Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

28 MAR 2022

FDA ADVISORY
No. 2022-0677

TO : **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

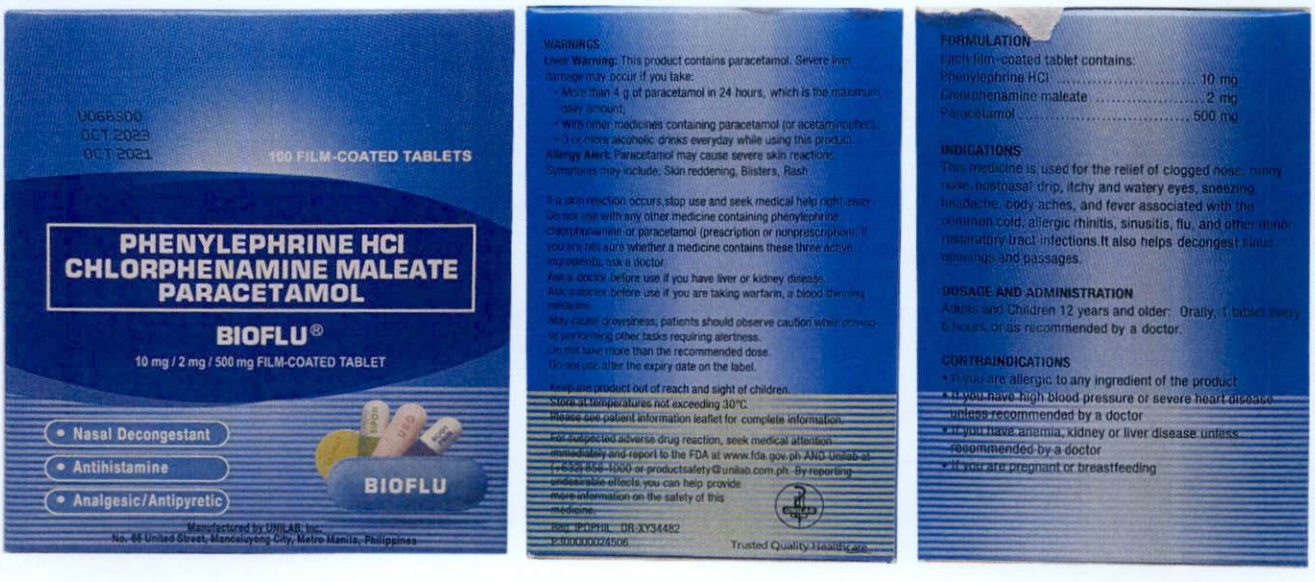
SUBJECT : **Public Health Warning Against the Purchase and Use of the following Verified Counterfeit Drug Products:**

1. **Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Bioflu®) 10 mg / 2 mg / 500 mg Tablet**
2. **Dextromethorphan HBr / Phenylpropanolamine HCl / Paracetamol (Tuseran® Forte) 15 mg/ 25 mg/ 325 mg**
3. **Carbocisteine (Solmux®) 500 mg Capsule**
4. **Mefenamic Acid (Dolfenal®) 500 mg Film-Coated Tablet**
5. **Aluminum Hydroxide / Magnesium Hydroxide / Simeticone (Kremil-S®) 178 mg / 233 mg / 30 mg Chewable Tablet**
6. **Loperamide (Diatabs®) 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:

AUTHENTIC

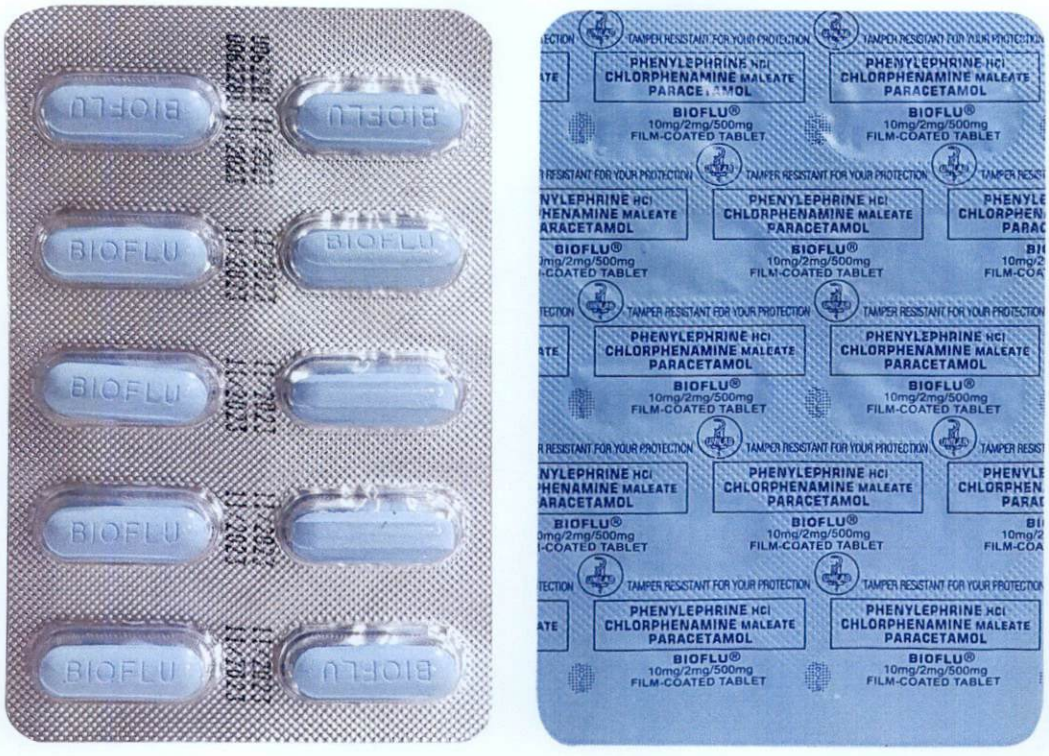
COUNTERFEIT



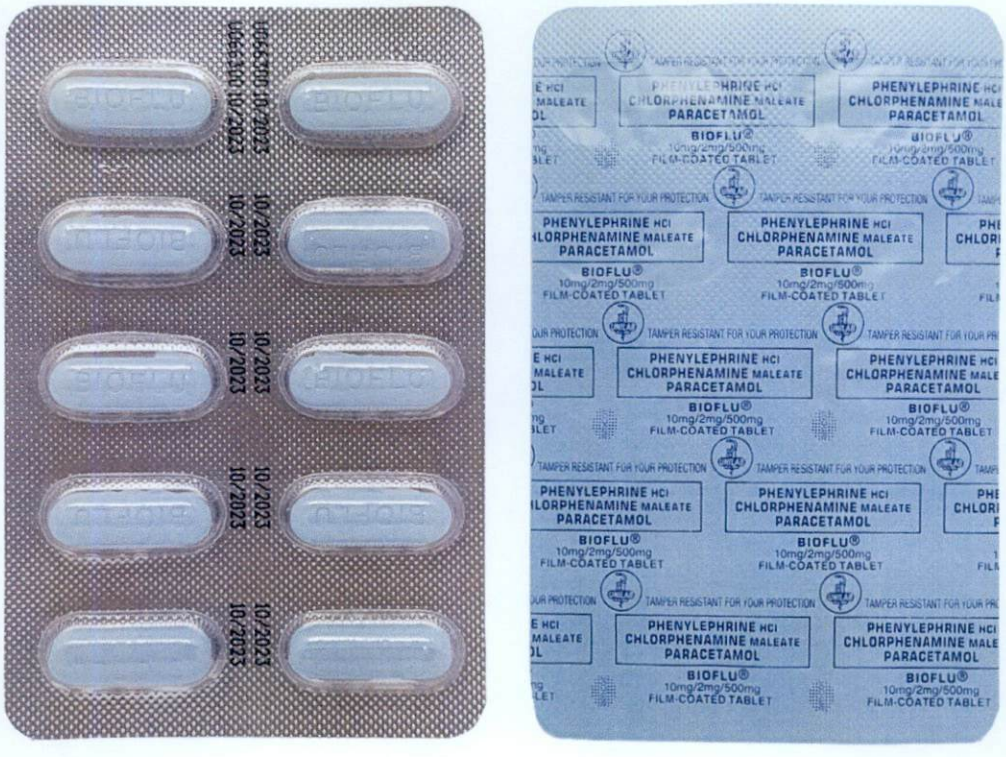
Counterfeit – Print appearance of the box is not comparable with the standard features of the registered product.

Figure 1. Comparison between the Authentic and Counterfeit Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Bioflu®) 10 mg / 2 mg / 500 mg Tablet (Lot No. U066300)

AUTHENTIC



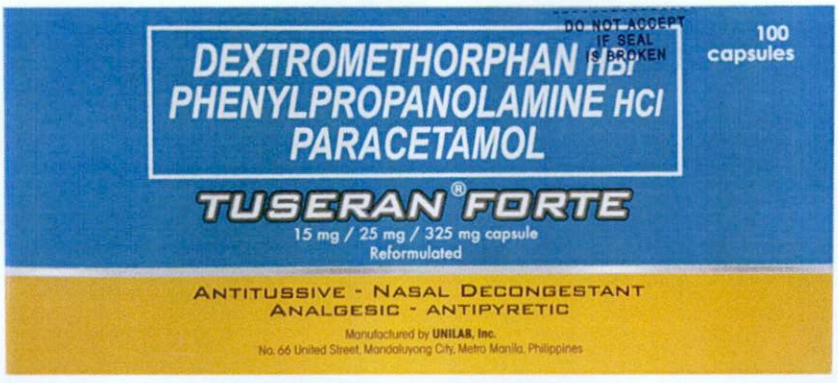
COUNTERFEIT

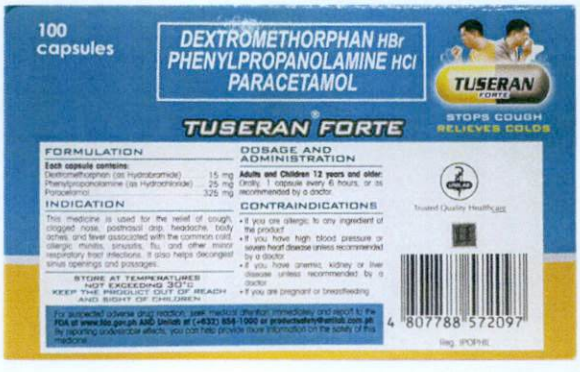


Counterfeit – The tablet, knurling, security mark and print appearance are not comparable with the registered product.

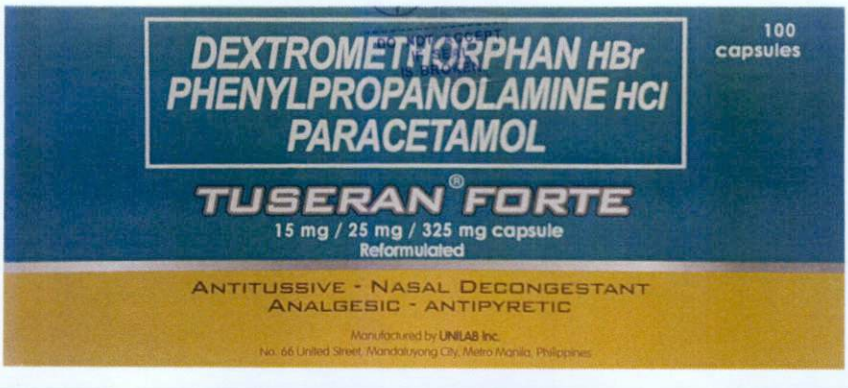
Figure 2. Comparison between the Authentic and Counterfeit Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Bioflu®) 10 mg / 2 mg / 500 mg Tablet (Lot No. U066300)

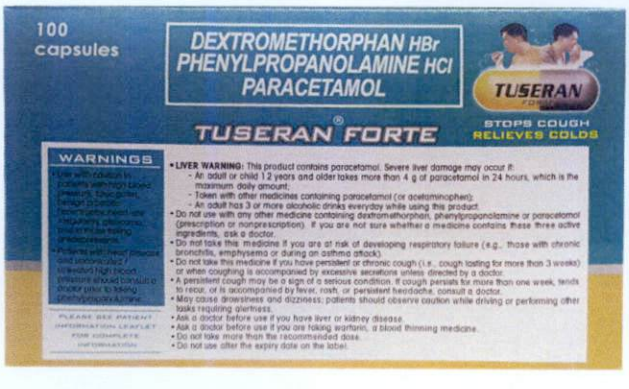
AUTHENTIC





COUNTERFEIT

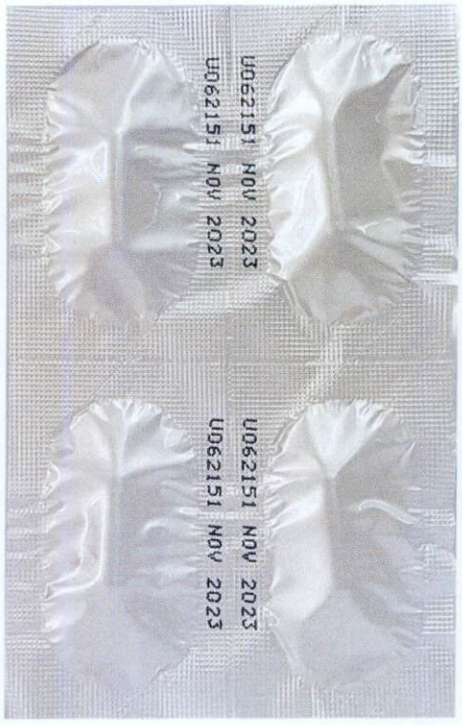


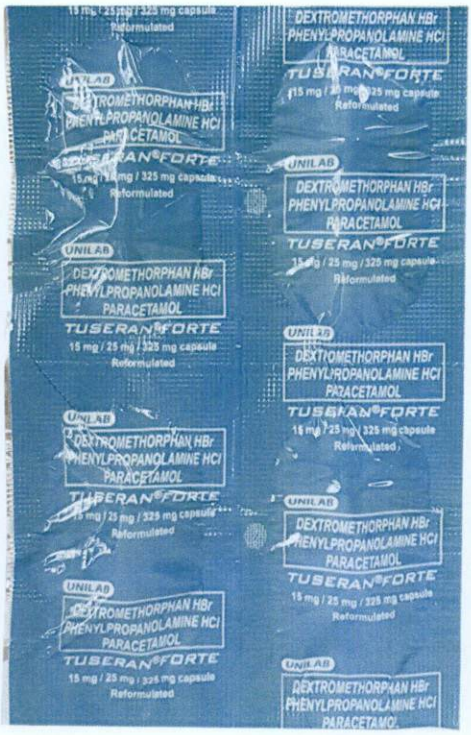


Counterfeit – Print appearance of the box is not comparable with the standard features of the registered product.

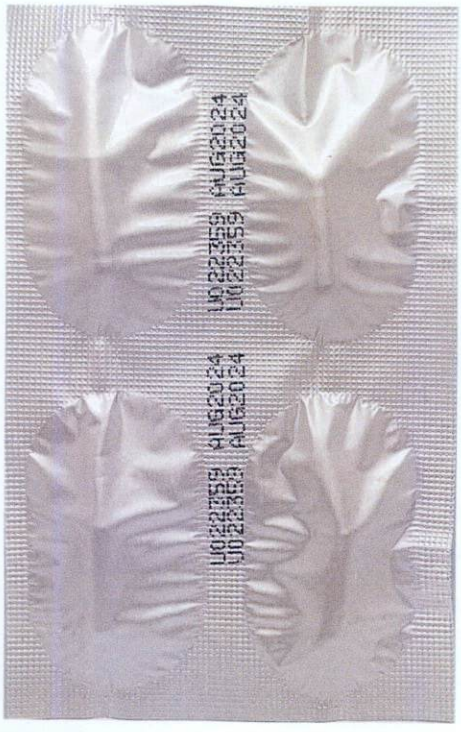
Figure 3. Comparison between the Authentic and Counterfeit Dextromethorphan HBr / Phenylpropanolamine HCl / Paracetamol (Tuseran® Forte) 15 mg/ 25 mg/ 325 mg Capsule (Lot No. U022359)

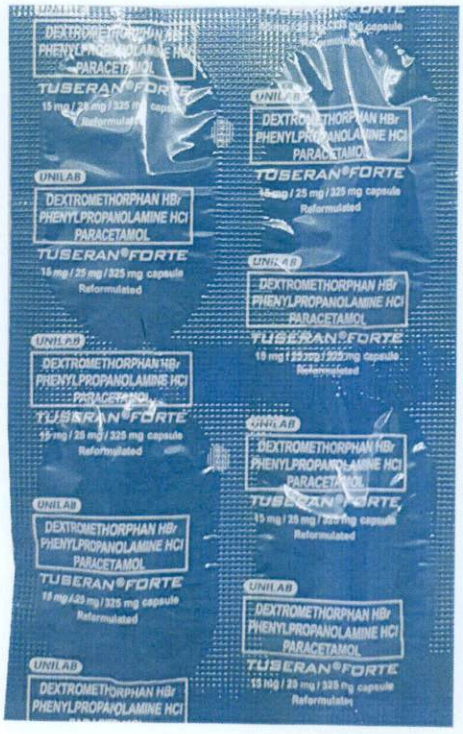
AUTHENTIC





COUNTERFEIT

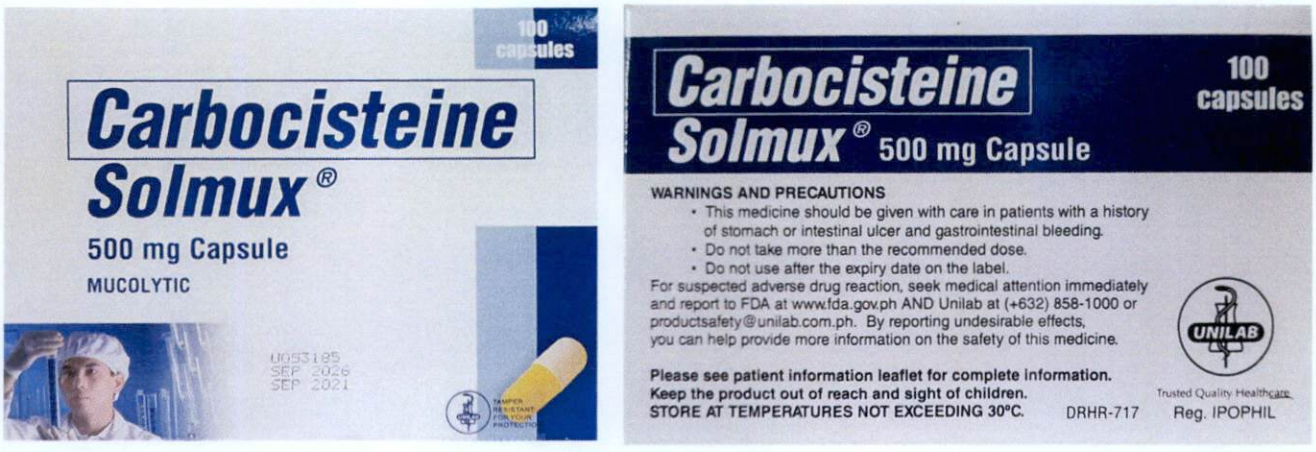




Counterfeit – The knurling, and print appearance of the strip are not comparable with the registered product.

Figure 4. Comparison between the Authentic and Counterfeit Dextromethorphan HBr / Phenylpropanolamine HCl / Paracetamol (Tuseran® Forte) 15 mg/ 25 mg/ 325 mg Capsule (Lot No. U022359)

AUTHENTIC

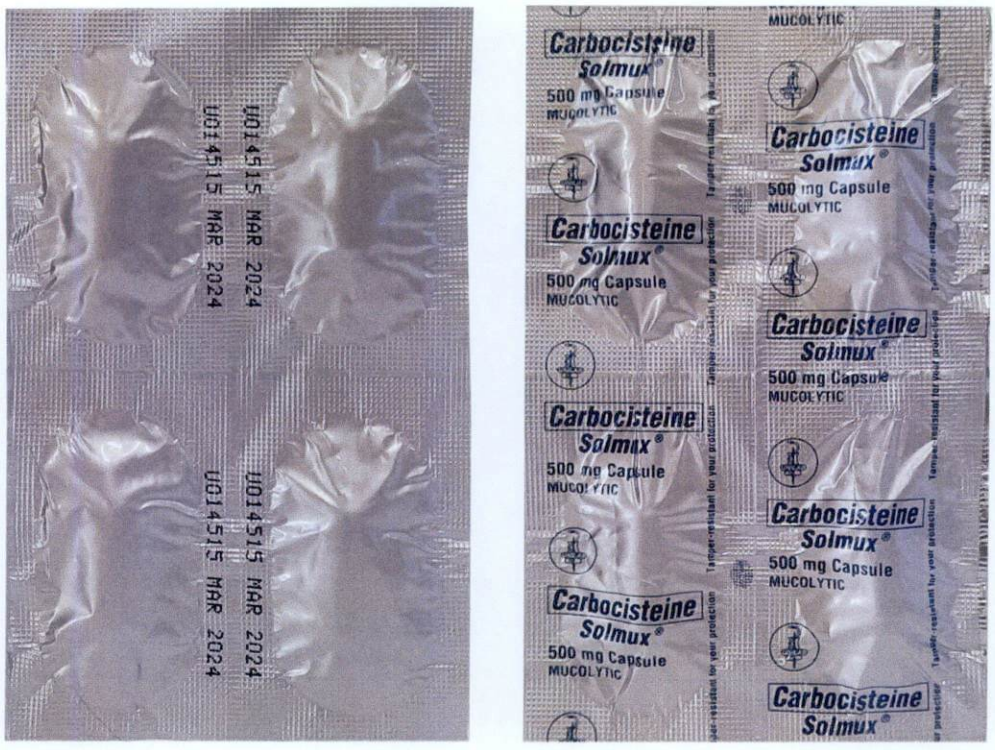


COUNTERFEIT

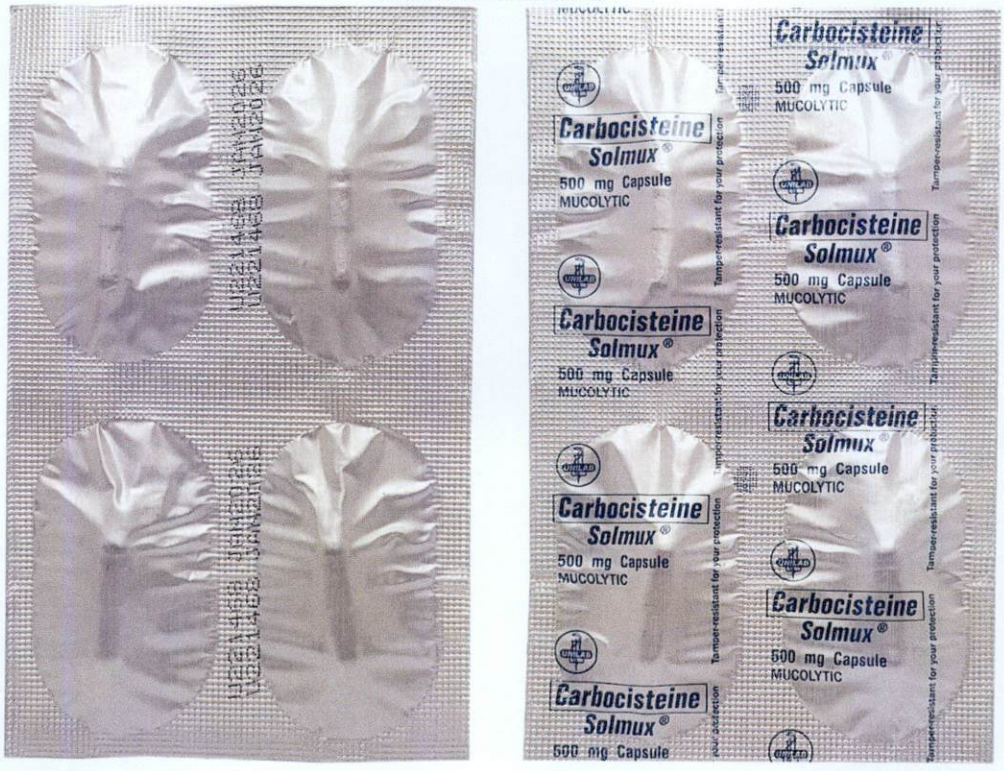
Counterfeit – Print appearance of the box is not comparable with the standard features of the registered product.

Figure 5. Comparison between the Authentic and Counterfeit (Solmux®) 500 mg (Lot No. U221468)

AUTHENTIC



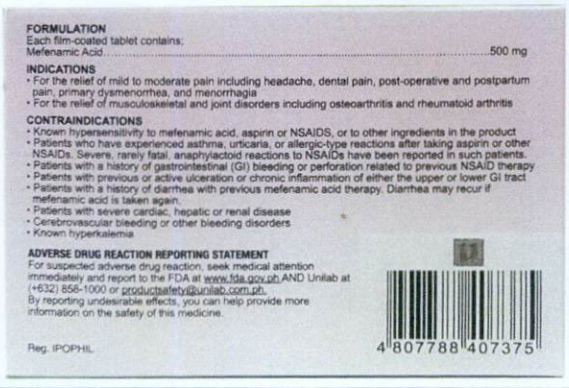
COUNTERFEIT

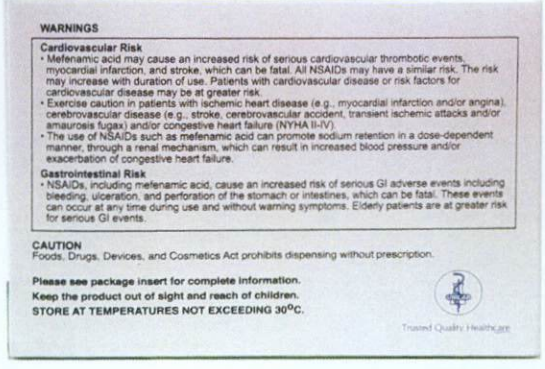


Counterfeit – The knurling, and print appearance of the strip are not comparable with the registered product.

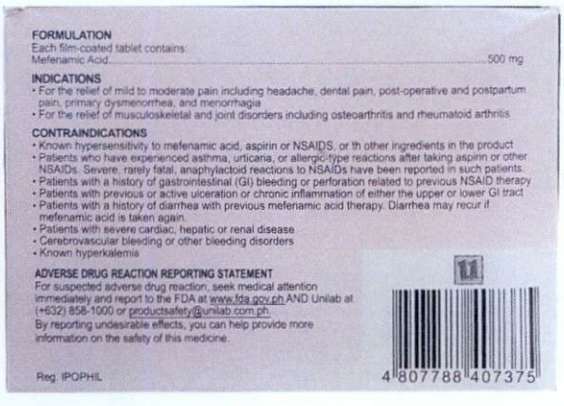
Figure 6. Comparison between the Authentic and Counterfeit (Solmux®) 500 mg (Lot No. U221468)

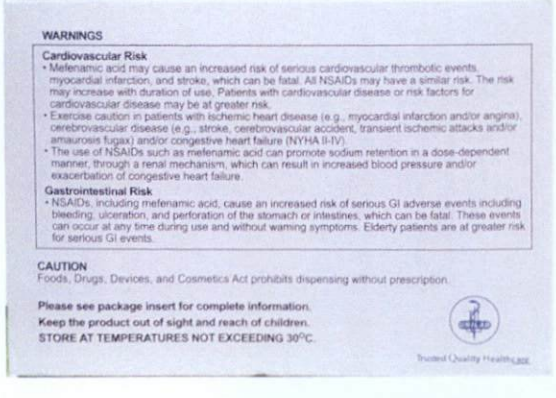
AUTHENTIC





COUNTERFEIT

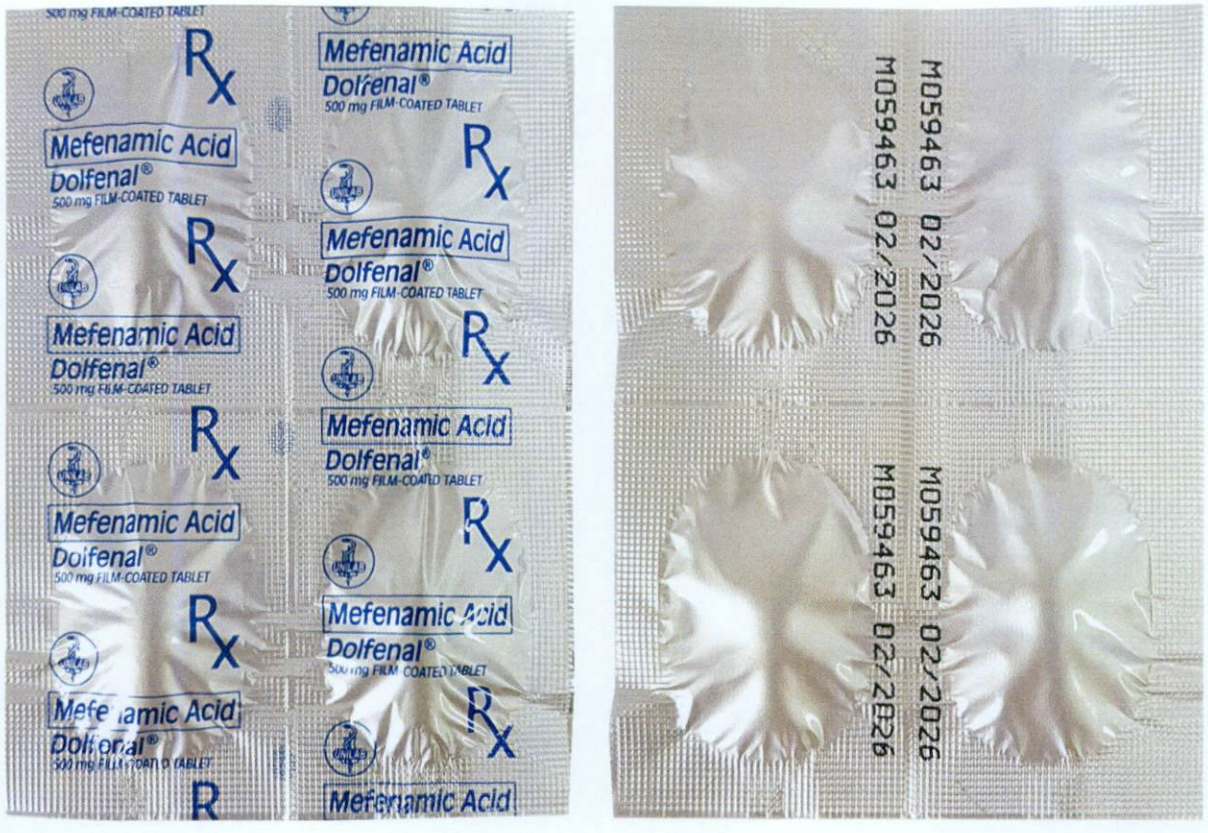




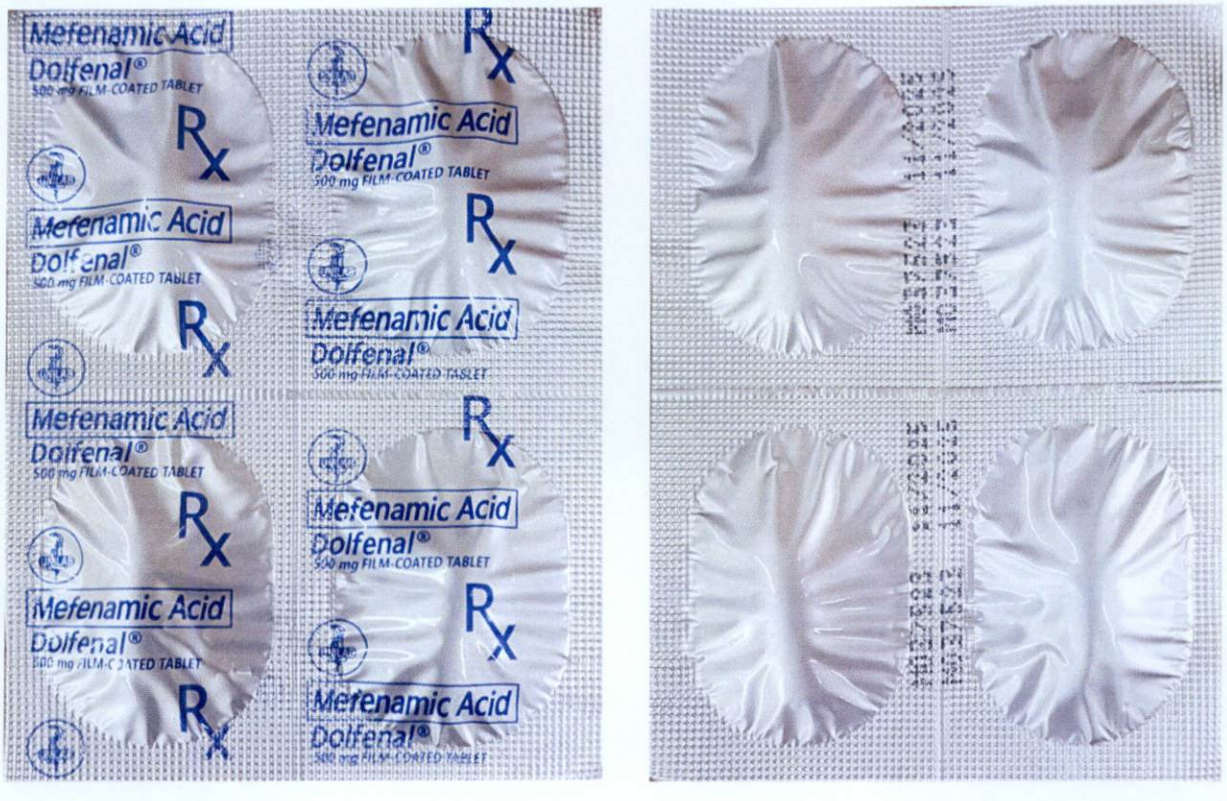
Counterfeit – Print appearance of the box is not comparable with the standard features of the registered product.

Figure 7. Comparison between the Authentic and Counterfeit Mefenamic Acid (Dolfenal®) 500 mg Film-Coated Tablet (Lot No. M037523)

AUTHENTIC



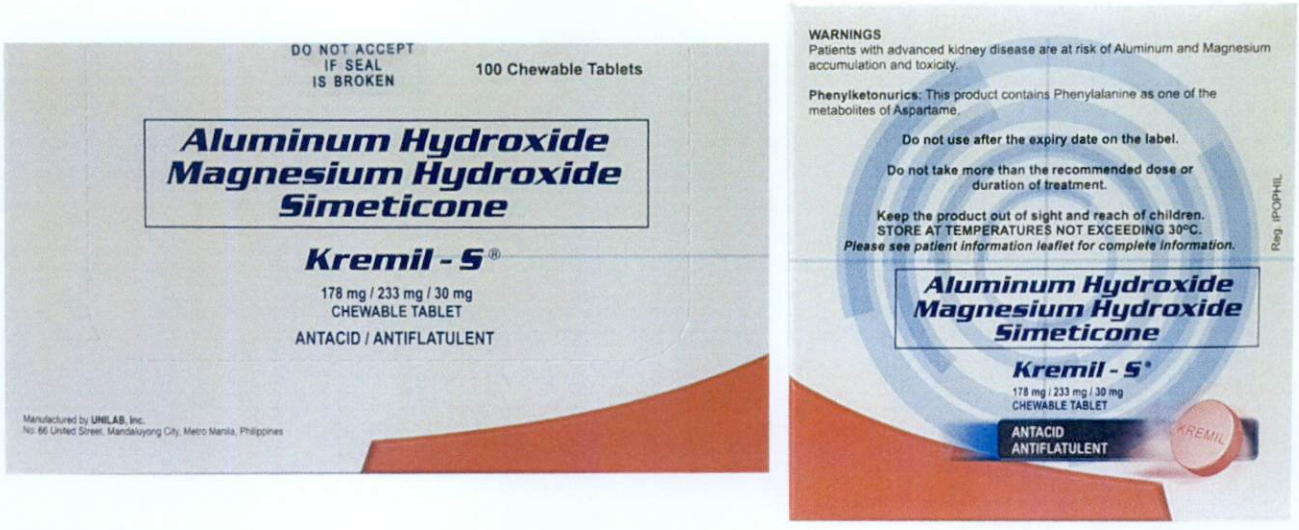
COUNTERFEIT



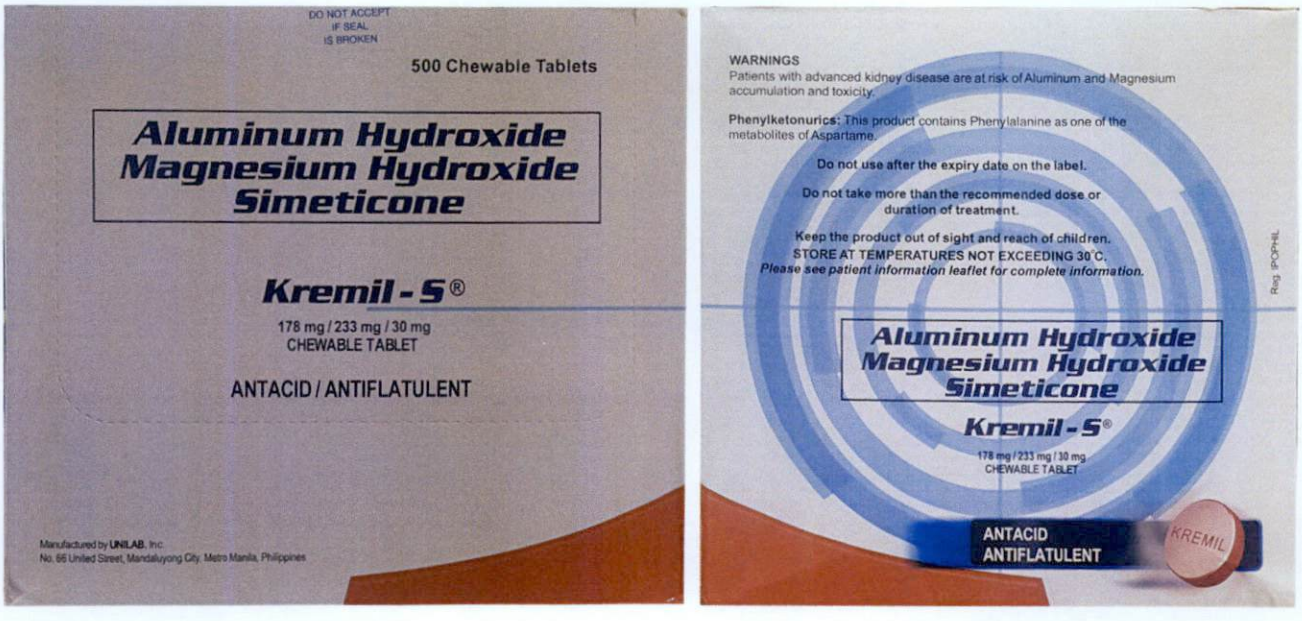
Counterfeit – The knurling, security mark, and print appearance of the strip are not comparable with the registered product.

Figure 8. Comparison between the Authentic and Counterfeit Mefenamic Acid (Dolfenal®) 500 mg Film-Coated Tablet (Lot No. M037523)

AUTHENTIC



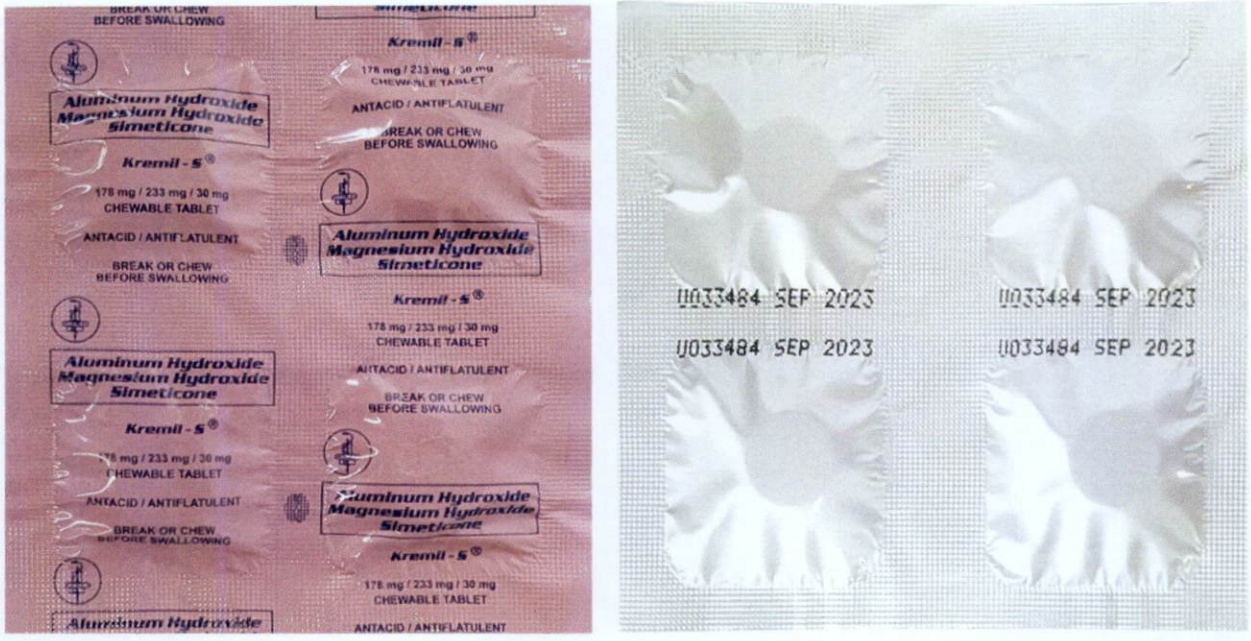
COUNTERFEIT



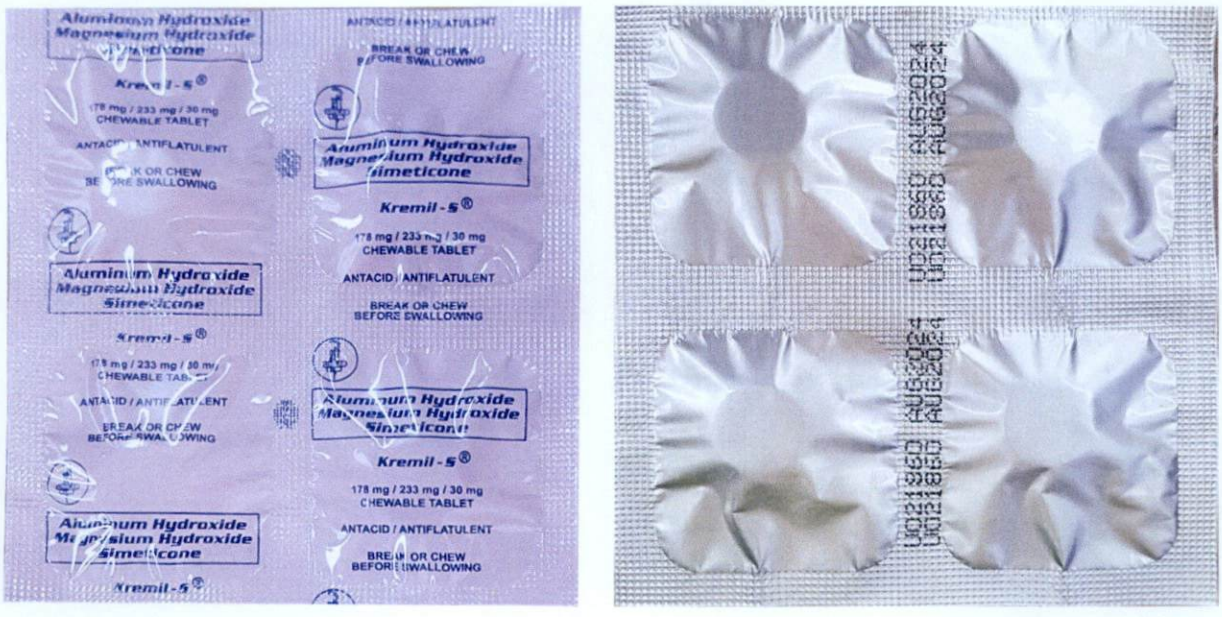
Counterfeit – Print appearance of the box is not comparable with the standard features of the registered product.

Figure 9. Comparison between the Authentic and Counterfeit Aluminum Hydroxide / Magnesium Hydroxide / Simeticone (Kremil-S®) 178 mg / 233 mg / 30 mg Chewable Tablet (Lot No. U021860)

AUTHENTIC



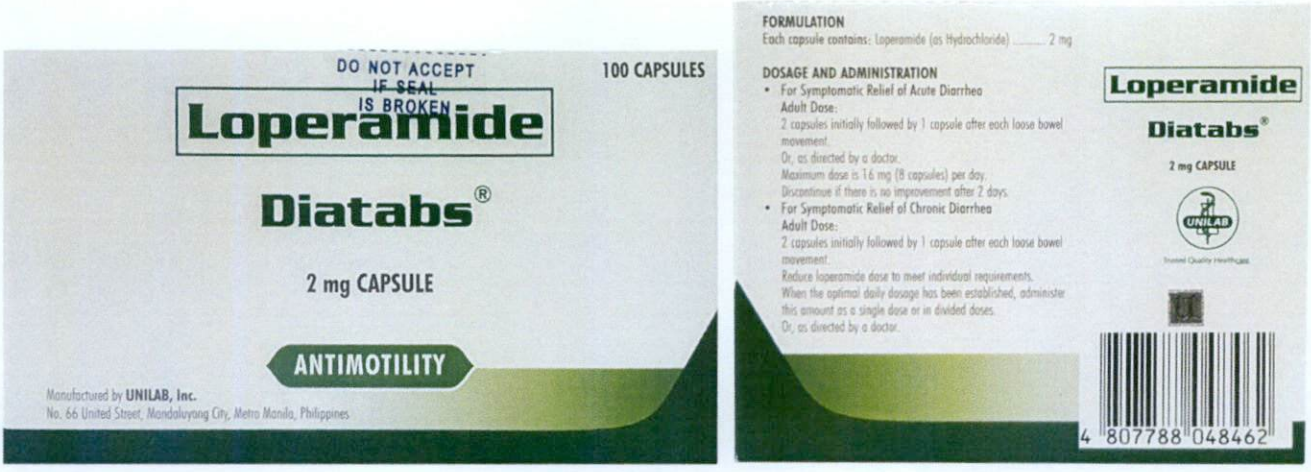
COUNTERFEIT



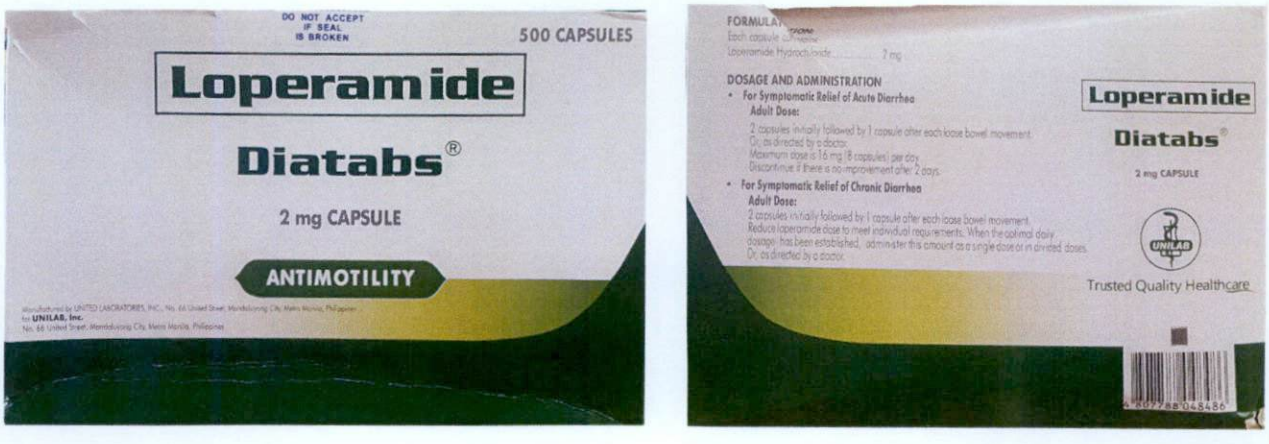
Counterfeit – The knurling, security mark, and print appearance of the strip are not comparable with the registered product.

Figure 10. Comparison between the Authentic and Counterfeit Aluminum Hydroxide / Magnesium Hydroxide / Simeticone (Kremil-S®) 178 mg / 233 mg / 30 mg Chewable Tablet (Lot No. U021860)

AUTHENTIC



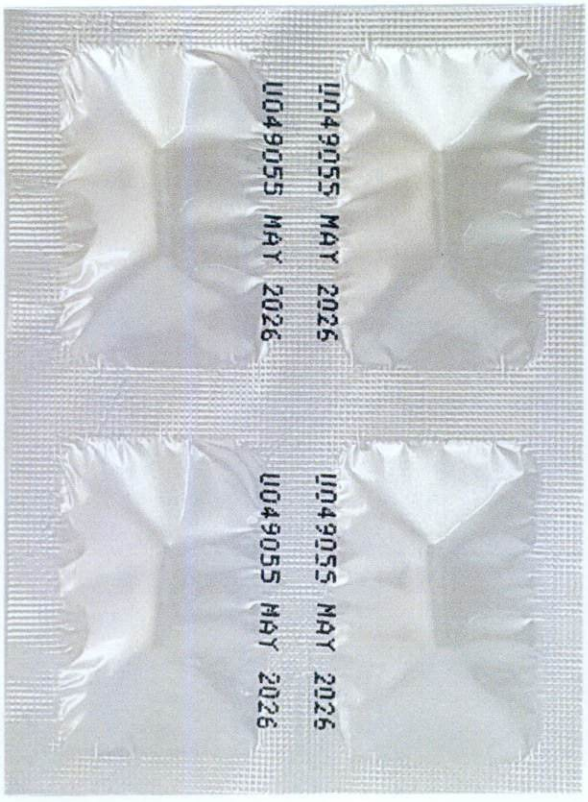
COUNTERFEIT

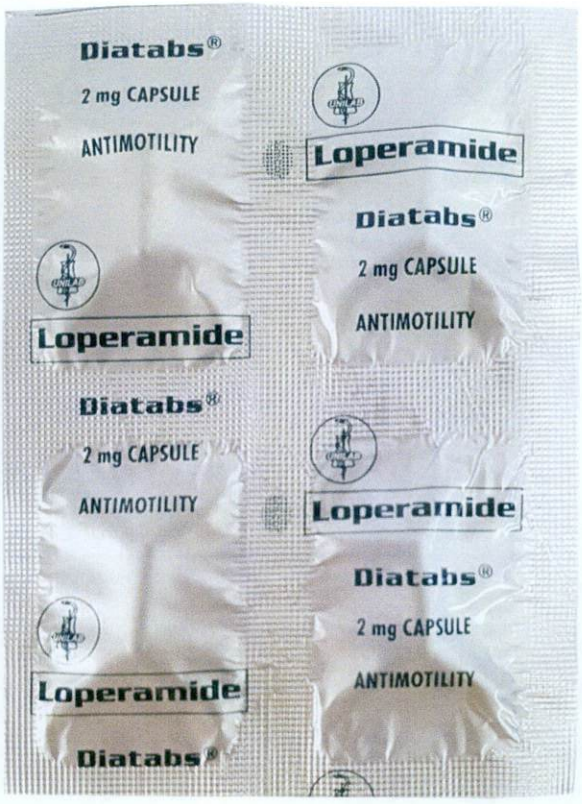


Counterfeit – Print appearance of the box is not comparable with the standard features of the registered product.

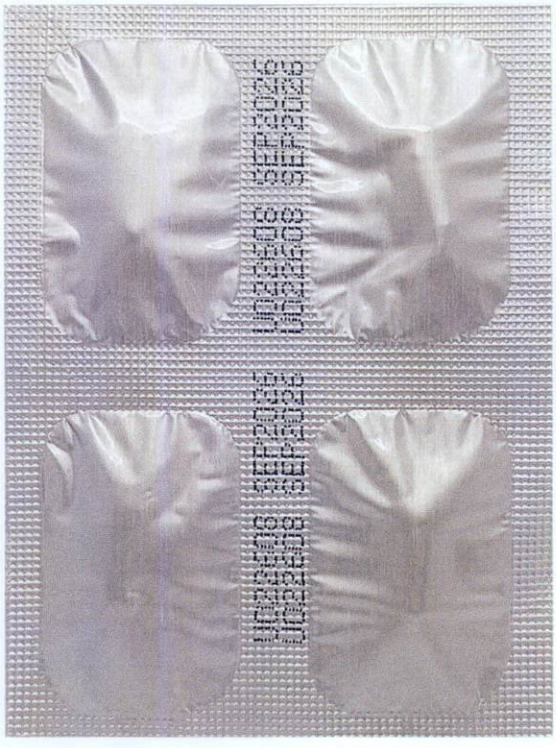
Figure 11. Comparison between the Authentic and Counterfeit Loperamide (Diatabs®) 2 mg Capsule (Lot No. U022608)

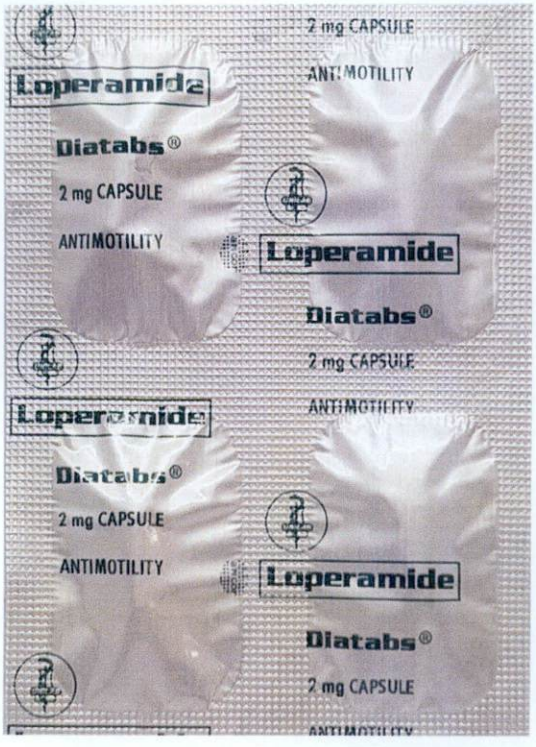
AUTHENTIC





COUNTERFEIT





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

Figure 12. Comparison between the Authentic and Counterfeit Loperamide (Diatabs®) 2 mg Capsule (Lot No. U022608)

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. 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: 20220227151642