



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2022-0621**

21 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 Hydrochloride / Chlorphenamine Maleate / Paracetamol (Bioflu®) 10 mg / 2 mg / 500 mg Film-Coated Tablet 100's**
- 2. Paracetamol (Biogesic®) 500 mg Tablet 100's**

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

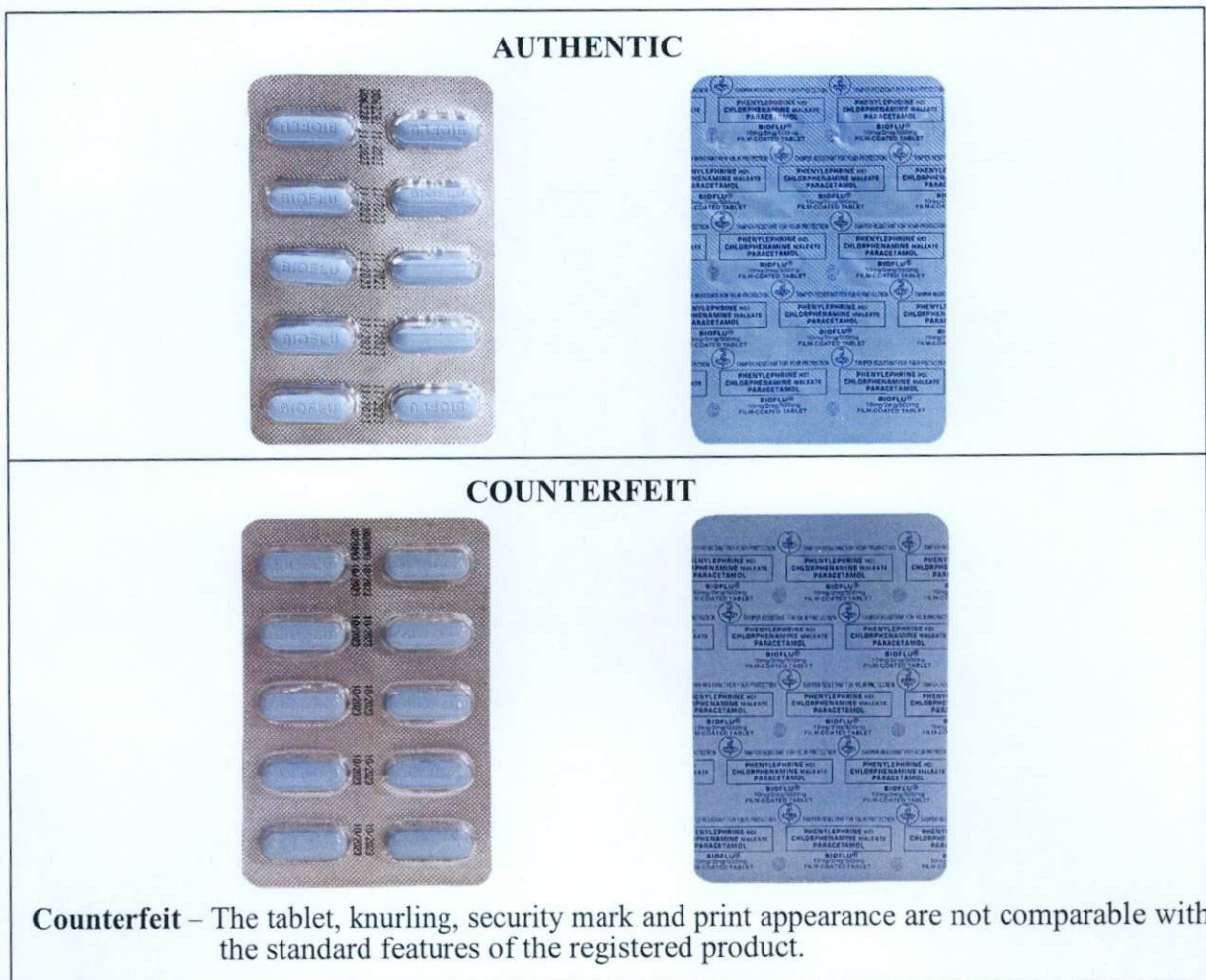


Figure 1. Comparison between the Authentic and Verified Counterfeit Phenylephrine Hydrochloride / Chlorphenamine Maleate / Paracetamol (Bioflu®) 10 mg / 2 mg / 500 mg Film-Coated Tablet 100's (Lot No. U028893)




AUTHENTIC



WARNINGS:
Liver Warning: This product contains paracetamol. Severe liver damage may occur if you take:
 • More than 4 g of paracetamol in 24 hours, which is the maximum daily amount.
 • With other medicines containing paracetamol (or acetaminophen) or more alcoholic drinks everyday while using this product.
Allergy Alert: Paracetamol may cause severe skin reactions. Symptoms may include: Skin reddening, Blisters, Rash.
 • If a skin reaction occurs, stop use and seek medical help right away.
 • Do not use with any other medicine containing phenylephrine, chlorpheniramine or paracetamol (prescription or nonprescription). If you are not sure whether a medicine contains these three active ingredients, ask a doctor.
 • Ask a doctor before use if you have liver or kidney disease.
 • Ask a doctor before use if you are taking warfarin, a blood thinning medicine.
 • May cause drowsiness; patients should observe caution while driving or performing other tasks requiring alertness.
 • Do not take more than the recommended dose.
 • Do not use after the expiry date on the label.
 Keep the product out of reach and sight of children.
 Store at temperatures not exceeding 30°C.
 For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 558-1000 or product.safety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.
 Please see patient information leaflet for complete information.

Reg. 2018, DR 103482, PHARMACIST


Trusted Quality Healthcare

FORMULATION
 Each film-coated tablet contains:
 Phenylephrine HCl 10 mg
 Chlorpheniramine maleate 2 mg
 Paracetamol 500 mg

INDICATIONS
 This medicine is used for the relief of clogged nose, runny nose, postnasal drip, itchy and watery eyes, sneezing, headache, body aches, and fever associated with the common cold, allergic rhinitis, sinusitis, flu, and other minor respiratory tract infections. It also helps decongest sinus openings and passages.

DOSAGE AND ADMINISTRATION
Adults and Children 12 years and older:
 Orally, 1 tablet every 6 hours, or as recommended by a doctor.

CONTRAINDICATIONS
 • If you are allergic to any ingredient of the product
 • If you have high blood pressure or severe heart disease unless recommended by a doctor
 • If you have anemia, kidney or liver disease unless recommended by a doctor
 • If you are pregnant or breastfeeding

COUNTERFEIT



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 Reg. 2018, DR 103482
 2-202303128508
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 • If you are pregnant or breastfeeding

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

Figure 2. Comparison between the Authentic and Verified Counterfeit Phenylephrine Hydrochloride / Chlorpheniramine Maleate / Paracetamol (Bioflu®) 10 mg / 2 mg / 500 mg Film-Coated Tablet 100's (Lot No. U028893)

AUTHENTIC



COUNTERFEIT



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

Figure 3. Comparison between the Authentic and Verified Counterfeit Paracetamol (Biogesic®) 500 mg Tablet 100's (Lot No. 21203226)

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.

Dissemination of the information to all concerned is requested.


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

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