Republic of the Philippines
Department of Health
**FOOD AND DRUG ADMINISTRATION**

FDA Food and Drug Administration PHILIPPINES

**FDA ADVISORY**
No. 2021-2616

27 OCT 2021

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

**SUBJECT:** **Product Recall of Specific Batches of Co-Amoxiclav 625 mg Film-Coated Tablet (Asiclav-625)**

---

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 | **CO-AMOXICLAV 625 mg FILM-COATED TABLET (ASICLAV-625)** | |
| REGISTRATION NO. | **DRP-8498** | |
| BATCH NO./EXP. DATE | **687200603** | **06/2022** |
| | **687200605** | |
| | **687200606** | |
| MANUFACTURER | **CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd. - No. 88 Yangzi Road, Shijiazhuang Economic & Technological Development Zone, Hebie Province, China** | |
| IMPORTER [MARKETING AUTHORIZATION HOLDER] | **AMB HK Enterprises Inc. - No. 6 Felipe Pike St., Bagong Ilog, Pasig City** | |


Figure 1. Co-Amoxiclav 625 mg Film-Coated Tablet (Asiclav-625) 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 specification 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.

Co-amoxiclav is indicated for the treatment of infections in adults and children such as acute bacterial sinusitis, acute otitis media, acute exacerbations of chronic bronchitis, community-acquired pneumonia, cystitis, pyelonephritis, skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis and, bone and joint infections, in particular osteomyelitis. Co-Amoxiclav 625 mg Film-Coated Tablet (Asiclav-625) is packed in an Alu/Alu blister pack x 7's with aluminum film pouch (Box of 14's).

Therefore, distributors, hospitals, retailers, pharmacies, or clinics that have the affected batch 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 AMB HK Enterprises Inc. by sending an e-mail to **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 **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.

**ROLANDO ENRIQUE D. DOMINGO, MD**
Director General

20211014143427