



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2022-1092**

MAY 25 2022

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Voluntary Product Recall of Specific Batches of Vancomycin Hydrochloride 500 mg (500,000 IU) Powder for IV Infusion

All healthcare professionals and the general public are hereby advised 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	VANCOMYCIN HYDROCHLORIDE 500 mg (500,000 IU) POWDER FOR IV INFUSION	
REGISTRATION NO.	DR-XY12581	
BATCH NO./EXP. DATE	H036913AAR	August 2022
	H036913AAR1	
MANUFACTURER	Hospira Australia Pty. Ltd. – 1-5, 7-23 and 25-39 Lexia Place, Mulgrave VIC 3170, Australia	
IMPORTER [MARKETING AUTHORIZATION HOLDER (MAH)]	Pfizer, Inc. – 19F-20F 8 Rockwell Building, Hidalgo Drive, Rockwell Center, Poblacion, Makati City	



Figure 1. Vancomycin Hydrochloride 500 mg Powder for IV Infusion (Batch No. H036913AAR) for voluntary recall





Figure 2. Vancomycin Hydrochloride 500 mg Powder for IV Infusion (Batch No. H036913AAR1) for voluntary recall

The voluntary recall is pursued by the MAH due to out-of-specification stability results which do not meet the shelf-life specification for potency and have atypically declining potency over the 30-month product shelf-life. While no adverse events or product complaints have been received regarding these batches to date, the analysis predicts that the product may be at 78% - 87% potency by end of shelf-life. Further investigation is ongoing to determine the root cause and identify preventive actions to avoid future impact on other Vancomycin Hydrochloride 500 mg batches.

The potential risk to a patient arising from using an impacted product towards the end of its shelf life has a reasonable probability of resulting in a lack of effect or development of resistance to susceptible organisms. Therefore, the MAH is recalling these batches prior to the end of shelf life. The amount of drug delivered may be insufficient to effectively treat the patient and therefore appropriate follow-up and monitoring of patients should be considered.


Vancomycin Hydrochloride for Intravenous Infusion is indicated for potentially life-threatening infections which cannot be treated with another effective, less toxic antimicrobial drug, including the penicillins and cephalosporins. Vancomycin Hydrochloride 500 mg (500,000 IU) Powder for IV Infusion is packed in Clear Type I Glass Vial with green flip-off seal (Box of 1's).

Therefore, distributors, hospitals, retailers, pharmacies, or clinics that have the affected lots 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 lot. You may contact Pfizer, Inc. by sending an e-mail to Pfizer Product Quality via pcom-qophl@pfizer.com for any questions or additional information regarding the recall.

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 the telephone number (02) 8809-5596. Any suspected adverse reaction experienced from the use of the product 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.


DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge Director General



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