



FDA ADVISORY
No. **20202204**

28 DEC 2020

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Product Recall of Specific Batches of Cloxacillin (as sodium) 500 mg Capsule (Philclox)

All healthcare professionals and the general public are hereby warned by the Food and Drug Administration (FDA) that the affected batches of the subject product are being recalled from the market. The details of the product are as follows:

DRUG PRODUCT	CLOXACILLIN (AS SODIUM) 500 mg CAPSULE (PHILCLOX)	
REGISTRATION NO.	DRP-7969	
BATCH NO./EXP. DATE	193131356	04/2021
	193131357	04/2021
	193131358	04/2021
MANUFACTURER	Jiangxi Xierkangtai Pharmaceutical Co., Ltd. – North Zone, High-New Technology Industrial Zone, Pingxiang, Jiangxi, China	
IMPORTER & DISTRIBUTOR	PhilRx Pharma Inc. – No. 6 Felipe Pike St., Bagong Ilog, Pasig City	



Figure 1. Cloxacillin (as sodium) 500 mg Capsule (Philclox) for recall



Based on the results of the laboratory analyses conducted by the FDA, it was found that the affected batches did not conform to the set specifications of assay test. The assay of a drug product determines the (1) presence of a substance and the amount of that substance, or (2) the pharmaceutical potency of a drug. Therefore, the stated batches present quality and efficacy concerns.


Cloxacillin is used to treat a wide variety of bacterial infections. Cloxacillin (as sodium) 500 mg Capsule (Philclox) is packed in an Alu/PVC Blister Pack x 10's (Box of 100's).

Therefore, distributors, hospitals, retailers, pharmacies, or clinics that have the affected batches of the product are instructed to discontinue further distribution, sale, and use. Likewise, all consumers are advised not to use or purchase the affected product batches and may contact PhilRx Pharma Inc. at telephone no. (02) 655-5492 or send an e-mail to philrx.regulatory@ambpharma.com for any question or additional information regarding the recall.

All Local Government Units (LGU) and Law Enforcement Agencies (LEAs) are requested to ensure that the affected product batches are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at cdr_postmarketsurveillance@fda.gov.ph. To report continuous sale or distribution of the abovementioned, kindly e-mail us via ereport@fda.gov.ph. You may also call the Center for Drug Regulation and Research at telephone number (02) 8809-5596. Any suspected adverse reaction experienced from the use of the products should be reported immediately to the FDA through this link: <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> and fill-out all of the required fields.

Dissemination of the information to all concerned is requested.


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Director General



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