



FDA ADVISORY

No. ~~2022-0939~~

20 APR 2022

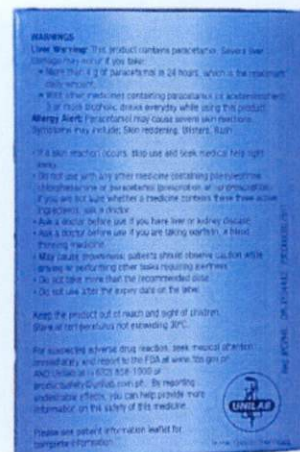
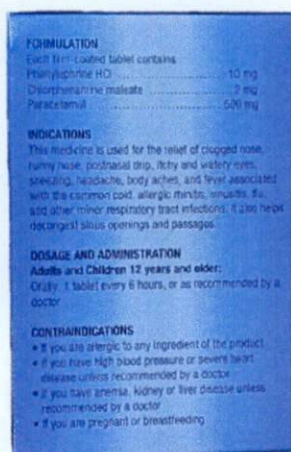
TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

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

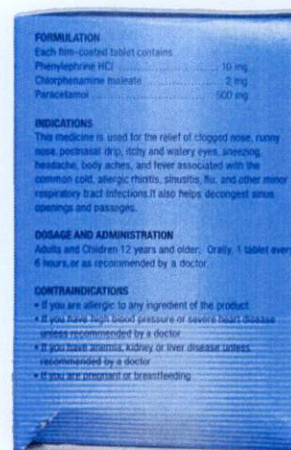
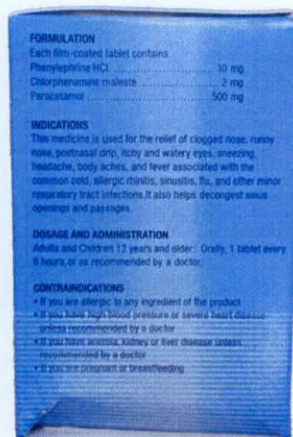
1. Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Bioflu[®]) 10 mg / 2 mg / 500 mg Film-Coated Tablet
2. Paracetamol / Caffeine (Rexidol[®] Forte) 500 mg / 65 mg Tablet
3. Ibuprofen / Paracetamol (Alaxan[®] FR) 200 mg / 325 mg Capsule
4. Naproxen Sodium (Flanax[®] Forte) 550 mg Tablet

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

AUTHENTIC



COUNTERFEIT



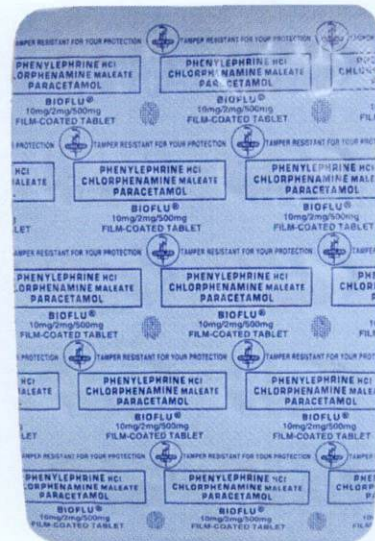
Counterfeit - The print appearance of the box is not comparable with the standard features of the registered product.

Figure 1. Comparison between the secondary packaging (box) of the Authentic and Verified Counterfeit Phenylephrine HCl, Chlorpheniramine Maleate/ Paracetamol (Bioflu[®]) 10 mg/ 2 mg/ 500 mg Film-Coated Tablet (Lot No. U118408 Exp. OCT 2023)

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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[®]) 10 mg/ 2 mg/ 500 mg Film-Coated Tablet (Lot No. U118408 Exp. OCT 2023)

AUTHENTIC



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 Paracetamol/ Caffeine (Rexidol[®] Forte) 500 mg/ 65 mg Tablet (Lot No. 20028500 Exp. MAY 2024)

AUTHENTIC



COUNTERFEIT



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

Figure 4. Comparison between the secondary packaging (box) of the Authentic and Verified Counterfeit Counterfeit Paracetamol/ Caffeine (Rexidol® Forte) 500 mg/ 65 mg Tablet (Lot No. 20028500 Exp. MAY 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/ Paracetamol (Alaxan® FR) 200 mg/ 325 mg Tablet (Lot No. 42957068 Exp. SEP 2024)

AUTHENTIC



COUNTERFEIT



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

Figure 6. Comparison between the Authentic and Verified Counterfeit Ibuprofen/ Paracetamol (Alaxan® FR) 200 mg/ 325 mg Tablet (Lot No. 42957068 Exp. SEP 2024)

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COUNTERFEIT



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

Figure 7. Comparison between the Authentic and Verified Counterfeit Naproxen Sodium (Flanax® Forte) 550 mg Tablet (Lot No. TNF8J985 Exp. AUG 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 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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