



12 DEC 2022

FDA ADVISORY
No. 2022-1913-A

PARA : SA LAHAT NG HEALTHCARE PROFESSIONALS AT SA PUBLIKO

PAKSA : Babala sa Publiko tungkol sa Paggamit ng Beripikadong Pekeng Gamot na “Cefuroxime [as Axetil] (Keef-125™) 12.5 mg/5 mL Granules for Oral Suspension 50 mL”

Pinapayuhan ng Food and Drug Administration (FDA) ang publiko laban sa pagbili at paggamit ng beripikadong pekeng gamot:

TUNAY / AUTHENTIC

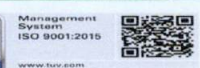
	<p>FORMULATION: Each 5 mL of reconstituted suspension contains: Cefuroxime (as axetil) 125 mg</p> <p>INDICATION: Cefuroxime axetil is indicated for the treatment of the infections listed below in adults and children from the age of 3 months.</p> <ul style="list-style-type: none"> • Acute streptococcal 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</p> <p>Mfg. Lic. No.: Q/1195</p> 	
--	---	--	---

PEKE / 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</p> <p>Mfg. Lic. No.: Q/1195</p> 	
---	---	--	--

Peke/Counterfeit – Ang batch details at label requirements ay hindi tugma sa rehistradong gamot.

Larawan 1. Paghahambing sa Tunay/Authentic at Peke/Counterfeit Cefuroxime [as Axetil] (Keef-125™) 12.5 mg/5 mL Granules for Oral Suspension 50 mL Batch No. DS20005




Ang lahat ng *healthcare professionals* at publiko ay binabalaan tungkol sa paglipana ng nasabing pekeng gamot sa merkado na maaaring magdulot ng panganib sa kalusugan ng mga gagamit nito. Ang publiko ay pinapaalalahanan ring bumili lamang sa mga establisyementong lisensyado ng FDA.

Gayundin, ang lahat ng establisyemento ay binabalaang huwag magbenta ng pekeng gamot na nagtataglay ng mga nasabing katangian. Ang pagaangkat, pagbebenta at pamamahagi nito ay paglabag sa *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*. Ang sino mang mapatunayang nagbebenta ng nasabing pekeng produkto ay mapaparusan.

Hinihiling sa lahat ng *Local Government Units (LGUs) and Law Enforcement Agencies (LEAs)* na tiyaking ang pekeng produktong ito ay hindi maibebenta o magagamit sa kanilang mga nasasakupan.

Para sa karagdagang impormasyon at katanungan, maaring mag-email sa info@fda.gov.ph. Upang mag-report ng patuloy na pagtitinda o pangangalakal ng mga pekeng gamot, mag-email sa report@fda.gov.ph, o mag-report gamit ang aming *online reporting facility*, **eReport**, sa www.fda.gov.ph/ereport. Maaari ring tumawag sa *Center for Drug Regulation and Research* sa numerong **(02) 8809-5596**. Para sa mga hinihinalang hindi kanais-nais na reaksyon sa gamot, i-report agad sa FDA gamit ang *link* na ito: <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> at kumpletuhin ang mga kinakailangang impormasyon.

Ang lahat ay hinihikayat na palaganapin ang mga nakasaad na impormasyon.


DR. SAMUEL A. ZACATE
Director General

DTN:



20221111084918