



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



19 MAY 2022

FDA ADVISORY
No. **2022-1081**

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
2. Loperamide (Diatabs®) 2 mg Capsule
3. Ibuprofen/ Paracetamol (Alaxan® FR) 200 mg / 325 mg Capsule
4. Dextromethorphan HBr/ Phenylpropanolamine HCl/ Paracetamol (Tuseran® Forte) 15 mg / 25 mg / 325 mg Capsule 100's
5. Phenylpropanolamine HCl/ Chlorphenamine Maleate/ Paracetamol (Decolgen® Forte) 25 mg / 2 mg / 500 mg Tablet 100's

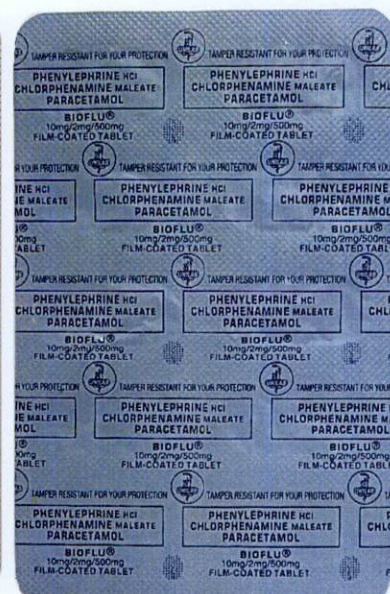
The Food and Drug Administration (FDA) advises the public against the purchase and use of the counterfeit version of the following products:



AUTHENTIC



COUNTERFEIT



Counterfeit – The tablet, 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 Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Bioflu®) 10 mg / 2 mg / 500 mg Film-Coated Tablet (Lot No. U028339, U026008)

AUTHENTIC



COUNTERFEIT



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

Figure 2. Comparison between the Authentic and Verified Counterfeit Loperamide (Diatabs®) 2 mg Capsule (Lot No. U029560)

AUTHENTIC



COUNTERFEIT



Counterfeit – The capsule, 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 Ibuprofen/ Paracetamol (Alaxan® FR) 200 mg / 325 mg Capsule (Lot No. 40379275)

AUTHENTIC



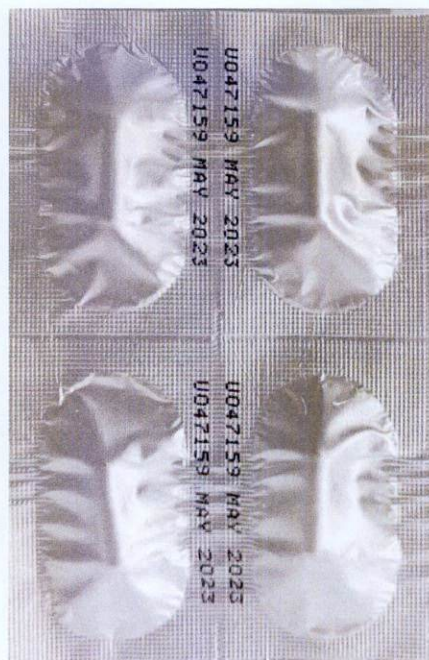
COUNTERFEIT



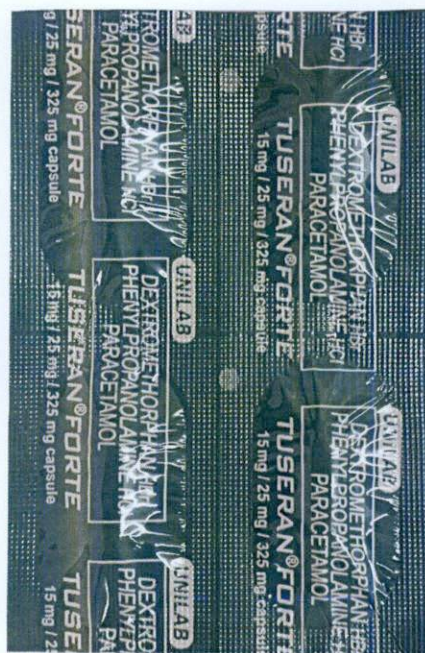
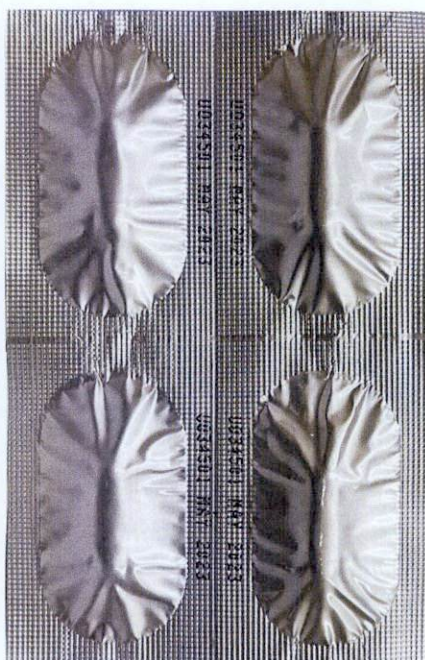
Counterfeit – The box is comparable with the standard features of the registered product.

Figure 4. Comparison between the Authentic and Verified Counterfeit Dextromethorphan HBr/ Phenylpropanolamine HCl/ Paracetamol (Tuseran® Forte) 15 mg / 25 mg / 325 mg Capsule 100's (Lot No.U034501)

AUTHENTIC



COUNTERFEIT



Counterfeit – The 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 Dextromethorphan HBr/ Phenylpropanolamine HCl/ Paracetamol (Tuseran® Forte) 15 mg / 25 mg / 325 mg Capsule 100's (Lot No.U034501)

AUTHENTIC

100 TABLETS

**Phenylpropanolamine HCl
Chlorphenamine Maleate
Paracetamol**

Decolgen® Forte

25 mg / 2 mg / 500 mg Tablet

- NASAL DECONGESTANT
- ANTIHISTAMINE
- ANALGESIC-ANTIPYRETIC

Manufactured by
PT. Medifarma Laboratories
Jl. Raya Jakarta - Bogor Km. 33
Kel. Curug, Kec. Cimanggis
Kota Depok, Jawa Barat, Indonesia
Imported and Distributed by
UNILAB, Inc.
No. 66 United Street, Mandaluyong City
Metro Manila, Philippines

DO NOT ACCEPT
IF SEAL
IS BROKEN

CONTRAINDICATIONS

- Allergy to any ingredient in the product
- Patients who have high blood pressure or severe heart disease unless recommended by a doctor
- Patients who have asthma, kidney or liver disease unless recommended by a doctor
- Patients who are pregnant or breastfeeding

WARNINGS

- Use with caution in patients with high blood pressure, heart failure, benign prostatic hypertrophy, heart rate irregularity, glaucoma, and in those taking antidepressants
- Patients with heart disease and uncontrolled/unstable high blood pressure should consult a doctor prior to taking Phenylpropanolamine
- **User 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
 • 3 or more alcoholic drinks everyday while using this product
 • Do not use with any other medicine containing Paracetamol (acetaminophen or paracetamol). If you are not sure whether a medicine contains Paracetamol, ask a doctor
 • Ask a doctor before use if the patient has liver or kidney disease
 • Ask a doctor before use if the patient is 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
Overdose Warning: In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical even if you do not notice any signs or symptoms.
 Please see patient information leaflet for complete information
 Keep the product out of reach and sight of children
STORE AT TEMPERATURES NOT EXCEEDING 30°C

FORMULATION

Each tablet contains:	Phenylpropanolamine HCl	25 mg
	Chlorphenamine Maleate	2 mg
	Paracetamol	500 mg

INDICATIONS

For the relief of congested nose, runny nose, post nasal drip, itchy and watery eyes, sneezing, headache, body aches, and fever associated with the common cold, allergy, 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.

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 856-1000 or product.safety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

Reg. IPOPHIL

COUNTERFEIT

100 TABLETS

**Phenylpropanolamine HCl
Chlorphenamine Maleate
Paracetamol**

Decolgen® Forte

25 mg / 2 mg / 500 mg Tablet

- NASAL DECONGESTANT
- ANTIHISTAMINE
- ANALGESIC-ANTIPYRETIC

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- Patients who have high blood pressure or severe heart disease unless recommended by a doctor
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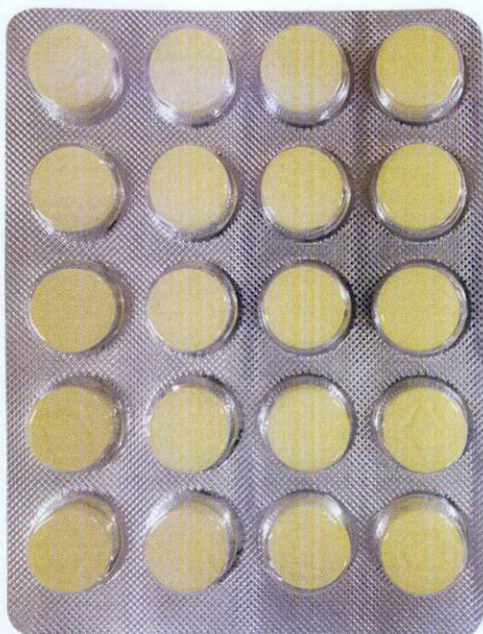
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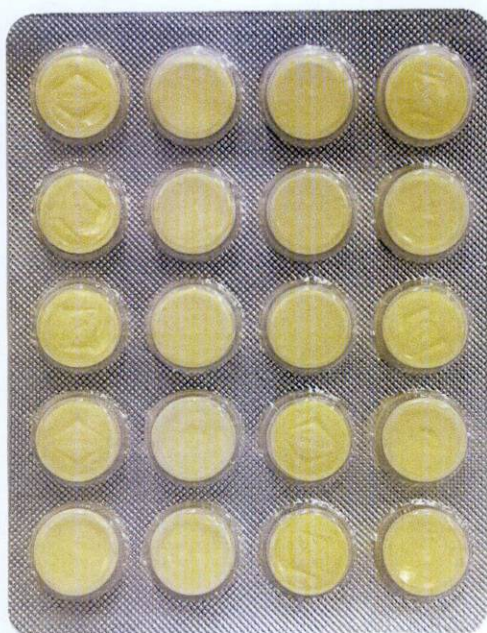
Counterfeit – The box is comparable with the standard features of the registered product.

Figure 6. Comparison between the Authentic and Verified Counterfeit Phenylpropanolamine HCl/ Chlorphenamine Maleate/ Paracetamol (Decolgen® Forte) 25 mg / 2 mg / 500 mg Tablet (Lot No. 21507865)

AUTHENTIC



COUNTERFEIT



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

Figure 7. Comparison between the Authentic and Verified Counterfeit Phenylpropanolamine HCl/ Chlorphenamine Maleate/ Paracetamol (Decolgen® Forte) 25 mg / 2 mg / 500 mg Tablet (Lot No. 21507865)


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 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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