



28 MAR 2022

FDA ADVISORY
No. 2022-0677-A

PARA : SA LAHAT NG HEALTHCARE PROFESSIONALS AT SA PUBLIKO

PAKSA : Babala sa Publiko tungkol sa Paggamit ng mga sumusunod na Beripikadong Pekeng Gamot na:

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 Capsule
3. Carbocisteine (Solmux[®]) 500 mg Capsule
4. Mefenamic Acid (Dolfenal[®]) 500 mg Film-Coated Tablet
5. Aluminum Hydroxide / Magnesium Hydroxide / Simethicone (Kremil-S[®]) 178 mg / 233 mg / 30 mg Chewable Tablet
6. Loperamide (Diatabs[®]) 2 mg Capsule

Pinapayuhan ng Food and Drug Administration (FDA) ang publiko laban sa pagbili at paggamit ng mga sumusunod na beripikadong pekeng gamot:



TUNAY/AUTHENTIC

U042036
JAN 2023
JAN 2021

100 FILM-COATED TABLETS

**PHENYLEPHRINE HCl
CHLORPHENAMINE MALEATE
PARACETAMOL**

BIOFLU®
10 mg / 2 mg / 500 mg FILM-COATED TABLET

- Nasal Decongestant
- Antihistamine
- Analgesic/Antipyretic

Manufactured by UNILAB, Inc.
No. 66 United Street, Mandaluyong City, Metro Manila, Philippines



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.

Reg. #PDPHIL-DR-XG4482-P00000027051
Trusted Quality Healthcare



FORMULATION
Each film-coated tablet contains:
 Phenylephrine HCl10 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.

DOSAGE 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

PEKE/COUNTERFEIT

U066300
OCT 2023
OCT 2021

100 FILM-COATED TABLETS

**PHENYLEPHRINE HCl
CHLORPHENAMINE MALEATE
PARACETAMOL**

BIOFLU®
10 mg / 2 mg / 500 mg FILM-COATED TABLET

- Nasal Decongestant
- Antihistamine
- Analgesic/Antipyretic

Manufactured by UNILAB, Inc.
No. 66 United Street, Mandaluyong City, Metro Manila, Philippines



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. #PDPHIL-DR-XG34482
E300000024506
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.

DOSAGE 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

Peke/Counterfeit – Ang print at hitsura ng karton ay hindi tugma sa pamantayan ng rehistradong gamot.

Larawan 1. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Bioflu®) 10 mg / 2 mg / 500 mg Tablet (Lot No. U066300)

TUNAY/AUTHENTIC



PEKE/COUNTERFEIT



Peke/Counterfeit – Ang tablet, *knurling*, *security mark* at *print appearance* ng gamot ay hindi tugma sa rehistradong gamot.

Larawan 2. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Bioflu®) 10 mg / 2 mg / 500 mg Tablet (Lot No. U066300)

TUNAY/AUTHENTIC

DO NOT ACCEPT IF SEAL IS BROKEN

100 capsules

**DEXTROMETHORPHAN HBr
PHENYLPROPANOLAMINE HCl
PARACETAMOL**

TUSERAN® FORTE
15 mg / 25 mg / 325 mg capsule
Reformulated

**ANTITUSSIVE - NASAL DECONGESTANT
ANALGESIC - ANTIPYRETIC**

Manufactured by **UNILAB, Inc.**
No. 66 United Street, Mandaluyong City, Metro Manila, Philippines

100 capsules

**DEXTROMETHORPHAN HBr
PHENYLPROPANOLAMINE HCl
PARACETAMOL**

TUSERAN® FORTE **STOPS COUGH
RELIEVES COLDS**

WARNINGS

- Use with caution in patients with high blood pressure, heart pain, heart disease, narrowing of the arteries, glaucoma, and in those taking antidepressants.
- Patients with heart disease and arrhythmias / uncontrolled high blood pressure should consult a doctor prior to taking this medicine.

LIVER WARNING: This product contains paracetamol. Severe liver damage may occur if:

- An adult or child 12 years and older takes more than 4 g of paracetamol in 24 hours, which is the maximum daily amount.
- Taken with other medicines containing paracetamol (or acetaminophen).
- An adult has 3 or more alcoholic drinks everyday while using the product.

 Do not use with any other medicine containing dextromethorphan, phenylpropylamine or paracetamol (prescription or nonprescription). If you are not sure whether a medicine contains these three active ingredients, ask a doctor.

Do not take this medicine if you are at risk of developing respiratory failure (e.g., those with chronic bronchitis, emphysema or during an asthma attack).

Do not take this medicine if you have persistent or chronic cough (i.e., cough lasting for more than 3 weeks) or when coughing is accompanied by excessive sputum unless directed by a doctor.

A persistent cough may be a sign of a serious condition. If cough persists for more than one week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor.

May cause drowsiness and dizziness; patients should observe caution while driving or performing other tasks requiring alertness.

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.

Do not take more than the recommended dose.

Do not use after the expiry date on the label.

PLEASE SEE PATIENT INFORMATION LEAFLET FOR CONTRAINDICATIONS AND PRECAUTIONS.

100 capsules

**DEXTROMETHORPHAN HBr
PHENYLPROPANOLAMINE HCl
PARACETAMOL**

TUSERAN® FORTE **STOPS COUGH
RELIEVES COLDS**

FORMULATION

Each capsule contains:
 Dextromethorphan (as Hydrobromide) 15 mg
 Phenylpropylamine (as Hydrochloride) 25 mg
 Paracetamol 325 mg

INDICATION

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

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 chronic kidney or liver disease unless recommended by a doctor.
 • If you are pregnant or breastfeeding.

DOSE AND ADMINISTRATION

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

**STORE AT TEMPERATURES NOT EXCEEDING 30°C
KEEP THE PRODUCT OUT OF REACH AND SIGHT OF CHILDREN.**

For detailed information on medical uses, contraindications and more, visit our website at www.unilab.com.ph or call our toll-free number at (832) 888-1000 or (832) 888-1000. For more information on the safety of this product, visit our website at www.unilab.com.ph or call our toll-free number at (832) 888-1000 or (832) 888-1000.

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Reg. 8/CPN/16

PEKE/COUNTERFEIT

100 capsules

**DEXTROMETHORPHAN HBr
PHENYLPROPANOLAMINE HCl
PARACETAMOL**

TUSERAN® FORTE
15 mg / 25 mg / 325 mg capsule
Reformulated

**ANTITUSSIVE - NASAL DECONGESTANT
ANALGESIC - ANTIPYRETIC**

Manufactured by **UNILAB, Inc.**
No. 66 United Street, Mandaluyong City, Metro Manila, Philippines

100 capsules

**DEXTROMETHORPHAN HBr
PHENYLPROPANOLAMINE HCl
PARACETAMOL**

TUSERAN® FORTE **STOPS COUGH
RELIEVES COLDS**

WARNINGS

- Use with caution in patients with high blood pressure, heart pain, heart disease, narrowing of the arteries, glaucoma, and in those taking antidepressants.
- Patients with heart disease and arrhythmias / uncontrolled high blood pressure should consult a doctor prior to taking this medicine.

LIVER WARNING: This product contains paracetamol. Severe liver damage may occur if:

- An adult or child 12 years and older takes more than 4 g of paracetamol in 24 hours, which is the maximum daily amount.
- Taken with other medicines containing paracetamol (or acetaminophen).
- An adult has 3 or more alcoholic drinks everyday while using the product.

 Do not use with any other medicine containing dextromethorphan, phenylpropylamine or paracetamol (prescription or nonprescription). If you are not sure whether a medicine contains these three active ingredients, ask a doctor.

Do not take this medicine if you are at risk of developing respiratory failure (e.g., those with chronic bronchitis, emphysema or during an asthma attack).

Do not take this medicine if you have persistent or chronic cough (i.e., cough lasting for more than 3 weeks) or when coughing is accompanied by excessive sputum unless directed by a doctor.

A persistent cough may be a sign of a serious condition. If cough persists for more than one week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor.

May cause drowsiness and dizziness; patients should observe caution while driving or performing other tasks requiring alertness.

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.

Do not take more than the recommended dose.

Do not use after the expiry date on the label.

PLEASE SEE PATIENT INFORMATION LEAFLET FOR CONTRAINDICATIONS AND PRECAUTIONS.

100 capsules

**DEXTROMETHORPHAN HBr
PHENYLPROPANOLAMINE HCl
PARACETAMOL**

TUSERAN® FORTE **STOPS COUGH
RELIEVES COLDS**

FORMULATION

Each capsule contains:
 Dextromethorphan (as Hydrobromide) 15 mg
 Phenylpropylamine (as Hydrochloride) 25 mg
 Paracetamol 325 mg

INDICATION

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

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 chronic kidney or liver disease unless recommended by a doctor.
 • If you are pregnant or breastfeeding.

DOSE AND ADMINISTRATION

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

**STORE AT TEMPERATURES NOT EXCEEDING 30°C
KEEP THE PRODUCT OUT OF REACH AND SIGHT OF CHILDREN.**

For detailed information on medical uses, contraindications and more, visit our website at www.unilab.com.ph or call our toll-free number at (832) 888-1000 or (832) 888-1000. For more information on the safety of this product, visit our website at www.unilab.com.ph or call our toll-free number at (832) 888-1000 or (832) 888-1000.

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Reg. 8/CPN/16

Peke/Counterfeit – Ang print at hitsura ng karton ay hindi tugma sa pamantayan ng rehistradong gamot.

Larawan 3. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Dextromethorphan HBr / Phenylpropanolamine HCl / Paracetamol (Tuseran® Forte) 15 mg/ 25 mg/ 325 mg Capsule (Lot No. U022359)

TUNAY/AUTHENTIC



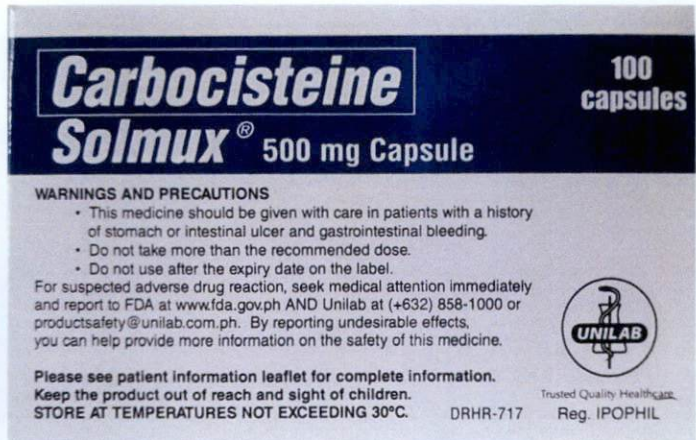
PEKE/COUNTERFEIT



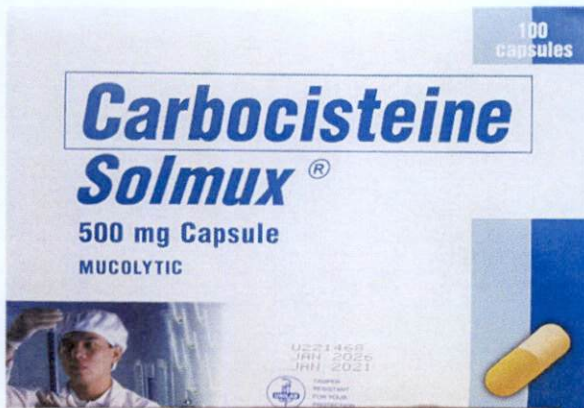
Peke/Counterfeit – Ang *knurling*, at *print appearance* ng gamot ay hindi tugma sa rehistradong gamot.

Larawan 4. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Dextromethorphan HBr / Phenylpropanolamine HCl / Paracetamol (Tuseran® Forte) 15 mg/ 25 mg/ 325 mg Capsule (Lot No. U022359)

TUNAY/AUTHENTIC



PEKE/COUNTERFEIT



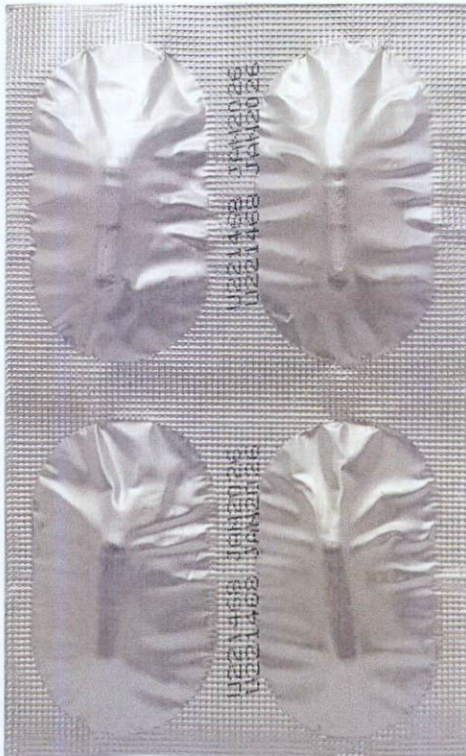
Peke/Counterfeit – Ang print at hitsura ng karton ay hindi tugma sa pamantayan ng rehistradong gamot.

Larawan 5. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na (Solmux®) 500 mg (Lot No. U221468)

TUNAY/AUTHENTIC



PEKE/COUNTERFEIT



Peke/Counterfeit – Ang *knurling*, at *print appearance* ng gamot ay hindi tugma sa rehistradong gamot.

Larawan 6. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na (Solmux®) 500 mg (Lot No. U221468)

TUNAY/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/pd/AND/Unilab or (+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

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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

PEKE/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/pd/AND/Unilab or (+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

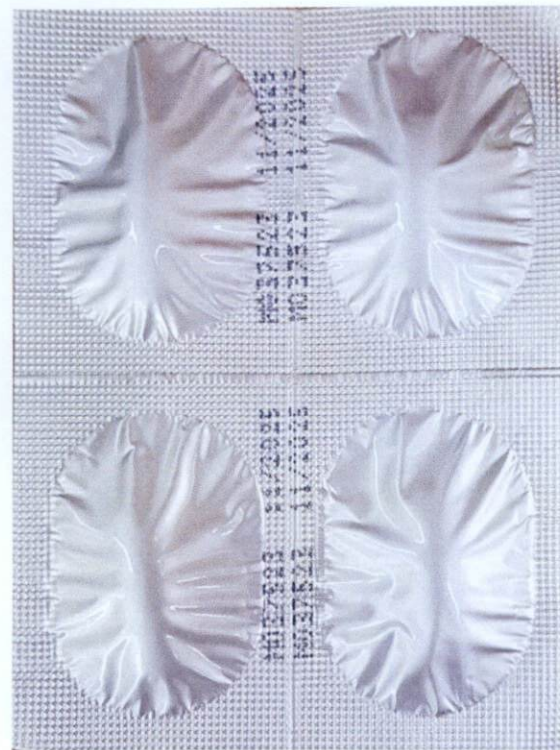
Peke/Counterfeit – Ang print at hitsura ng karton ay hindi tugma sa pamantayan ng rehistradong gamot.

Larawan 7. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Mefenamic Acid (Dolfenal®) 500 mg Film-Coated Tablet (Lot No. M037523)

TUNAY/AUTHENTIC



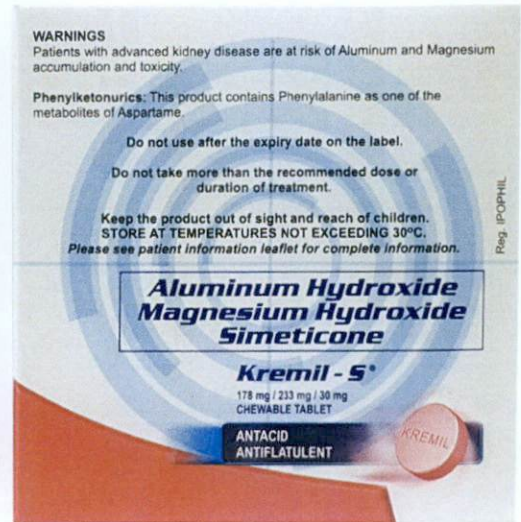
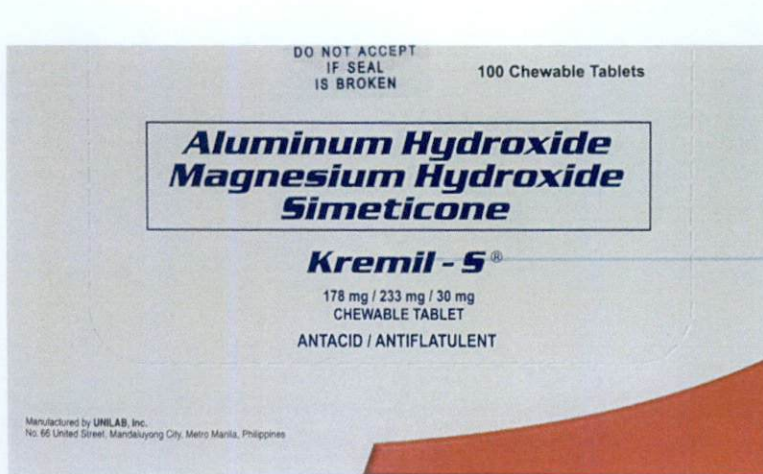
PEKE/COUNTERFEIT



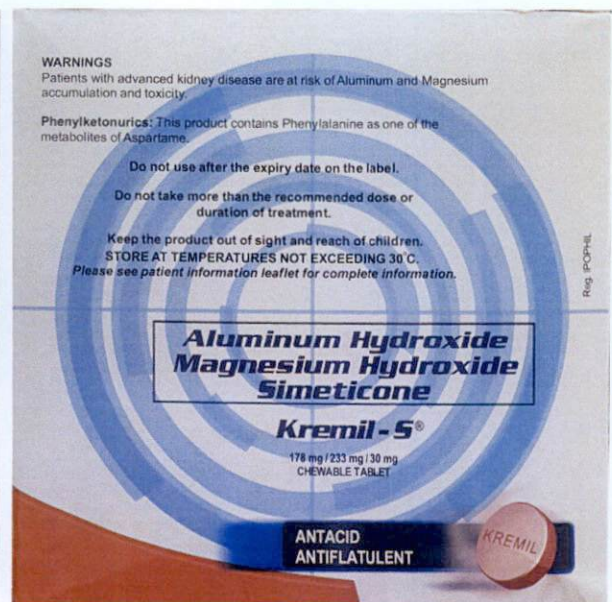
Peke/Counterfeit – Ang *knurling*, security mark at *print appearance* ng gamot ay hindi tugma sa rehistradong gamot.

Larawan 8. Paghahambing sa Tunay/*Authentic* at Peke/*Counterfeit* na Mefenamic Acid (Dolfenal[®]) 500 mg Film-Coated Tablet (Lot No. M037523)

TUNAY/AUTHENTIC



PEKE/COUNTERFEIT



Peke/Counterfeit – Ang print at hitsura ng karton ay hindi tugma sa pamantayan ng rehistradong gamot.

Larawan 9. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Aluminum Hydroxide / Magnesium Hydroxide / Simethicone (Kremil-S®) 178 mg / 233 mg / 30 mg Chewable Tablet (Lot No. U021860)

TUNAY/AUTHENTIC



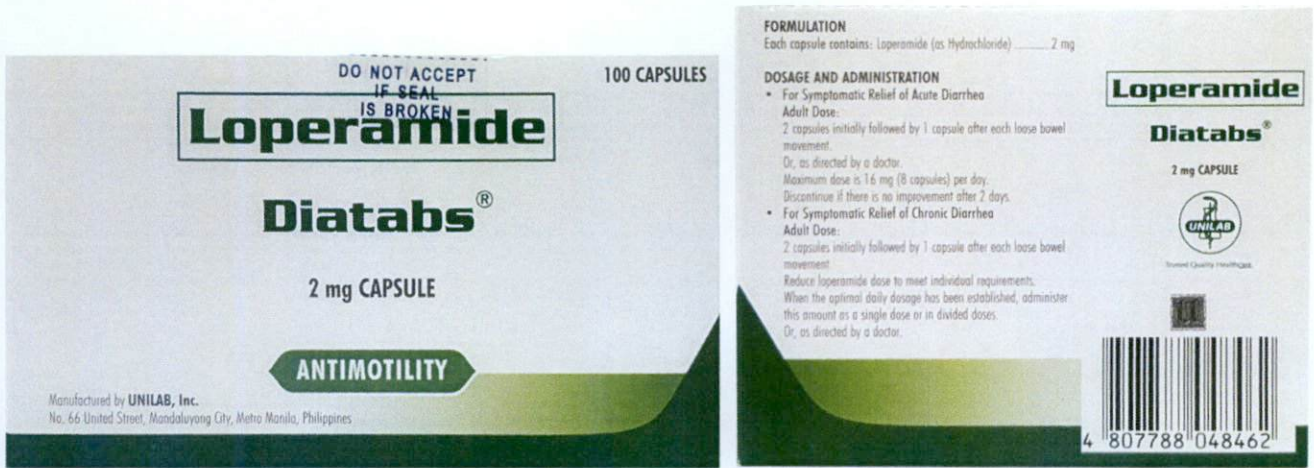
PEKE/COUNTERFEIT



Peke/Counterfeit – Ang *knurling*, security mark at *print appearance* ng gamot ay hindi tugma sa rehistradong gamot.

Larawan 10. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Aluminum Hydroxide / Magnesium Hydroxide / Simethicone (Kremil-S®) 178 mg / 233 mg / 30 mg Chewable Tablet (Lot No. U021860)

TUNAY/AUTHENTIC



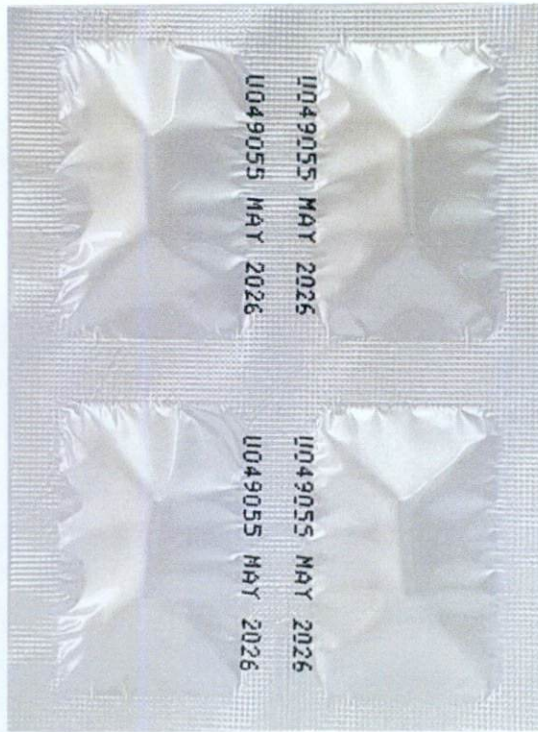
PEKE/COUNTERFEIT



Peke/Counterfeit – Ang print at hitsura ng karton ay hindi tugma sa pamantayan ng rehistradong gamot.

Larawan 11. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Loperamide (Diatabs®) 2 mg Capsule (Lot No. U022608)

TUNAY/AUTHENTIC



PEKE/COUNTERFEIT



Peke/Counterfeit – Ang *knurling*, security mark at *print appearance* ng gamot ay hindi tugma sa rehistradong gamot.

Larawan 12. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Loperamide (Diatabs®) 2 mg Capsule (Lot No. U022608)


Ang lahat ng *healthcare professionals* at publiko ay binabalaan tungkol sa paglipana ng mga nasabing pekeng gamot sa merkado na maaaring magdulot ng panganib sa kalusugan ng mga gagamit nito. Ang publiko ay pinapaalalahanan ring bumili lamang sa mga establisyementong lisensyado ng FDA.

Gayundin, ang lahat ng establisyemento ay binabalaang huwag magbenta ng mga pekeng gamot na nagtataglay ng mga nasabing katangian. Ang pagaangkat, pagbebenta at pamamahagi nito ay paglabag sa *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*. Ang sino mang mapatunayang nagbebenta ng nasabing pekeng produkto ay mapaparusahan.

Hinihiling sa lahat ng *Local Government Units (LGUs) and Law Enforcement Agencies (LEAs)* na tiyaking ang pekeng produktong ito ay hindi maibebenta o magagamit sa kanilang mga nasasakupan.

Para sa karagdagang impormasyon at katanungan, maaring mag-email sa info@fda.gov.ph. Upang mag-report ng patuloy na pagtitinda o pangangalakal ng mga pekeng gamut, mag-email sa ereport@fda.gov.ph. Maaari ring tumawag sa *Center for Drug Regulation and Research* sa numerong (02) 8809-5596. Para sa mga hinihinalang hindi kanais-nais na reaksyon sa gamot, i-report agad sa FDA gamit ang link na ito: <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> at kumpletuhin ang mga kinakailangang impormasyon.

Ang lahat ay hinihikayat na palaganapin ang mga nakasaad na impormasyon.


DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge Director General

DTN:



20220227151734