Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20201268

JUN 26 2020

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Product Recall of Specific Batches of Levofloxacin (as Hemihydrate) 500 mg/100 mL Solution for IV Infusion (Kingfloxin)**

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	**LEVOFLOXACIN (AS HEMIHYDRATE) 500 mg/100 mL SOLUTION FOR IV INFUSION (KINGFLOXIN)**	
REGISTRATION NO.	**DRP-7652**	
BATCH NO./EXP. DATE	**9254001**	**MARCH 2022**
	9254002	**MARCH 2022**
	9254004	**MARCH 2022**
MANUFACTURER	**Geofman Pharmaceuticals – 204, E.I. Lines, Dr. Daud Pota Road, Karachi, Pakistan**	
IMPORTER AND DISTRIBUTOR	**Sahar International Trading, Inc. – 354 Aguirre Ave., Phase III BF Homes, Parañaque City**	

Figure 1. Levofloxacin (as Hemihydrate) 500 mg/100 mL Solution for IV Infusion (Kingfloxin) 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 safety concerns.

Levofloxacin is indicated in adults for the treatment of tuberculosis, uncomplicated urinary-tract infection, chronic bacterial prostatitis, complicated skin infections, hospital acquired pneumonia, community acquired pneumonia, acute bacterial sinusitis, complicated urinary-tract infections, acute pyelonephritis, and inhalational anthrax. Levofloxacin (as Hemihydrate) 500 mg/100 mL Solution for IV Infusion (Kingfloxin) is packed in a clear USP Type I glass vial x 100 mL (Box of 1'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 Sahar International Trading, Inc. at telephone no. (02) 7901-6863 or mobile no. +639778422456 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 **cdrr_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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