

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2018-081

11 6 MAR 2018

TO

: ALL HEALTHCARE PROFESSIONALS AND THE

GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of

the Verified Counterfeit Drug Product Paracetamol

(Biogesic) 500 mg Tablet

The Food and Drug Administration (FDA) advises the public against the purchase and use of the verified counterfeit drug product Paracetamol (Biogesic) 500 mg Tablet:

COUNTERFEIT AUTHENTIC AUTHENTIC COUNTERFEIT Tablet color, print appearance and foil pattern are different

Figure 1. Comparison between the authentic and verified counterfeit/fake Paracetamol (Biogesic) 500 mg tablet





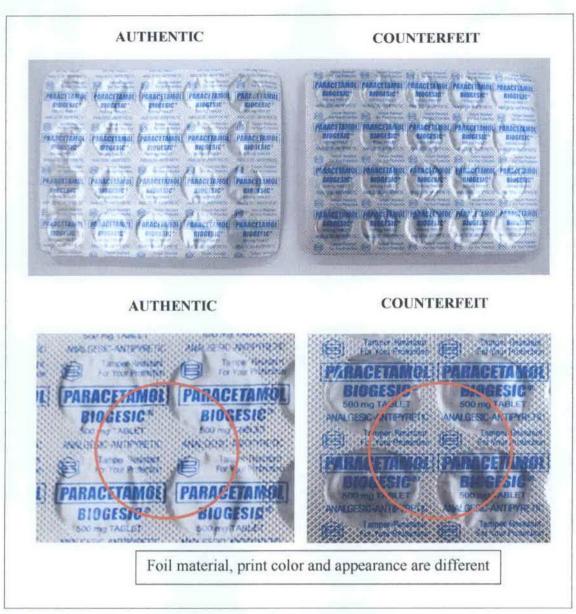


Figure 2. Comparison between the authentic and verified counterfeit/fake Paracetamol (Biogesic) 500 mg tablet

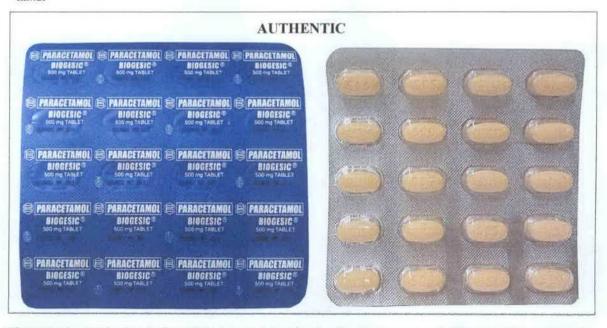


Figure 3. New packaging design of the duly-registered and authentic Paracetamol (Biogesic) 500 mg Tablet

The FDA together with the Marketing Authorization Holder (MAH), United Laboratories, Inc., have verified that the abovementioned sample drug product is counterfeit. Moreover, please take note of the new packaging of Paracetamol (Biogesic) 500 mg Tablet (see Figure 3).

All healthcare professionals and the general public are hereby warned as to the availability of this counterfeit drug product in the market which poses 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 this verified counterfeit drug product 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, therefore a penalty shall be imposed.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this counterfeit product is 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 and/or counterfeit 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) 809-5596. 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.

NELA CHARADE G. PUNO, RPh

Director General