



07 SEP 2021

FDA ADVISORY
No. **2021-2263**

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. Carbocisteine (Solmux®) 500 mg Capsule
2. Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Bioflu®) 10 mg/2 mg/500 mg Film-Coated Tablet
3. Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Neozep® Forte) 10 mg/2 mg/500 mg Tablet
4. Loperamide (Diatabs®) 2 mg Capsule
5. Mefenamic Acid (Dolfenal®) 500 mg Film-Coated Tablet
6. Paracetamol (Biogesic®) 500 mg Tablet
7. Aluminum Hydroxide / Magnesium Hydroxide / Simeticone (Kremil-S®) 178 mg / 233 mg / 30 mg Chewable Tablet
8. Ibuprofen (Medicol® Advance) 200 mg Softgel Capsule
9. Hyoscine N-butylbromide (Buscopan®) 10 mg Tablet
10. Ibuprofen / Paracetamol (Alaxan® FR) 200 mg / 325 mg Capsule
11. Meclizine HCl (Bonamine*) 25 mg Chewable Tablet
12. Loperamide HCl (Lomotil®) 2 mg Tablet
13. Dexamethasone (Decilone® Forte) 4 mg Tablet
14. Loperamide (Imodium) 2 mg Capsule



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 Counterfeit Carbocisteine (Solmux®) 500mg Capsule (Lot nos. U089512, U182208, and U011221)

AUTHENTIC



COUNTERFEIT



Counterfeit – Logo, security mark, knurling, print color and appearance are different from standard.

Figure 2. Comparison between the Authentic and Counterfeit Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Bioflu®) 10 mg/2 mg/500 mg Film-Coated Tablet (Lot nos. U091223 and U201710)

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COUNTERFEIT



Counterfeit – Logo, security mark, knurling, print color and appearance are different from standard.

Figure 3. Comparison between the Authentic and Counterfeit Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Neozep® Forte) 10 mg/2 mg/500 mg Tablet (Lot nos. 13127758 and 20110411)

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COUNTERFEIT



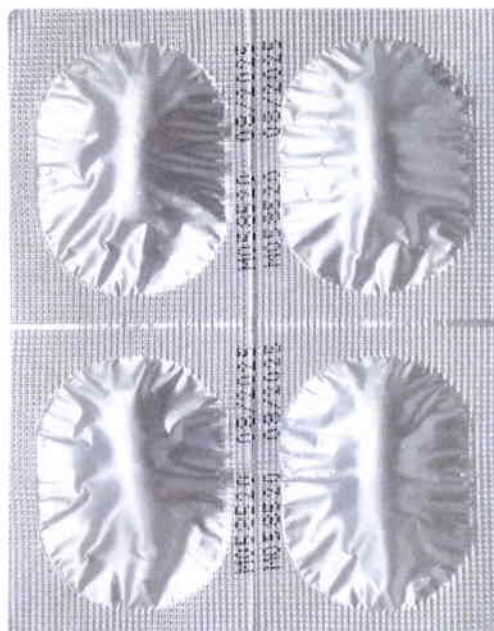
Counterfeit – Logo, security mark, knurling, print color and appearance are different from standard.

Figure 4. Comparison between the Authentic and Counterfeit Loperamide (Diatabs®) 2 mg Capsule (Lot nos. U032570, U113766, and U092468)

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COUNTERFEIT



Counterfeit – Logo, security mark, knurling, print color and appearance are different from standard.

Figure 5. Comparison between the Authentic and Counterfeit Mefenamic Acid (Dolifenal[®]) 500 mg Film-Coated Tablet (Lot no. M058520)

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COUNTERFEIT



Counterfeit – Logo, security mark, knurling, print color and appearance are different from standard.

Figure 6. Comparison between the Authentic and Counterfeit Paracetamol (Biogesic®) 500 mg Tablet (Lot no. 25180922)

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Counterfeit – Logo, security mark, knurling, print color and appearance are different from standard.

Figure 7. Comparison between the Authentic and Counterfeit Aluminum Hydroxide / Magnesium Hydroxide / Simeticone (Kremil-S®) 178 mg/ 233 mg/ 30 mg Chewable Tablet (Lot no. U020639)

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COUNTERFEIT



Counterfeit – Logo, security mark, knurling, print color and appearance are different from standard.

Figure 8. Comparison between the Authentic and Counterfeit Ibuprofen (Medical® Advance) 200 mg Softgel Capsule (Lot no. M073688)

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COUNTERFEIT



Counterfeit – Logo, security mark, knurling, print color and appearance are different from standard.

Figure 9. Comparison between the Authentic and Counterfeit Hyoscine N-butylbromide (Buscopan®) 10 mg Tablet (Batch no. 20030194)

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COUNTERFEIT



Counterfeit – Logo, security mark, knurling, print color and appearance are different from standard.

Figure 10. Comparison between the Authentic and Counterfeit Ibuprofen / Paracetamol (Alaxan® FR) 200 mg / 325 mg Capsule (Lot No.: 18011951)

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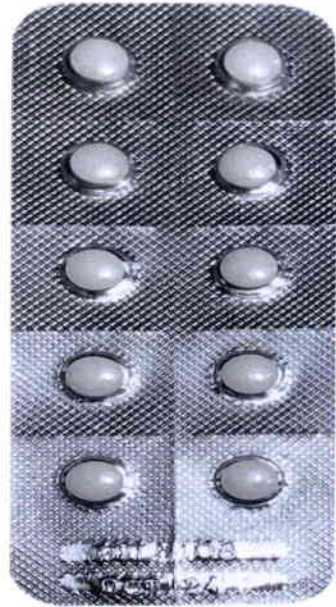
COUNTERFEIT



Counterfeit – Logo, security mark, knurling, print color and appearance are different from standard.

Figure 11. Comparison between the Authentic and Counterfeit Meclizine HCl (Bonamine*) 25 mg Chewable Tablet (Lot No.: 19322)

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Counterfeit – Logo, security mark, knurling, print color and appearance are different from standard.

Figure 12. Comparison between the Authentic and Counterfeit Loperamide HCl (Lomotil®) 2 mg Tablet (Lot No.: 19LMT06)

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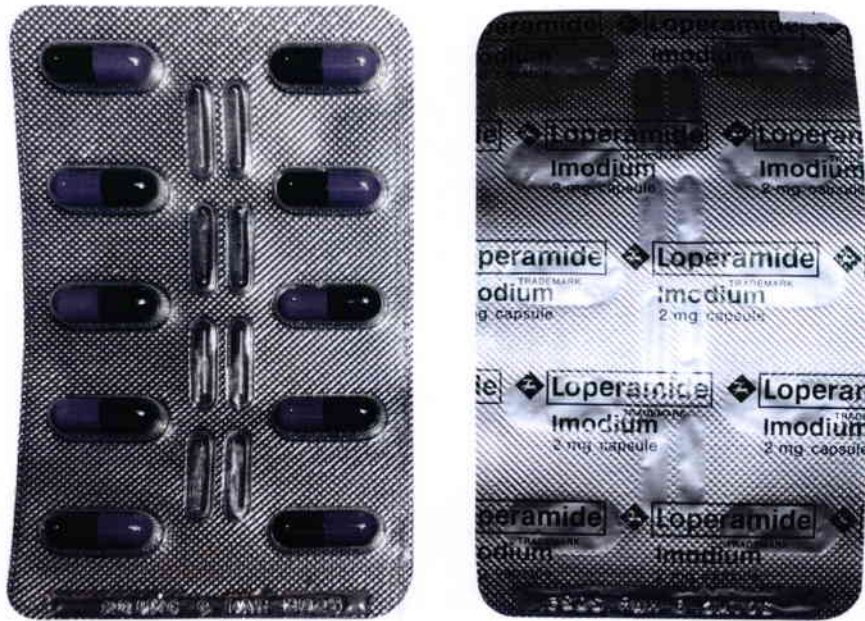
COUNTERFEIT



Counterfeit – Logo, security mark, knurling, print color and appearance are different from standard.

Figure 13. Comparison between the Authentic and Counterfeit Dexamethasone (Decilone® Forte) 4 mg Tablet (Lot No.: A019730)

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Counterfeit – Logo, security mark, knurling, print color and appearance are different from standard.

Figure 14. Comparison between the Authentic and Counterfeit Loperamide (Imodium) 2 mg Capsule (Lot No.: 19IMC-8)

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 report@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.


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Director General

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