



FDA ADVISORY
No. **2022-1913**

12 DEC 2022

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the Counterfeit Drug Product “Cefuroxime [as Axetil] (Keef-125™) 12.5 mg/5 mL Granules for Oral Suspension 50 mL”

The Food and Drug Administration (FDA) advises the public against the purchase and use of the counterfeit version of the following product:

AUTHENTIC				
	<p>FORMULATION: Each 5 mL of reconstituted suspension contains: Cefuroxime (as axetil) 125 mg</p> <p>INDICATION: Cefuroxime axetil is indicated for the treatment of the infections listed below in adults and children from the age of 3 months</p> <ul style="list-style-type: none"> • Acute streptococcal tonsillitis and pharyngitis. • Acute bacterial sinusitis. • Acute otitis media. • Acute exacerbations of chronic bronchitis. • Cystitis. • Pyelonephritis. • Uncomplicated skin and soft tissue infections. • Treatment of early Lyme disease. <p>Consideration should be given to official guidance on the appropriate use of antibacterial agents.</p> <p>DOSAGE AND ADMINISTRATION/ CONTRAINDICATIONS/ WARNINGS AND PRECAUTIONS/ INTERACTIONS/ ADVERSE DRUG REACTIONS: See package insert for information.</p> <p>DIRECTION FOR RECONSTITUTION: Tap the bottle to loosen the powder. Slowly add 21 mL purified water and shake well. The reconstituted suspension should be stored in refrigerator (2-8°C) and should be used within 10 days after reconstitution.</p> <p>Keep taking the medicine until the course is completed.</p>	<p>CAUTION: Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.</p> <p>For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph</p> <p>STORAGE CONDITIONS: Store at temperatures not exceeding 30°C.</p> <p>Reg. No.: DRP-7990 Mfg. Lic. No.: G/1195</p> 		
COUNTERFEIT				
	<p>FORMULATION: Each 5 mL of reconstituted suspension contains: Cefuroxime (as axetil) 125 mg</p> <p>INDICATION: Cefuroxime axetil is indicated for the treatment of the infections listed below in adults and children from the age of 3 months</p> <ul style="list-style-type: none"> • Acute streptococcal tonsillitis and pharyngitis. • Acute bacterial sinusitis. • Acute otitis media. • Acute exacerbations of chronic bronchitis. • Cystitis. • Pyelonephritis. • Uncomplicated skin and soft tissue infections. • Treatment of early Lyme disease. <p>Consideration should be given to official guidance on the appropriate use of antibacterial agents.</p> <p>DOSAGE AND ADMINISTRATION/ CONTRAINDICATIONS/ WARNINGS AND PRECAUTIONS/ INTERACTIONS/ ADVERSE DRUG REACTIONS: See package insert for information.</p> <p>DIRECTION FOR RECONSTITUTION: Shake the bottle to loosen the powder. Slowly add 21 mL purified water and shake well. The reconstituted suspension should be stored in refrigerator (2-8°C) and should be used within 10 days after reconstitution.</p> <p>Keep taking the medicine until the course is completed.</p>	<p>CAUTION: Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.</p> <p>For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph</p> <p>STORAGE CONDITIONS: Store at temperatures not exceeding 30°C.</p> <p>Reg. No.: DRP-7990 Mfg. Lic. No.: G/1195</p> 		

Counterfeit – The batch details and labeling requirements are not comparable with the standard features of the registered product.

Figure 1. Comparison between the Authentic and Verified Counterfeit Cefuroxime [as Axetil] (Keef-125™) 12.5 mg/5 mL Granules for Oral Suspension 50 mL Batch No. DS20005



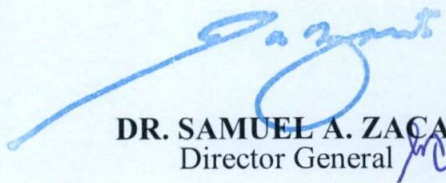
All healthcare professionals and the general public are hereby warned as to the availability of this counterfeit drug product in the market which pose potential danger or injury to consumers. Consumers are also reminded to purchase drug product only from FDA-licensed establishments.

Likewise, all establishments and outlets are hereby warned against selling and/or dispensing of the said counterfeit product with the abovementioned features. The importation, selling or offering for sale of such is in direct violation of Republic Act No. 9711 or the Food and Drug Administration Act of 2009, and Republic Act No. 8203 or the Special Law on Counterfeit Drugs. Anyone found selling the said counterfeit drug product will be penalized.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at info@fda.gov.ph. To report continuous sale or distribution of unregistered health products, kindly e-mail us via ereport@fda.gov.ph, or through the online reporting facility, **eReport**, at www.fda.gov.ph/ereport. You may also call the Center for Drug Regulation and Research at telephone number **(02) 8809-5596**. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> and fill out all the required fields.

Dissemination of the information to all concerned is requested.


DR. SAMUEL A. ZACATE
Director General

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