



20 APR 2022

FDA ADVISORY
No. 2022-0939-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 Film-Coated Tablet
2. Paracetamol / Caffeine (Rexidol® Forte) 500 mg / 65 mg Tablet
3. Ibuprofen / Paracetamol (Alaxan® FR) 200 mg / 325 mg Capsule
4. Naproxen Sodium (Flanax® Forte) 550 mg Tablet

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

TUNAY/AUTHENTIC



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 plugged nose, runny nose, postnasal drip, itchy and watery eyes, sneezing, headache, body aches, and fever associated with the common cold, allergic rhinitis, sinusitis, etc., 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.

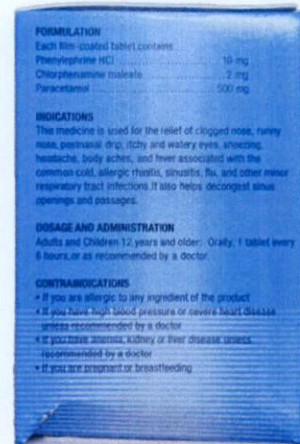
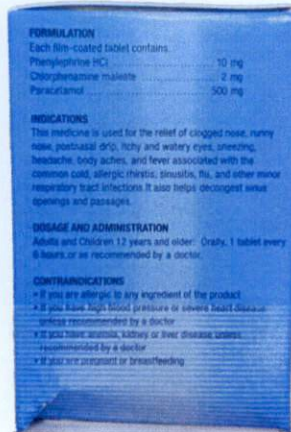
CONTRAINDICATIONS

- 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

WARNING
Use Warning: This product contains pseudoephedrine. Severe liver damage may occur if you take:
• More than 1 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.
Alergy Alert: Pseudoephedrine may cause severe skin reactions. Symptoms may include: skin redness, blisters, rash.
• If a skin reaction occurs, stop use and seek medical help right away.
• Do not use with any other medicine containing pseudoephedrine, chlorpheniramine or paracetamol (acetaminophen or paracetamol).
• If you are not sure whether a medicine contains these three active ingredients, ask a doctor.
• Ask a doctor before use if you have been 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 of the lot.
Keep the product out of reach and sight of children. Store at temperature not exceeding 30°C.
For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph or 1-800-888-1000 or provide a copy of this leaflet to the nearest FDA office. By reporting undesirable effects, you can help provide more information on the safety of this medicine.
Please see other information leaflet for complete information.



PEKE/COUNTERFEIT



Peke/Counterfeit – Ang print appearance ng kahon ay hindi tugma sa rehistradong gamot.

Larawan 1. Paghahambing sa kahon ng Tunay/Authentic at Peke/Counterfeit na Phenylephrine HCl, Chlorphenamine Maleate/ Paracetamol (Bioflu®) 10 mg/ 2 mg/ 500 mg Film-Coated Tablet (Lot No. U118408 Exp. OCT 2023)

TUNAY/AUTHENTIC



PEKE/COUNTERFEIT



Peke/Counterfeit – Ang tableta, *knurling*, *security mark*, at *print appearance* 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 Film-Coated Tablet (Lot No. U118408 Exp. OCT 2023)

TUNAY/AUTHENTIC



PEKE/COUNTERFEIT



Peke/Counterfeit – Ang print appearance ng kahon ay hindi tugma sa rehistradong gamot.

Larawan 3. Paghahambing sa kahon ng Tunay/Authentic at Peke/Counterfeit na Paracetamol/ Caffeine (Rexidol® Forte) 500 mg/ 65 mg Tablet (Lot No. 20028500 Exp. MAY 2024)

TUNAY/AUTHENTIC



PEKE/COUNTERFEIT



Peke/Counterfeit – *Knurling at print appearance ng strip ay hindi tugma sa rehistradong gamot.*

Larawan 4. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Counterfeit Paracetamol/Caffeine (Rexidol® Forte) 500 mg/ 65 mg Tablet (Lot No. 20028500 Exp. MAY 2024)

TUNAY/AUTHENTIC



PEKE/COUNTERFEIT



Peke/Counterfeit – Ang print appearance ng kahon ay hindi tugma sa rehistradong gamot.

Larawan 5. Paghahambing sa kahon ng Tunay/Authentic at Peke/Counterfeit na Ibuprofen/Paracetamol (Alaxan® FR) 200 mg/ 325 mg Tablet (Lot No. 42957068 Exp. SEP 2024)

TUNAY/AUTHENTIC



PEKE/COUNTERFEIT



Peke/Counterfeit – Knurling, security mark at print appearance ng strip ay hindi tugma sa Rehistradong gamot.

Larawan 6. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Ibuprofen/ Paracetamol (Alaxan® FR) 200 mg/ 325 mg Tablet (Lot No. 42957068 Exp. SEP 2024)

TUNAY/AUTHENTIC



PEKE/COUNTERFEIT



Peke/Counterfeit – Ang *Batch no.* ay hindi gawa ng *Marketing Authorization Holder (MAH)* Taisho Pharmaceutical Philippines, Inc.

Larawan 7. Paghahambing sa *Tunay/Authentic* at *Peke/Counterfeit* na Naproxen Sodium (Flanax[®] Forte) 550 mg Tablet (Lot No. TNF8J985 Exp. AUG 2024)


Ang lahat ng *healthcare professionals* at publiko ay binabalaan tungkol sa paglipana ng 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 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 gamot, mag-email sa report@fda.gov.ph, o mag-report gamit ang aming *online reporting facility*, **eReport**, sa www.fda.gov.ph/ereport. 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:



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