# URGENT DRUG RECALL
# PENICILLIN V POTASSIUM for Oral Solution, USP
# Initiated 12/21/2021

***Teva Pharmaceuticals USA, Inc.***

| Lot # (s) | Expiration Date | Fill Size | NDC | Strength |
|---|---|---|---|---|
| 35446365A | 03/2022 | 100 mL | 0093-4125-73 | 125 mg/5 mL |
| 35447040A | 08/2022 | 100 mL | 0093-4125-73 | 125 mg/5 mL |
| 35447948B | 03/2023 | 100 mL | 0093-4125-73 | 125 mg/5 mL |
| 35446318B | 05/2022 | 200 mL | 0093-4125-74 | 125 mg/5 mL |
| 35447947A | 03/2023 | 200 mL | 0093-4125-74 | 125 mg/5 mL |

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (Teva USA) is voluntarily recalling the above referenced lots of **PENICILLIN V POTASSIUM for Oral Solution, USP 125 mg/ 5 mL** to the Retail Level. The affected product lots were distributed under the label of Teva Pharmaceuticals USA, Inc. Please take the following actions as given below.

This recall has been initiated because of a potential for the content of some bottles to be below specification limits for the active ingredient. This drug product is indicated in the treatment of mild to moderately severe bacterial infections caused by penicillin-G sensitive microorganisms. The active ingredient below the specification limits for this drug product could result in an underdose of medication. Consequently, there may be a decrease in treatment effectiveness that may lead to persistence of infection, worsening of infection or bacterial resistance as well as diminished therapeutic response for medical conditions in which oral penicillin therapy is indicated as prophylaxis. The overall risk to patients taking this product are considered to be low. To date, Teva USA has received no reports for lack of efficacy or efficacy that is lower than expected.

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

**ACTIONS: Please *promptly* perform the following actions that are necessary for this recall:**

- Examine your inventory for the specified recalled product lots.
- Quarantine and cease distribution of the product lots affected by this recall.
- Teva USA distribution records indicate that the above referenced lots were shipped from 4/15/2020 through 11/08/2021.
- Even if you have **no** product to return, it is necessary that you promptly complete the attached recall stock response form (SRF) and return by mail, email, or FAX to Inmar, Attn: Recall Coordinator,

  Inmar, 635 Vine Street, Winston Salem, NC 27101.

  Email address: **rxrecalls@inmar.com** FAX: 817-868-5362.
- **If you have further distributed product lots affected by this recall please perform a SUB-RECALL to your accounts using this Recall Notification and Stock Response Form as a basis of your recall notification.**

After receipt of your completed SRF, Inmar will send labels for Return Goods Authorization (RGA) and for return shipping of the recalled merchandise. Appropriate credit for your product returns, plus handling and shipping expenses, will be issued after receipt of said product and your RGA. All recalled product returned without a RGA may 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**:<br>Contact Inmar at 855-868-1820 (Hours of Operation: 9 am to 5 pm Eastern Time)<br>Recall Stock Response Forms - Contact Inmar at 855-868-1820 or acquire forms from clsnetlink.com. |
| **Medical-related Questions or to report an Adverse Event**:<br>Contact 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 |
| **Product Quality Complaint-related Questions**:<br>Contact 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 |
| **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.

**URGENT DRUG RECALL**
**PENICILLIN V POTASSIUM for Oral Solution, USP**
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*Teva Pharmaceuticals USA, Inc.*

# STOCK RESPONSE FORM

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

**Please fill out completely** **Date:** _____

**DIRECT CUSTOMERS ONLY:** Does this response include **all** your DC locations? ☐ YES ☐ NO

| Customer/Store Name: | |
|---|---|
| *DEA #: | *Debit Memo # |

***DEA # is required; in order to process your form.***

Address: _____

City: _____ State: _____ Zip: _____

Contact Name (please print): _____ Telephone #: _____

**I have checked my stock and:**

_____ I **do not** have stock of the recalled item(s) **OR** _____ I **do** have stock of the recalled item(s) listed above.

| **PENICILLIN V POTASSIUM for Oral Solution, USP 125 mg/ 5 mL** | | |
|---|---|---|
| **Lot # (s)** | **NDC** | **Quantity to Return** |
| 35446365A | 0093-4125-73 | |
| 35447040A | 0093-4125-73 | |
| 35447948B | 0093-4125-73 | |
| 35446318B | 0093-4125-74 | |
| 35447947A | 0093-4125-74 | |

Please send me _____ shipping box labels

**NON DIRECT CUSTOMERS ONLY: Please complete the following:**

Purchased From (Wholesaler name): _____ DEA #: _____

***DEA # is required; in order to process your form.***

City: _____ State: _____

**Please promptly return this form by FAX to: 817-868-5362 or by E-mail at: rxrecalls@inmar.com or Mail to: Inmar, Attn: Recall Coordinator, Inmar, 635 Vine Street, Winston Salem, NC 27101.**

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