



FDA ADVISORY
No. **2020-2130**

10 DEC 2020

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the Verified Counterfeit Phenytoin Sodium (Dilantin®) 50mg/ml Solution for Injection (IM/IV)

The Food and Drug Administration (FDA) advises the public against the purchase and use of the verified counterfeit Phenytoin Sodium (Dilantin®) 50mg/ml Solution for Injection (IM/IV):

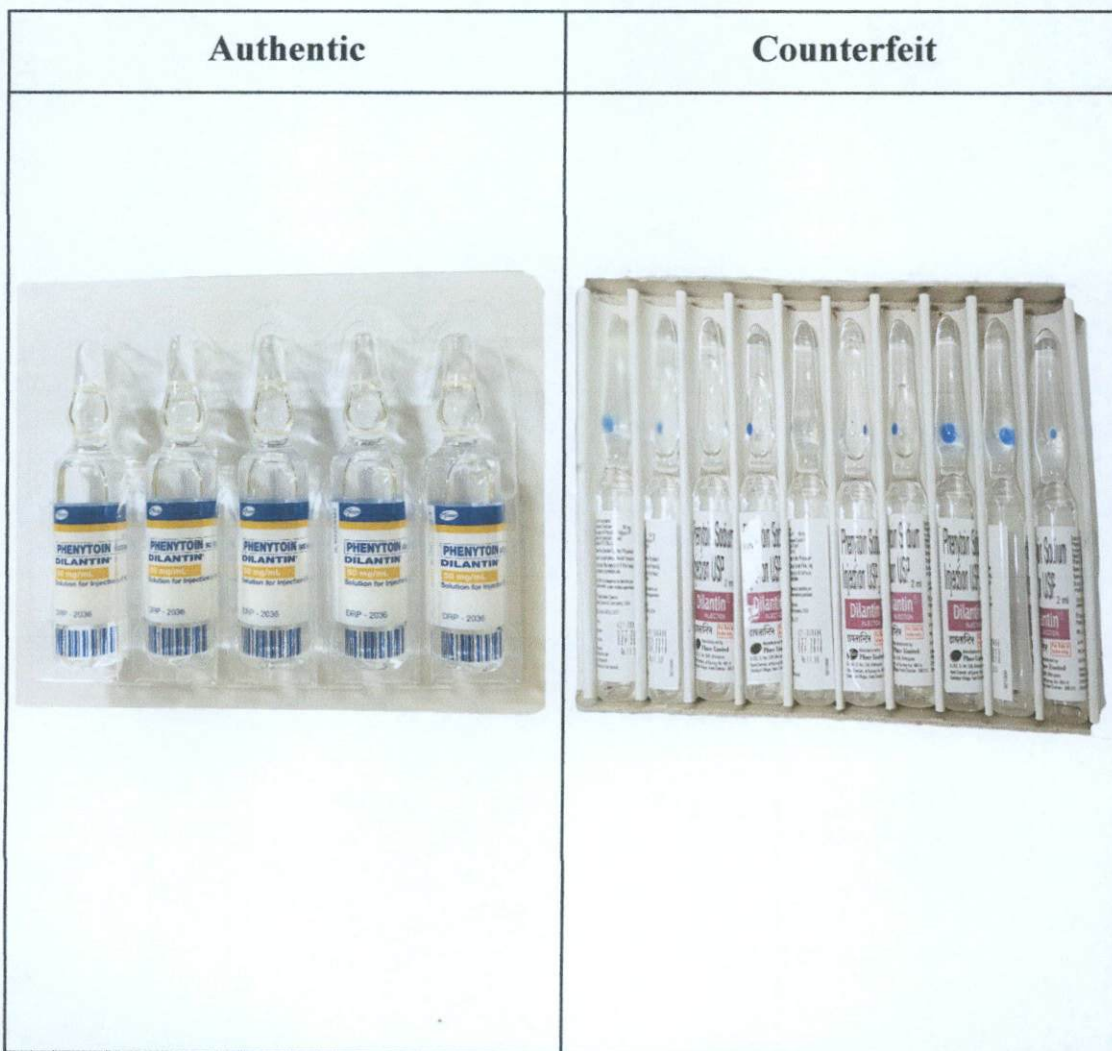
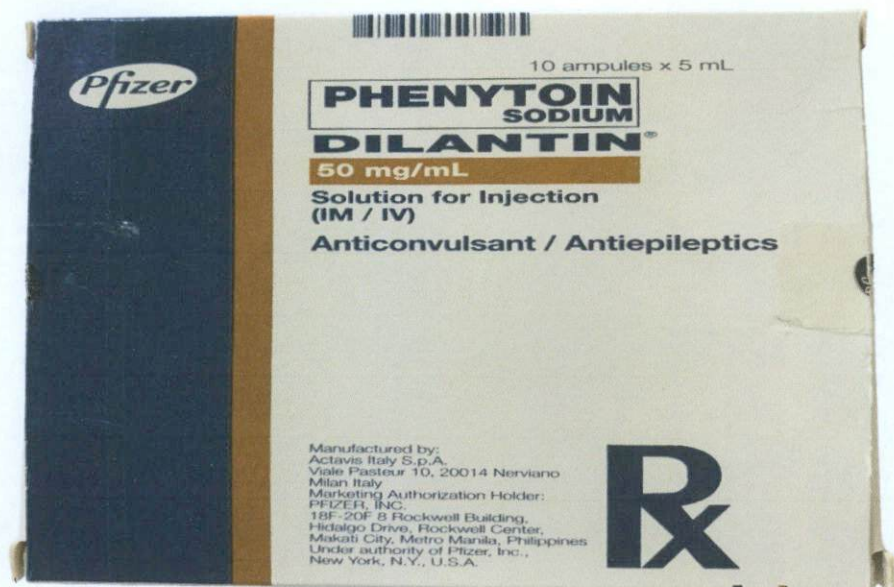


Figure 1. Comparison between the Authentic and Verified Counterfeit Phenytoin Sodium (Dilantin®) 50mg/ml Solution for Injection (IM/IV)



Authentic



Counterfeit

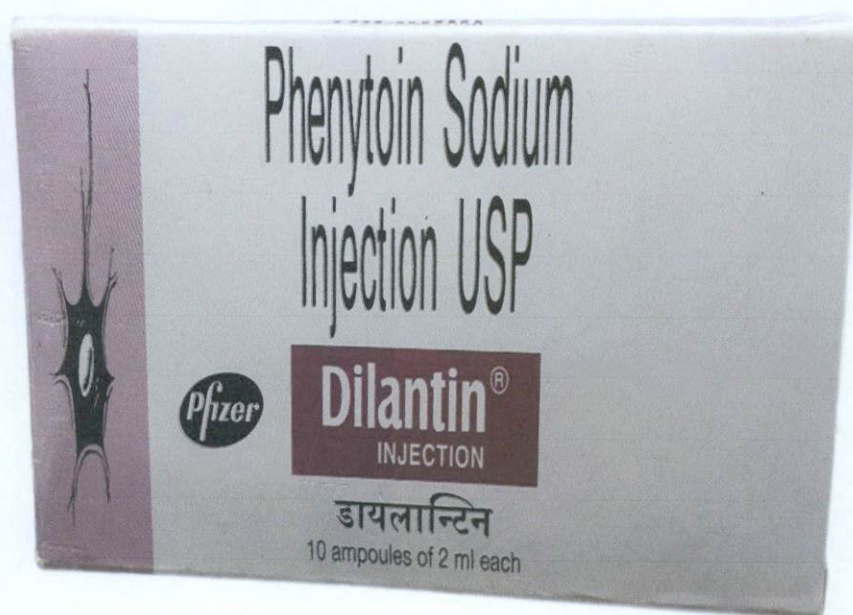


Figure 2. Comparison between the Authentic and Verified Counterfeit Phenytoin Sodium (Dilantin[®]) 50mg/ml Solution for Injection (IM/IV)

The FDA together with the Marketing Authorization Holder (MAH), Pfizer, Inc., have verified that the above-mentioned sample drug product is counterfeit. The comparison of the collected counterfeit drug product and the distinguishing feature of the authentic are as follows:

Authentic	Counterfeit
<ol style="list-style-type: none"> 1. Pfizer logo in blue print 2. Product Description: (Phenytoin Sodium) Dilantin 50mg/mL Solution for Injection (IM/IV) 3. Pack size: 10 ampules x 5 mL 4. Two (2) separate trays containing 5 labeled ampules per tray 	<ol style="list-style-type: none"> 1. Pfizer logo in black print 2. Product Description: Phenytoin Sodium Injection USP (Dilantin Injection) 3. Pack size: 10 ampoules of 2 mL each 4. Ten (10) labeled ampoules placed in a paper tray

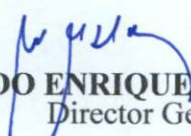
All healthcare professionals and the general public are hereby warned as to the availability of this counterfeit drug product in the market which poses potential danger or injury to consumers. Consumers are also reminded to purchase drug product only from FDA-licensed establishments.

Likewise, all establishments and outlets are hereby warned against selling and/or dispensing of this drug product with the abovementioned features of a counterfeit drug product. 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 product will be penalized.

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 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) 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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