

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY Nor 2023-2526 1 3 DEC 2023

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. Paracetamol (Biogesic) 500 mg Tablet
- 2. Ibuprofen + Paracetamol (Alaxan® FR) 200 mg/ 325 mg Capsule
- 3. Phenylephrine HCl + Chlorphenamine Maleate + Paracetamol (Bioflu®) 10 mg/ 2 mg/ 500 mg Film-Coated Tablet
- 4. Dextromethorphan HBr + Phenylpropanolamine HCl + Paracetamol (Tuseran® Forte) 15 mg/ 25 mg/ 325 mg Capsule
- 5. Phenylpropanolamine hydrochloride + Chlorphenamine Maleate + Paracetamol (Decolgen® Forte) 25 mg/ 2 mg/ 500 mg Tablet

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



TÜVRhei

Management System ISO 9001:2015

WWW.tuv.com





COUNTERFEIT



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

Figure 1. Comparison between the Authentic and Counterfeit Paracetamol (Biogesic) 500 mg Tablet (Lot No.: 22237901)





COUNTERFEIT





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

Figure 2. Comparison between the Authentic and Counterfeit Ibuprofen + Paracetamol (Alaxan® FR) 200 mg/ 325 mg Capsule (Lot No.: 31258448)





COUNTERFEIT





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

Figure 3. Comparison between the Authentic and Counterfeit Phenylephrine HCl + Chlorphenamine Maleate + Paracetamol (Bioflu®) 10 mg/ 2 mg/ 500 mg Film-Coated Tablet





COUNTERFEIT





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

Figure 4. Comparison between the Authentic and Counterfeit Dextromethorphan HBr + Phenylpropanolamine HCl + Paracetamol (Tuseran® Forte) 15 mg/ 25 mg/ 325 mg Capsule (Lot No.: U063975)





COUNTERFEIT





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

Figure 5. Phenylpropanolamine HCl + Chlorphenamine Maleate + Paracetamol (Decolgen® Forte) 25 mg/ 2 mg/ 500 mg Tablet (Lot No.: 20218006)

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 products 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 <a href="mailto: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.

DTN:

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