



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



WARNINGS

Liver 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.

Allergy Alert: Paracetamol may cause severe skin reactions. Symptoms may include: Skin reddening, Blisters, Rash.

- If a skin reaction occurs, stop use and seek medical help right away.
- Do not use with any other medicine containing phenylephrine, chlorphenamine or paracetamol (prescription or nonprescription). If you are not sure whether a medicine contains these three active ingredients, ask a doctor.
- Ask a doctor before use if you have liver or kidney disease.
- Ask a doctor before use if you are 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.
- Do not use after the expiry date on the label.

Keep the product out of reach and sight of children.
Store at temperatures not exceeding 30°C.

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

Please see patient information leaflet for complete information.



Trusted Quality HealthCare

FORMULATION

Each film-coated tablet contains:

Phenylephrine HCl	10 mg
Chlorphenamine maleate	2 mg
Paracetamol	500 mg

INDICATIONS

This medicine is used for the relief of clogged nose, runny nose, postnasal drip, itchy and watery eyes, sneezing, headache, body aches, and fever associated with the common cold, allergic rhinitis, sinusitis, flu, and other minor respiratory tract infections. It also helps decongest sinus openings and passages.

DOSE AND ADMINISTRATION

Adults and Children 12 years and older:
Orally, 1 tablet every 6 hours, or as recommended by a doctor.

CONTRAINDICATIONS

- If you are allergic to any ingredient of the product
- If you have high blood pressure or severe heart disease unless recommended by a doctor
- If you have anemia, kidney or liver disease unless recommended by a doctor
- If you are pregnant or breastfeeding

COUNTERFEIT



WARNINGS

Liver 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.

Allergy Alert: Paracetamol may cause severe skin reactions. Symptoms may include: Skin reddening, Blisters, Rash.

- If a skin reaction occurs, stop use and seek medical help right away.
- Do not use with any other medicine containing phenylephrine, chlorphenamine, or paracetamol (prescription or nonprescription). If you are not sure whether a medicine contains these three active ingredients, ask a doctor.
- Ask a doctor before use if you have liver or kidney disease.
- Ask a doctor before use if you are 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.
- Do not use after the expiry date on the label.

Keep the product out of reach and sight of children.
Store at temperatures not exceeding 30°C.

Please see patient information leaflet for complete information.

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects you can help provide more information on the safety of this medicine.

Reg. (PDPH) DR-XY34482
P-30000024506



Trusted Quality HealthCare

FORMULATION

Each film-coated tablet contains:

Phenylephrine HCl	10 mg
Chlorphenamine maleate	2 mg
Paracetamol	500 mg

INDICATIONS

This medicine is used for the relief of clogged nose, runny nose, postnasal drip, itchy and watery eyes, sneezing, headache, body aches, and fever associated with the common cold, allergic rhinitis, sinusitis, flu, and other minor respiratory tract infections. It also helps decongest sinus openings and passages.

DOSE AND ADMINISTRATION

Adults and Children 12 years and older: Orally, 1 tablet every 6 hours, or as recommended by a doctor.

CONTRAINDICATIONS

- If you are allergic to any ingredient of the product
- If you have high blood pressure or severe heart disease unless recommended by a doctor
- If you have anemia, kidney or liver disease unless recommended by a doctor
- If you are pregnant or breastfeeding

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 / Phenylpropranolamine HCl / Paracetamol (Tuseran® Forte) 15 mg/ 25 mg/ 325 mg Capsule (Lot No. U022359)

AUTHENTIC



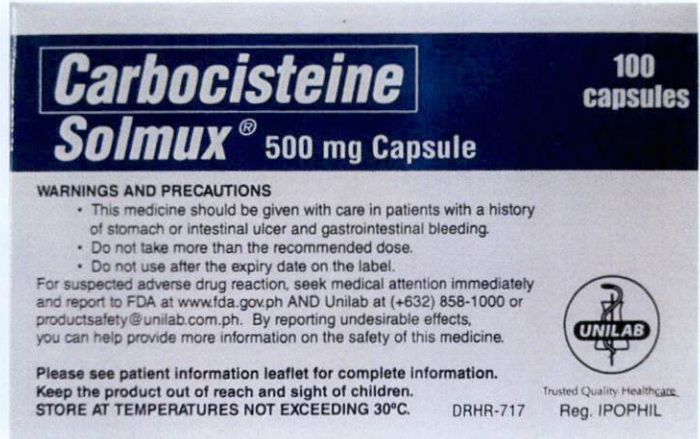
COUNTERFEIT



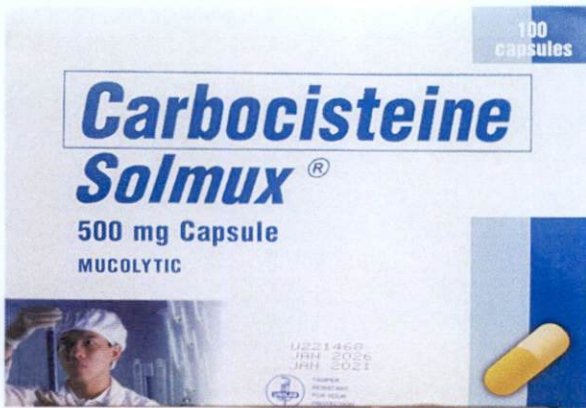
Counterfeit – The knurling, and print appearance of the strip are not comparable with the registered product.

Figure 4. Comparison between the Authentic and Counterfeit Dextromethorphan HBr / Phenylpropranolamine 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



FORMULATION
Each film-coated tablet contains:
Mefenamic Acid.....500 mg

INDICATIONS
• For the relief of mild to moderate pain including headache, dental pain, post-operative and postpartum pain, primary dysmenorrhea, and menorrhagia
• For the relief of musculoskeletal and joint disorders including osteoarthritis and rheumatoid arthritis

CONTRAINDICATIONS
• Known hypersensitivity to mefenamic acid, aspirin or NSAIDs, or to other ingredients in the product
• Patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactoid reactions to NSAIDs have been reported in such patients.
• Patients with a history of gastrointestinal (GI) bleeding or perforation related to previous NSAID therapy
• Patients with previous or active ulceration or chronic inflammation of either the upper or lower GI tract
• Patients with a history of diarrhea with previous mefenamic acid therapy. Diarrhea may recur if mefenamic acid is taken again.
• Patients with severe cardiac, hepatic or renal disease
• Cerebrovascular bleeding or other bleeding disorders
• Known hyperkalemia

ADVERSE DRUG REACTION REPORTING STATEMENT
For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov/and Unilab at (+632) 858-1000 or productsafety@unilab.com.ph.
By reporting undesirable effects, you can help provide more information on the safety of this medicine.

Reg. IPOPHIL

4 807788 407375

WARNINGS

Cardiovascular Risk
• Mefenamic acid may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. All NSAIDs may have a similar risk. The risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.
• Exercise caution in patients with ischemic heart disease (e.g., myocardial infarction and/or angina), cerebrovascular disease (e.g., stroke, cerebrovascular accident, transient ischemic attacks and/or amaurosis fugax) and/or congestive heart failure (NYHA II-IV).
• The use of NSAIDs such as mefenamic acid can promote sodium retention in a dose-dependent manner, through a renal mechanism, which can result in increased blood pressure and/or exacerbation of congestive heart failure.

Gastrointestinal Risk
• NSAIDs, including mefenamic acid, cause an increased risk of serious GI adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious GI events.

CAUTION
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

Please see package insert for complete information.
Keep the product out of sight and reach of children.
STORE AT TEMPERATURES NOT EXCEEDING 30°C.

Trusted Quality Healthcare

COUNTERFEIT



FORMULATION
Each film-coated tablet contains:
Mefenamic Acid.....500 mg

INDICATIONS
• For the relief of mild to moderate pain including headache, dental pain, post-operative and postpartum pain, primary dysmenorrhea, and menorrhagia
• For the relief of musculoskeletal and joint disorders including osteoarthritis and rheumatoid arthritis

CONTRAINDICATIONS
• Known hypersensitivity to mefenamic acid, aspirin or NSAIDs, or to other ingredients in the product
• Patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactoid reactions to NSAIDs have been reported in such patients.
• Patients with a history of gastrointestinal (GI) bleeding or perforation related to previous NSAID therapy
• Patients with previous or active ulceration or chronic inflammation of either the upper or lower GI tract
• Patients with a history of diarrhea with previous mefenamic acid therapy. Diarrhea may recur if mefenamic acid is taken again.
• Patients with severe cardiac, hepatic or renal disease
• Cerebrovascular bleeding or other bleeding disorders
• Known hyperkalemia

ADVERSE DRUG REACTION REPORTING STATEMENT
For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov/and Unilab at (+632) 858-1000 or productsafety@unilab.com.ph.
By reporting undesirable effects, you can help provide more information on the safety of this medicine.

Reg. IPOPHIL

4 807788 407375

WARNINGS

Cardiovascular Risk
• Mefenamic acid may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. All NSAIDs may have a similar risk. The risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.
• Exercise caution in patients with ischemic heart disease (e.g., myocardial infarction and/or angina), cerebrovascular disease (e.g., stroke, cerebrovascular accident, transient ischemic attacks and/or amaurosis fugax) and/or congestive heart failure (NYHA II-IV).
• The use of NSAIDs such as mefenamic acid can promote sodium retention in a dose-dependent manner, through a renal mechanism, which can result in increased blood pressure and/or exacerbation of congestive heart failure.

Gastrointestinal Risk
• NSAIDs, including mefenamic acid, cause an increased risk of serious GI adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious GI events.

CAUTION
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

Please see package insert for complete information.
Keep the product out of sight and reach of children.
STORE AT TEMPERATURES NOT EXCEEDING 30°C.

Trusted Quality Healthcare

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



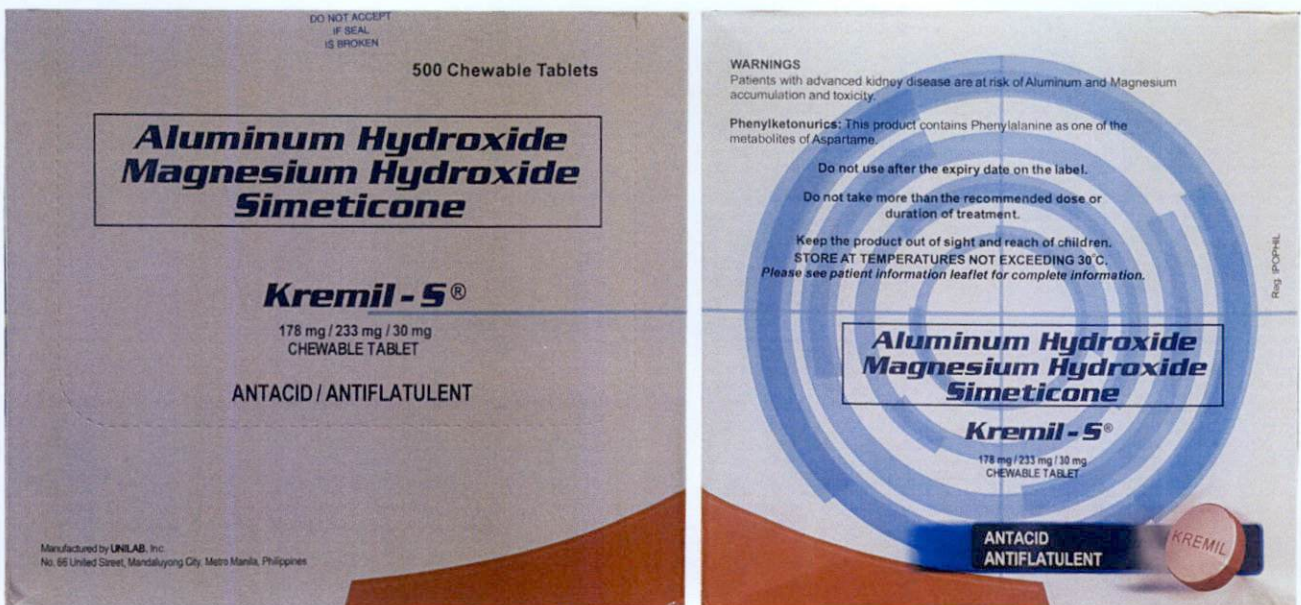
Counterfeit – The knurling, security mark, and print appearance of the strip are not comparable with the registered product.

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



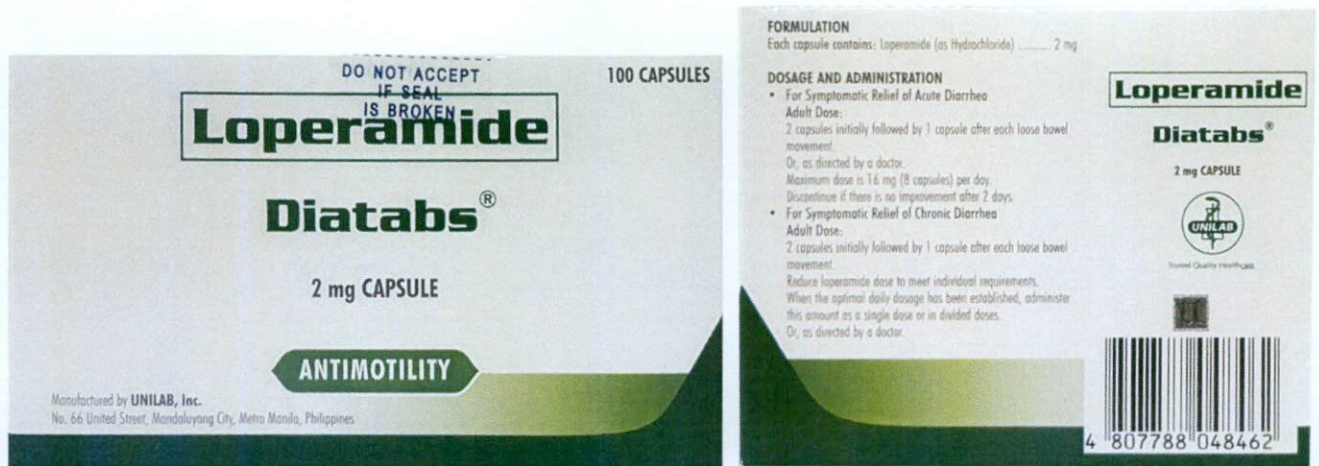
COUNTERFEIT



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



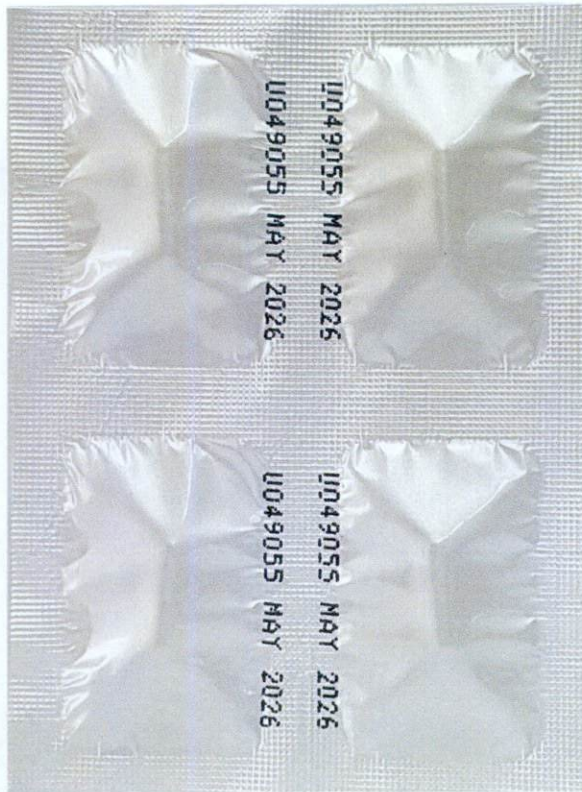
COUNTERFEIT



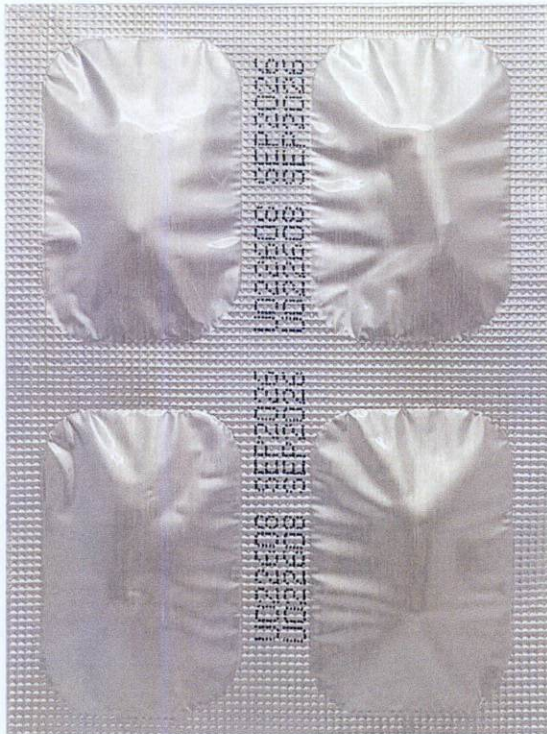
Counterfeit – Print appearance of the box is not comparable with the standard features of the registered product.

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