

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No: 20220008 1 2 JAN 2022

TO

ALL HEALTHCARE PROFESSIONALS AND THE GENERAL

PUBLIC

SUBJECT

Public Health Warning Against the Purchase and Use of the

Verified Counterfeit Drug Product "Phenylpropanolamine HCl/ 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 verified counterfeit drug product:

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COUNTERFEIT Phenylpropanolamine HC renylpropanolamine HC Chlorphenamine Maleate Chlorphenamine Maleate Decolgen° Forte Decolgen Forte HASAU DECONGESTANT HASAL DECONGESTANT ANALGESIC-ANTIPYRETIC DR-XY45716

Figure 1. 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. 20628132 Expiry date JUN 2023)

Counterfeit – Print appearance of the box are not comparable with the standard features of the

registered product.

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COUNTERFEIT





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

Figure 2. Comparison between the secondary packaging (Blister pack) of the Authentic and Verified Counterfeit Phenylpropanolamine HCl/ Chlorphenamine Maleate/ Paracetamol (Decolgen® Forte) 25 mg/ 2 mg/ 500 mg Tablet (Lot no. 20200916 Expiry date SEP 2022)

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 products 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 manufacture, 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 this product is 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 report@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.

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

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