



08 FEB 2022

FDA ADVISORY
No. **2022-0134**

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

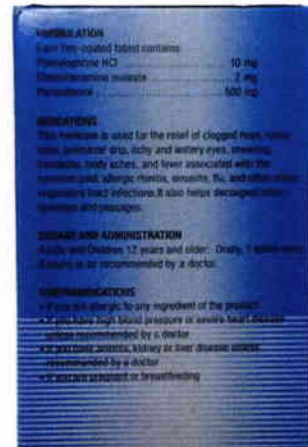
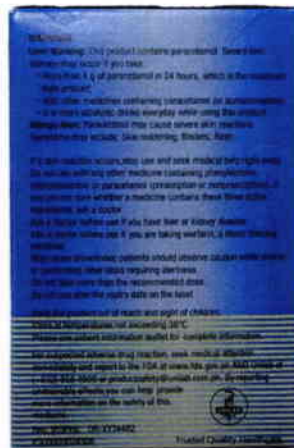
SUBJECT : Public Health Warning Against the Purchase and Use of the Verified Counterfeit Drug Product “Phenylephrine HCl/ Chlorphenamine Maleate/ Paracetamol (Bioflu®) 10 mg/ 2 mg/ 500 mg Film-Coated Tablet”

The Food and Drug Administration (FDA) advises the public against the purchase and use of the verified counterfeit drug product:

AUTHENTIC



COUNTERFEIT



Counterfeit – The print appearance of the box are 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®) 10 mg/ 2 mg/ 500 mg Film-Coated Tablet (Lot No. U056260 Expiry date SEP 2023)

AUTHENTIC



COUNTERFEIT



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

Figure 1. Comparison between the primary packaging (blister pack) of the Authentic and Verified Counterfeit Phenylephrine HCl/ Chlorphenamine Maleate/ Paracetamol (Bioflu®) 10 mg/ 2 mg/ 500 mg Film-Coated Tablet (Lot No. U056260 Expiry date SEP 2023)

All healthcare professionals and the general public are hereby warned as to the availability of this counterfeit drug product in the market which pose potential danger or injury to consumers. Consumers are also reminded to purchase drug product only from FDA-licensed establishments.

Likewise, all establishments and outlets are hereby warned against selling and/or dispensing of the said counterfeit product 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 product 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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