3. Comparison between the secondary packaging (box) of the Authentic and Verified Counterfeit Ibuprofen/ Paracetamol (Alaxan® FR) 200 mg/ 325 mg Tablet (Lot No. 21623400 Exp. OCT 2024)

**AUTHENTIC**



**COUNTERFEIT**



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

Figure 4. Comparison between the Authentic and Verified Counterfeit Ibuprofen/ Paracetamol (Alaxan® FR) 200 mg/ 325 mg Tablet (Lot No. 21623400 Exp. OCT 2024)

**AUTHENTIC**



**COUNTERFEIT**



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

Figure 5. Comparison between the secondary packaging (box) of the Authentic and Verified Counterfeit Ibuprofen (Medical® Advance) 200 mg Softgel Capsule (Lot No. F000939 Exp. OCT. 2024)

### AUTHENTIC



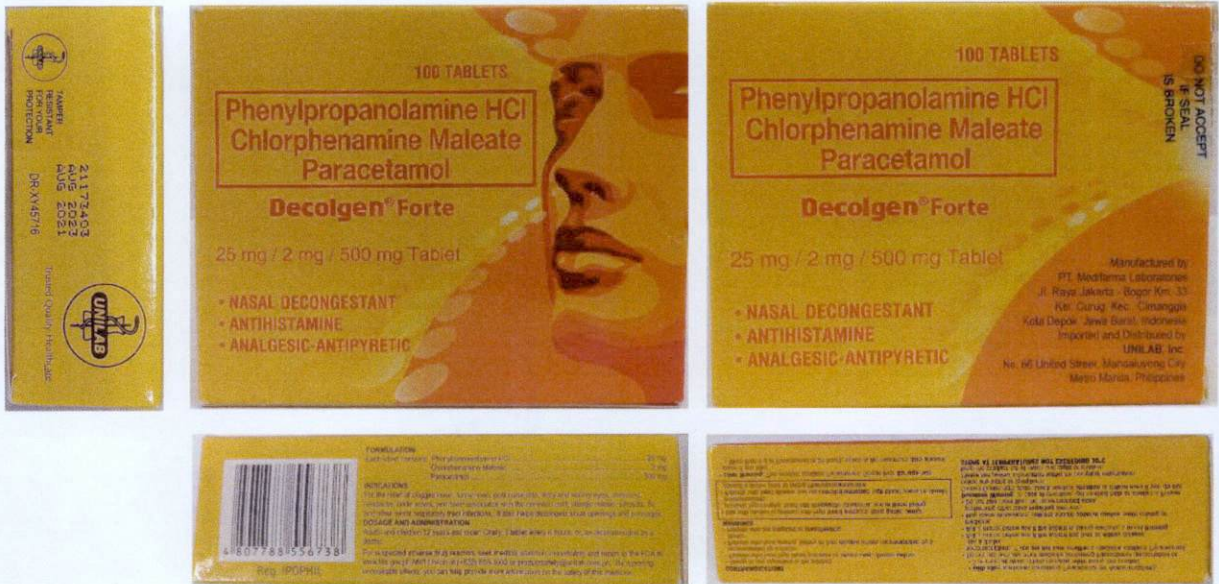
### COUNTERFEIT



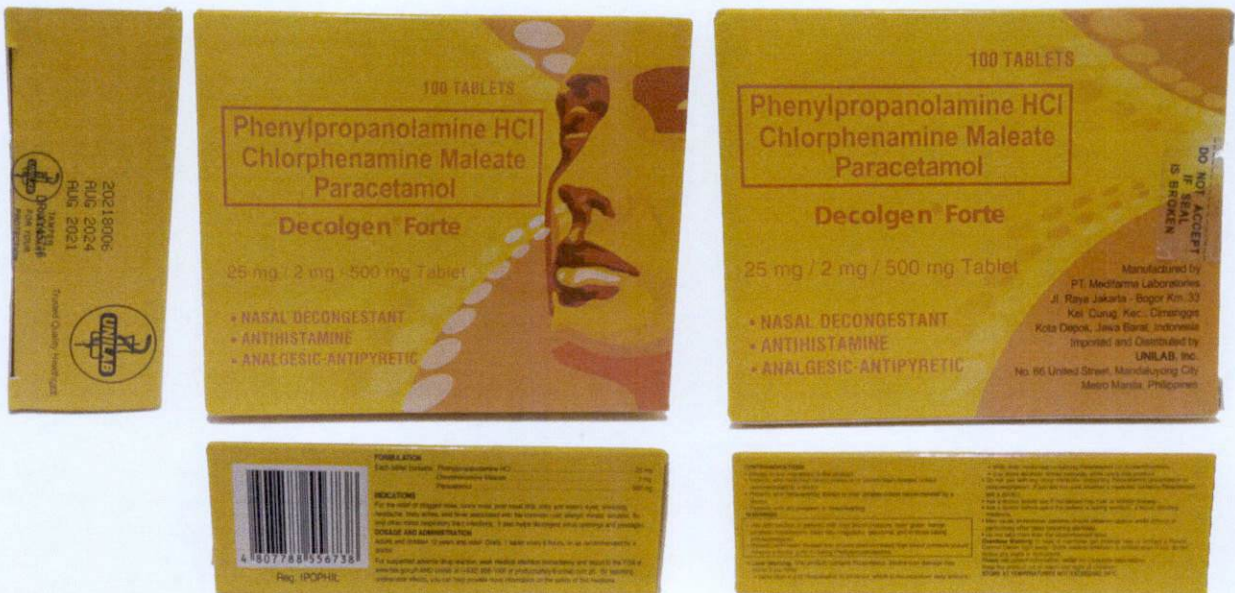
**Counterfeit** – The capsule, knurling, security mark, and print appearance are not comparable with the standard features of the registered product.

Figure 6. Comparison between the Authentic and Verified Counterfeit Ibuprofen (Medical<sup>®</sup> Advance) 200 mg Softgel Capsule (Lot No. F000939 Exp. OCT. 2024) and (Lot No. M058680 Exp. 09/2024)

**AUTHENTIC**



**COUNTERFEIT**

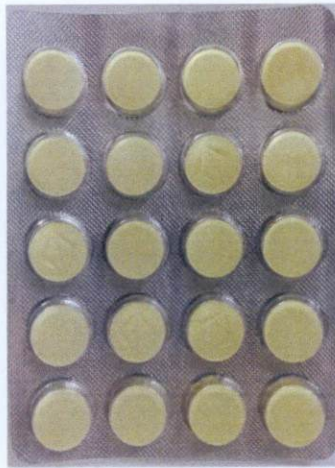


**Counterfeit** – The print appearance of the box is not comparable with the standard features of the registered product.

Figure 7. Comparison between the secondary packaging (box) of the Authentic and Verified Counterfeit Phenylpropanolamine HCl, Chlorphenamine Maleate/ Paracetamol (Decolgen® Forte) 25 mg/ 2 mg/ 500 mg Tablet (Lot No. 20218006 Exp. AUG 2024)



**AUTHENTIC**



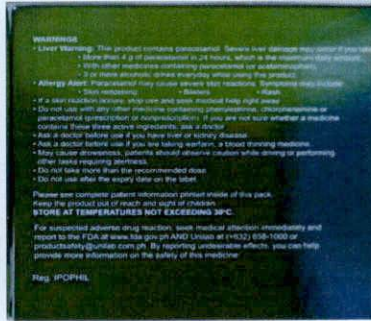
**COUNTERFEIT**



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

Figure 8. Comparison between the Authentic and Verified Counterfeit Phenylpropanolamine HCl, Chlorphenamine Maleate/ Paracetamol (Decolgen® Forte) 25 mg/ 2 mg/ 500 mg Tablet (Lot No. 20218006 Exp. AUG 2024) and (Lot. No. 22566850 Exp. AUG 2025)

## AUTHENTIC



## COUNTERFEIT



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

Figure 9. Comparison between the secondary packaging (box) of the Authentic and Verified Counterfeit Phenylephrine HCl, Chlorpheniramine Maleate/ Paracetamol (Neozep® Forte) 10 mg/ 2 mg/ 500 mg Tablet (Lot No. 25076022 Exp. Aug 2025)

**AUTHENTIC**



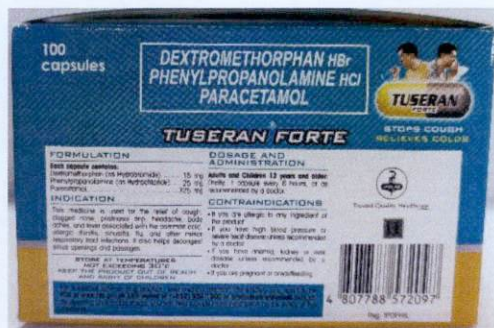
**COUNTERFEIT**



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

Figure 10. Comparison between the Authentic and Verified Counterfeit Phenylephrine HCl, Chlorphenamine Maleate/ Paracetamol (Neozep<sup>®</sup> Forte) 10 mg/ 2 mg/ 500 mg Tablet (Lot No. 25076022 Exp. Aug 2025)

**AUTHENTIC**



**COUNTERFEIT**



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

Figure 11. 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. U260785 Exp. AUG 2024)

**AUTHENTIC**



**COUNTERFEIT**



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

Figure 12. Comparison between the Authentic and Verified Counterfeit Dextromethorphan HBr/ Phenylpropranolamine HCl/ Paracetamol (Tuseran<sup>®</sup> Forte 15 mg/ 25 mg/ 325 mg Capsule (Lot No. U260785 Exp. AUG 2024) and (Lot. No. U021822 Exp. JUN 2024)

**AUTHENTIC**



**COUNTERFEIT**



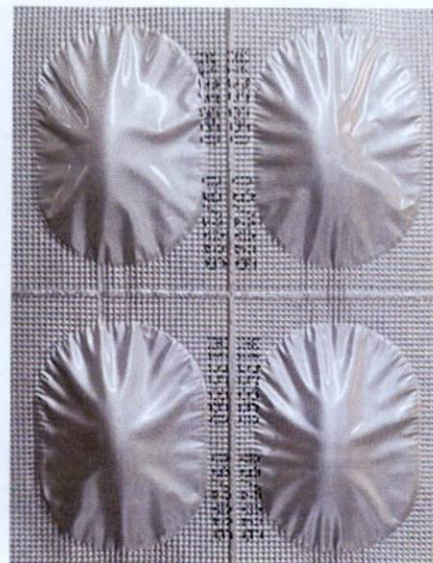
**Counterfeit** – The lot number was not manufactured by the Marketing Authorization Holder (MAH).

Figure 13. Comparison between the Authentic and Counterfeit Naproxen Sodium (Flanax<sup>®</sup> Forte) 550 mg Tablet (Lot No. TFF6L458 Exp. JUN 2024)

**AUTHENTIC**



**COUNTERFEIT**



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

Figure 14. Comparison between the Authentic and Counterfeit Mefenamic Acid (Dolifenal<sup>®</sup>) 500 mg Film-Coated Tablet (Lot No. M135860 Exp. 09/2026)

**AUTHENTIC**



**COUNTERFEIT**



**Counterfeit** – Not a legitimate product of the MAH.

Figure 15. Comparison between the Authentic and Counterfeit Mefenamic Acid (Gardan<sup>®</sup>) 500 mg Tablet (Lot No. 19143 Exp. 04/2023)



### AUTHENTIC



### COUNTERFEIT



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

Figure 16. Comparison between the Authentic and Counterfeit Loperamide (Diatabs<sup>®</sup>) 2 mg Capsule (Lot No. U022608 Exp. SEP 2026)

**AUTHENTIC**



**COUNTERFEIT**



**Counterfeit** – The lot number is not distributed by the MAH.

Figure 17. Comparison between the Authentic and Counterfeit Loperamide (Imodium<sup>®</sup>) 2 mg Capsule (Lot No. 201MC 0 Exp. OCT 2025)

**AUTHENTIC**



**COUNTERFEIT**



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

Figure 18. Comparison between the Authentic and Counterfeit d-Alpha Tocopherol [Vitamin E] (Myra e) 400 IU mg Capsule (Lot No. 0856T2 Exp. 12/2024)

**AUTHENTIC**



**COUNTERFEIT**



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

Figure 19. Comparison between the Authentic and Counterfeit Aluminum Hydroxide/ Magnesium Hydroxide/ Simeticone (Kremil-S<sup>®</sup>) 178 mg/ 233 mg/ 30 mg Chewable Tablet (Lot No. U021860 Exp. AUG 2024) and (U035433 Exp. APR 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](mailto:info@fda.gov.ph). To report continuous sale or distribution of unregistered health products, kindly e-mail us via [ereport@fda.gov.ph](mailto:ereport@fda.gov.ph), or through the online reporting facility, **eReport**, at [www.fda.gov.ph/ereport](http://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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