*Teva Pharmaceuticals USA, Inc.*

# URGENT DRUG RECALL

## Amoxicillin and Clavulanate Potassium for Oral Suspension, USP 200 mg/28.5 mg per 5mL

## October 13, 2025

| Amoxicillin and Clavulanate Potassium for Oral Suspension, USP 200 mg/28.5 mg per 5mL | | | |
|---|---|---|---|
| NDC | Lot # | Exp. Date | Size |
| 0093-2277-73 | 100062316 | 01/2026 | 100 mL |

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (Teva USA) is initiating a voluntary nationwide recall of *the above one (1) lot* of Amoxicillin and Clavulanate Potassium for Oral Suspension, USP 200 mg/28.5 mg per 5mL to the RETAIL LEVEL. The product in this recall is distributed under the Teva Pharmaceuticals USA, Inc. label. The reason for the recall is out-of-specification (OOS) assay results for Clavulanic acid, associated with this specific lot. The main safety concern that may potentially arise from the lower Clavulanate Potassium result is a decrease in the efficacy of Amoxicillin/Clavulanic acid. According to the Health Hazard Assessment by Teva USA, exposure to the product of concern could lead to severe adverse events in vulnerable populations and the likelihood of the harm was assessed as remote/unlikely. The overall risk of harm in the patient population is medium.

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

***Please take the following actions upon receipt of this letter:***

- Immediately examine your inventory for Amoxicillin and Clavulanate Potassium for Oral Suspension, USP 200 mg/28.5 mg per 5 mL lot # 100062316.
- Immediately discontinue distribution of and quarantine Amoxicillin and Clavulanate Potassium for Oral Suspension, USP 200 mg/28.5 mg per 5mL lot # 100062316.
- Teva USA's records indicate that the recalled lot was commercially distributed/shipped to its direct customers from 01/09/2025 through 08/05/2025.
- **If you have further distributed Amoxicillin and Clavulanate Potassium for Oral Suspension, USP 200 mg/28.5 mg per 5mL lot # 100062316, 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. Please note: The Recall BRF must be filled out. If the Recall BRF form is not filled out correctly and, in its entirety, no credit will be issued. Please return the completed Recall BRF in its entirety to Inmar, Attention: 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. Products returned that are not the subject of the recall will not be credited and will be destroyed.

| **CONTACT INFORMATION AND CREDIT** |
|---|
| **Product Returns:**<br>Contact Inmar at 855-905-4376 (Hours of Operation: M – F, 9.00 am to 5.00 pm Eastern Time) for Recall Stock Response forms or acquire from: clsnetlink.com |
| **Medical-related Questions or to report an Adverse Event:**<br>Contact Teva Medical Information at: 888-838-2872, option 3, then option 4<br>Live calls received: M - F, 9:00 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:**<br>Contact Teva Quality Assurance Services: 888-838-2872, option 4<br>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.QAS@tevapharm.com |
| **Customer Service-related Questions:**<br>Contact Teva Customer Service: 888-838-2872, option 3, then option 2<br>Live calls received: M - F, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week |
| **FDA contact information for reporting adverse events/quality complaints:**<br>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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## October 13, 2025

## RECALL BUSINESS REPLY FORM

**Date Form Completed** _____

**This form must be filled out completely. If this form is not filled out correctly and, in its entirety, no credit will be issued. 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 #:<br>***DEA # is required; in order to process your form.*** | *Debit Memo #<br>***Debit Memo # is required; in order to process your form.*** |
| 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

Did you communicate the recalls to your direct accounts ☐ YES ☐ NO

**Non-Direct Customer**

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

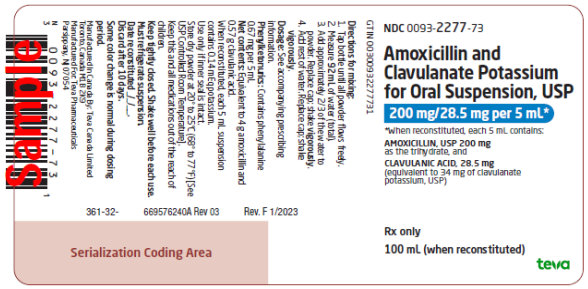
Name of Your Wholesaler/Distributor and Location

**Section 2 – 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.***

| NDC # | Lot # | Exp Date | Size | Quantity of Product to Return (Count Partial Bottles as 1) |
|---|---|---|---|---|
| 0093-2277-73 | 100062316 | 01/26 | 100 mL | |

Image Shown Has Not Been Reproduced to Scale of Actual Label




***Please indicate the number of shipping labels that you need to return the recalled product(s):*** _____

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