URGENT DRUG RECALL
Amoxicillin and Clavulanate Potassium Tablets USP, (Chewable) 400 mg/57 mg
June 04, 2024

Teva Pharmaceuticals USA, Inc.

Amoxicillin and Clavulanate Potassium Tablets USP, (Chewable) 400 mg/57 mg			
NDC	Lot	Exp. Date	Size
0093-2272-34	35449379A	07 2024	20 Count bottle
0093-2272-34	100047634	04 2025	20 Count bottle

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (TEVA USA) is initiating a voluntary nationwide recall of the above referenced drug products to the **RETAIL LEVEL.** The products in this recall were distributed to TEVA USA direct customers under the Teva Pharmaceuticals USA, Inc. label. The reason for the recall is out-of-specification (OOS) assay results for the clavulanate potassium, associated with a portion of the specified lots. The addition of clavulanic acid to amoxicillin increases the susceptibility of amoxicillin-resistant bacterial strains to amoxicillin. A reduced amount of clavulanic acid in the product, due to the OOS, could result in reduced effectiveness in certain situations, potentially causing an infection to worsen. Nonetheless, scientific literature suggests that because of the variability in absorption of clavulanic acid, a reduced amount of clavulanic acid is not likely to have a significant consequence in the efficacy of the drug combination. According to the Health Hazard Assessment by Teva USA, exposure to the product of concern could potentially lead to severe adverse health consequences, but the likelihood of harm was assessed as remote.

This recall is being made with the knowledge of the Food and Drug Administration.

Please take the following actions upon receipt of this letter:

- Immediately examine your inventory for the specified lots being recalled **and** Immediately discontinue distribution.
- TEVA's distribution records indicate that the specified lots were shipped to its direct customers from 10/17/2022 - 5/9/2024.
- **If you have further distributed the recall lots, please perform a SUB-RECALL to your sub-accounts using this Recall Notification and Business Reply Form (BRF) as a basis for your recall notification.**
- Promptly complete the attached Recall BRF, even if you have **no** product to return, and return the completed Recall BRF to Inmar, Attn: Recall Coordinator by any one of these means:

  MAIL: Inmar, One West Fourth Street, Suite 500, Winston Salem, NC 27101
  EMAIL: **rxrecalls@inmar.com**.
  FAX: 817-868-5362.

After receipt of your Recall BRF, Inmar will send labels for your Return Goods Authorization (RGA) and shipping of your product return. Appropriate credit for your product returns, plus expenses for handling and shipping, will be issued after receipt of said product with your RGA. All recalled product returned without a RGA will delay the issuance of a credit. Products returned that are not the subject of the recall will not be credited and will be destroyed.

CONTACT INFORMATION AND CREDIT
Product Returns: Contact Inmar at 877 883 3695 (Hours of Operation: M – F, 9.00 am to 5.00 pm Eastern Time) for Recall Business Stock Response forms or acquire from clsnetlink.com
Medical-related Questions or to report an Adverse Event: Contact Teva Medical Information at: 888-838-2872, option 3, then, option 4 Live calls received: M - F, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week or by email at druginfo@tevapharm.com
Product Quality Complaint-related Questions: Contact Teva Quality Assurance Services: 888-838-2872, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week or by email at QAS@tevapharm.com
Customer Service-related Questions: Contact Teva Customer Service: 888-838-2872, option 3, then option 2 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
FDA contact information for reporting adverse events/quality complaints: Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088

Sincerely,

Regulatory Compliance, Teva Pharmaceuticals USA, Inc.

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June 04, 2024

Teva Pharmaceuticals USA, Inc.

Date Form Completed _____

RECALL BUSINESS REPLY FORM

Promptly return your completed Business Reply Form (BRF) by any one of these means to Inmar, Attn: Recall Coordinator

MAIL: Inmar, 1 W 4th St., Winston Salem, NC 27101 **EMAIL: rxrecalls@inmar.com** **FAX: 817-868-5362**

Section 1 – Customer Information

This Stock Response is for (Check One): ☐ **Teva Direct Account** ☐ **Non-Direct Customer**

Customer/Store Name:	Address (Street/City/State/Zip)
*DEA #: ***DEA # is required; in order to process your form.***	*Debit Memo #
Contact Name (please print):	Telephone #:

Please mark your answer - I have checked my stock and):

☐ I ***do*** have stock of the recalled item(s) **(complete section 2)** **OR** ☐ I **do not** have stock of the recalled item(s).

Teva Direct Accounts

Does your response include **all** your DC locations? ☐ YES ☐ NO

Non-Direct Customer

The product(s) in this recall were purchased from: _____ / Location: _____

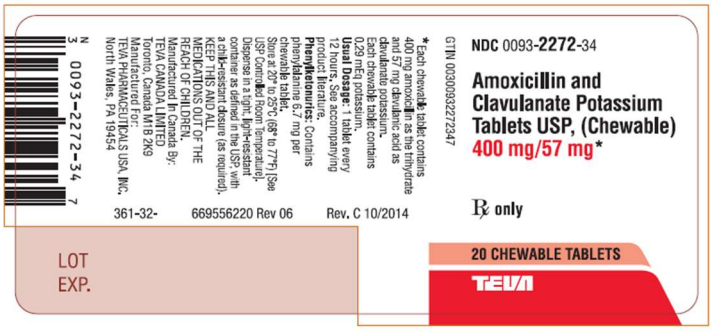
Section 2– Wholesalers/Distributors/Retailers – Quantity of Product to Return

Enter the information of the recalled product(s) to be returned in the table below. If additional space is needed, please make copies of this form.

Lot	Quanty of product to return.
35449379A	
100047634	

Images Shown Have Not Been Reproduced to Scale of Actual Product Cartons

Lot # 35449379A



Lot # 100047634

Inmar/MedTurn Use Only:				
Scan	Labels	Store	Kit	D.B