



13 SEP 2021

FDA ADVISORY
No. **20212291**

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. Hyoscine N-Butylbromide (Buscopan) 10 mg Tablet
2. Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Neozep® Forte) 10 mg/2 mg/500 mg Tablet
3. Naproxen Sodium (Flanax® Forte) 550 mg Tablet

The Food and Drug Administration (FDA) advises the public against the purchase and use of the following verified counterfeit drug products:

	AUTHENTIC	COUNTERFEIT
Blister strip sample		
Batch details and expiry date printing	Printed in two (2) lines in bold/ darker ink	Printed in one line in lighter ink
Expiry date	ED 09 2021	12/2024
Transparent line in the center	Continuous line	Dotted line

Figure 1. Comparison between the Authentic and Verified Counterfeit Hyoscine N-Butylbromide (Buscopan) 10 mg Tablet (Batch no. 18071017 Expiry date 12/2024)



AUTHENTIC



COUNTERFEIT



Counterfeit – Logo, security mark, knurling, print color and appearance are different with the standard features of the registered product.

Figure 2. Comparison between the Authentic and Verified Counterfeit Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (NeoZep® Forte) 10 mg/2 mg/500 mg Tablet (Lot no. 19072003 Expiry date JUL 2022)









1. Batch Details (Lot No. and Expiration Date)	AUTHENTIC LN: TFF8K410 ED: OCT 2021	COUNTERFEIT LN: TFFBK410 ED: AUG 2022
Code Interpretation: T- Taisho; F- Flanax; F- Forte; 8 – Year it was produced; K – Code of the month it was produced; 401 – Last 3-digits batch sequence Expiration Date: Product shelf-life: 36 months		
2. Batch Details Position	Embossed in inverted position	Embossed in upright position
		
3. Printed Details per Pocket	410 OCT 21	410 AUG 22
		
4. Knurling on Blisters	Crisscross-type	Dotted-type
		

Figure 3. Comparison between the Authentic and Verified Counterfeit Naproxen Sodium (Flanax® Forte) 550 mg Tablet (Lot no. TFFBK410 Expiry date AUG 2022)

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. Always check if a product is registered with the FDA by using the FDA Verification Portal feature accessible at <http://verification.fda.gov.ph>.

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 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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