



FDA ADVISORY
No. **2016-141**

16 NOV 2016

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Use of the following Counterfeit Drug Products:

1. Mefenamic Acid (Dolphenal) 500 mg Tablet
2. Dextromethorphan HBr + Phenylephrine HCl + Paracetamol (Tuseran Forte) 15 mg / 10 mg / 325 mg Capsule
3. Loperamide (Diatabs) 2 mg Capsule
4. Ibuprofen + Paracetamol (Alaxan FR) 200 mg / 325 mg Capsule
5. Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Neozep Forte) 10 mg / 2 mg / 500 mg Tablet

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



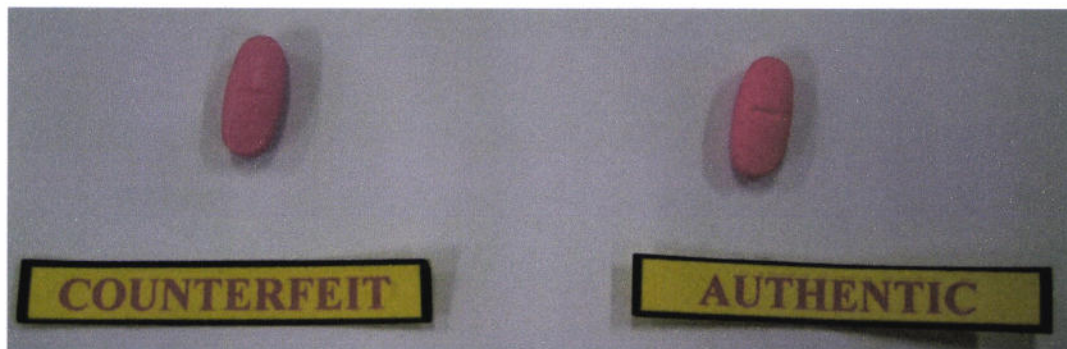
Figure 1. Counterfeit and Authentic Mefenamic Acid (Dolphenal) 500 mg Tablet





Foil pattern, print of Lot number and Expiry date are different.

Figure 2. Counterfeit and Authentic Mefenamic Acid (Dolphenal) 500 mg Tablet



Tablet color is different

Figure 3. Counterfeit and Authentic Mefenamic Acid (Dolphenal) 500 mg Tablet



Foil color, logo, print color and appearance are different.

Figure 4. Counterfeit and Authentic Dextromethorphan HBr + Phenylephrine HCl + Paracetamol (Tuseran Forte) 15 mg / 10 mg / 325 mg Capsule



Foil pattern, print of Lot number and Expiry date are different.

Figure 5. Counterfeit and Authentic Dextromethorphan HBr + Phenylephrine HCl + Paracetamol (Tuseran Forte) 15 mg / 10 mg / 325 mg Capsule



Counterfeit

Authentic

Capsule color and print are different

Figure 6. Counterfeit and Authentic Dextromethorphan HBr + Phenylephrine HCl + Paracetamol (Tuseran Forte) 15 mg / 10 mg / 325 mg Capsule



Security mark, logo, print color and appearance are different.

Figure 7. Counterfeit and Authentic Loperamide (Diatabs) 2 mg Capsule



Foil pattern, print of Lot number and Expiry Date are different.

Figure 8. Counterfeit and Authentic Loperamide (Diatabs) 2 mg Capsule



Capsule color is different

Figure 9. Counterfeit and Authentic Loperamide (Diatabs) 2 mg Capsule



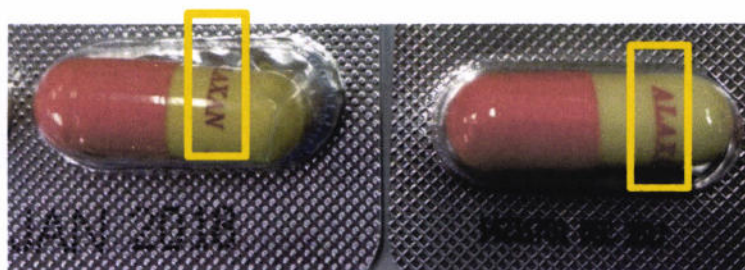
Foil pattern, print color and appearance are different.

Figure 10. Counterfeit and Authentic Ibuprofen + Paracetamol (Alaxan FR) 200 mg / 325 mg Capsule



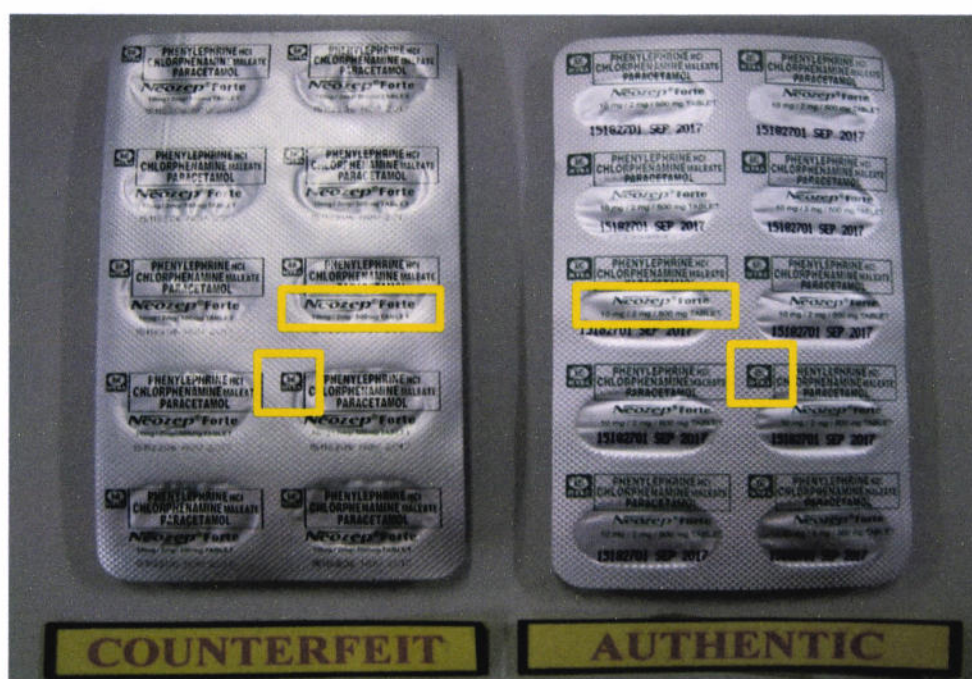
Capsule color and print of Lot number and Expiry Date are different.

Figure 11. Counterfeit and Authentic Ibuprofen + Paracetamol (Alaxan FR) 200 mg / 325 mg Capsule



Capsule color and print are different

Figure 12. Counterfeit and Authentic Ibuprofen + Paracetamol (Alaxan FR) 200 mg / 325 mg Capsule



Foil pattern, logo, print of Lot number and Expiry date are different.

Figure 13. Counterfeit and Authentic Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Neozept Forte) 10 mg / 2 mg / 500 mg Tablet



Figure 14. Counterfeit and Authentic Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Neozep Forte) 10 mg / 2 mg / 500 mg Tablet

The Food and Drug Administration together with United Laboratories, Inc. – 66 United St., Mandaluyong City, has confirmed that the above-mentioned drug products are counterfeit.

All healthcare professionals and the general public are hereby warned to be vigilant of the abovementioned counterfeit drug products. These pose potential danger or injury to the consuming public and 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.

In the interest of protecting public health and safety, the Officers of the Field Regulatory Operations Office (FROO) are hereby mandated to exercise their regulatory function pursuant to Section 14 of Republic Act No. 9711.

All establishments and outlets are hereby warned against selling and/or dispensing the above identified counterfeit drug products. Anyone found selling the said drug products will be penalized.

Likewise, all local government units and law enforcement agencies are requested to ensure that these drug products are not sold or offered for sale in their localities or area of jurisdiction.

All consumers are advised to purchase their medications only from FDA-licensed establishments. Please note that, in addition to inspection of establishments, product evaluation, registration, and testing are measures that the government undertakes to ensure the quality, safety, and efficacy of health products. Please look for the FDA Registration number on the product label. Moreover, please be reminded that drug products registered with FDA Philippines bear in their labels information in English and/or in Filipino for all consumers to understand.

For more information and inquiries, please e-mail us at info@fda.gov.ph. To report continuous sale or distribution of counterfeit drug products, kindly e-mail us via report@fda.gov.ph or you may call the telephone number (02)807-8275. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill out all the required fields.

Dissemination of the information to all concerned is requested.


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Director General

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