

12 March 2021

VOLUNTARY PRODUCT RECALL ADVISORY

We would like to inform you that, we have voluntarily conducted a Class 3 recall of **Amoxicillin (as trihydrate) 125 mg/5 mL Powder for Suspension (Himox) [DR-XY12740], Net Content: 60 mL**, an antibacterial drug, due to incorrect text of volume of water for reconstitution as indicated in the individual box. The text reflected in the individual box is 63mL instead of 36mL of water for reconstitution.

The affected batches are as follows:

Batch no.	Mfg. Date	Exp. Date
A003561	02/12/2020	02/11/2022
A004007	06/10/2020	06/10/2022
A004128	08/10/2020	08/10/2022
A004129	08/11/2020	08/11/2022

The misprint involves the instruction indicated in the individual box which states to reconstitute with 63mL of water instead of 36mL of water which is the correct volume of water for SKU of 60mL. This misprint has no serious impact on the safety or efficacy of the product.

We note that the product label of the bottle and the product insert contain the correct information on volume of water for reconstitution as 36 mL.

In any case, we conducted a voluntary product recall as a precautionary measure as an exercise of utmost diligence.

With this, we have informed our distribution partners to pull-out and segregate the affected stocks in their respective warehouses.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph or through <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH>.

Should you have queries or concerns, please call +632-8-8645221 for Metro Manila or toll free +1-800-10-UNILAB-1 for provincial, or e-mail productsafety@unilab.com.ph.

We thank you for your patronage of our products. Rest assured that we will continue our efforts to provide quality and affordable medicines.