

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



2 8 MAR 2022

FDA ADVISORY No. **2022**0678

TO

: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT:

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

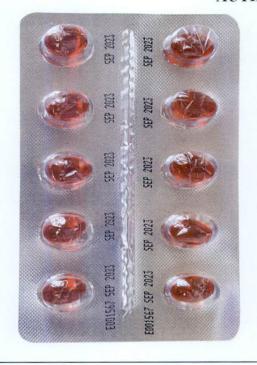
- 1. Ibuprofen (Medicol®Advance) 200 mg Softgel Capsule
- 2. Mefenamic Acid (Gardan®) 500 mg Tablet
- 3. Phenylpropanolamine HCl / Chlorphenamine Maleate / Paracetamol (Decolgen®Forte) 25mg/ 2 mg/ 500 mg
- 4. Ibuprofen/ Paracetamol (Alaxan®FR) 200 mg / 325 mg Capsule
- 5. Phenylephrine HCl / Chlorphenamine 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 counterfeit version of the following products:



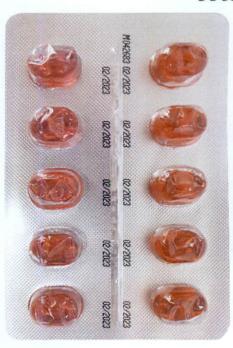
Website: www.fda.gov.ph

Email: info@fda.gov.ph





COUNTERFEIT





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

Figure 1. Comparison between the Authentic and Verified Counterfeit Ibuprofen (Medicol®Advance) 200 mg Softgel Capsule (Lot No. M042683)

AUTHENTIC MEFENAMIC ACID MEFENAMIC ACID GARDAN® SANOFIS SANOFI MEFENAMIC ACID MEFENAMIC ACID GARDAN SANOFI SANOFIS MEFENAMIC ACID MEFENAMIC ACID GARDAN 500 mg Film-coated Tablet GARDAN SANOFI SANOFI MEFENAMIC ACID MEFENAMIC ACID SANOFI SANOFI MEFENAMIC ACID MEFENAMIC ACID SANOFIS SANOFI MEFENAMIC ACID MEFENAMIC ACID GARDAN See mg Film control fables See mg Film control fa SANOFI SANOFI 3 COUNTERFEIT MEFENAMIC ACID GARDAN* 500 mg Tablet MEFENAMIC ACID /2023 500 mg Tablet sanofi aventis sanofi aventis MEFENAMIC ACID MEFENAMIC ACID GARDAN® 500 mg Tablet 500 mg Tablet sanofi aventis MEFENAMIC ACID MEFENAMIC ACID 500 mg Tablet 500 mg Tablet sanofi aventis sanofi aventis MEFENAMIC ACID MEFENAMIC ACID anofi aventis MEFENAMIC ACID GARDAN® 500 mg Tablet MEFENAMIC ACID MEFENAMIC ACID MEFENAMIC ACID

Figure 2. Comparison between the Authentic and Verified Counterfeit Mefenamic Acid (Gardan®) 500 mg Tablet (Lot No. 19070)

Counterfeit - The lot no. was not manufactured by the Marketing Authorization Holder

(MAH)





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 Phenylpropanolamine HCl/ Chlorphenamine Maleate/ Paracetamol (Decolgen®Forte) 25 mg/2 mg/500 mg Tablet (Lot No. 20200916)





COUNTERFEIT





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

Figure 4. Comparison between the Authentic and Verified Counterfeit Ibuprofen/ Paracetamol (Alaxan® FR) 200 mg / 325 mg Capsule (Lot No. 35720384)





COUNTERFEIT





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

Figure 5. Comparison between the Authentic and Verified Counterfeit Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Bioflu®) 10 mg / 2 mg / 500 mg Film-Coated Tablet (Lot No. U285070)

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 <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

DTN:

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