McKESSON

Date: August 25, 2026

Event: 2026-209-1

IMPORTANT NOTICE
Urgent Recall

URGENT!!! DRUG RECALL!!! URGENT!!!

FDA/SUPPLIER CLASS OF RECALL: **Not Yet Classified**
LEVEL OF NOTIFICATION: McKesson Customer
SUPPLIER: Teva - # 26107

Description	Lot #	Exp Date	NDC #	UPC #	Econo #
TRAZODONE TAB 50MG TEV 100	1394026	2/29/2028	50111056001	35011156001	1573138

Event Description:
Teva is voluntarily recalling the above item/lot due to a single tablet of Buspirone 15mg that was discovered in each of two individual sealed bottles of Trazodone. This recall is to the McKesson Customer level. Affected product started shipping April 14, 2026.

Retailer/Customer Information:
McKesson Customer, please examine your inventory for the affected item completely and stop dispensing immediately. If you have the affected lot number(s), please complete and return the response form to Inmar via fax at 817-868-5362 or email to rxrecalls@inmar.com. Upon receipt, Inmar will issue a Returns Kit. If you have affected product and need a response form, contact Inmar at 888-302-6077 or via web at https://clsnetlink.com. Click on Recall Info. PLEASE NOTE: Customers currently participating in a McKesson administered Return to Vendor program should return this product to their designated returns processor. All others should follow the instructions provided by the manufacturer.

Information contained in this document was provided by Teva who is coordinating directly with the FDA.

URGENT DRUG RECALL
Trazodone Hydrochloride Tablets, USP
August 24, 2026

Teva Pharmaceuticals USA, Inc.

Trazodone Hydrochloride Tablets, USP 50mg			
NDC	Lot #	Exp. Date	Size
50111-560-01	1394026	02/2028	100 count bottle

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (TEVA) is initiating a voluntary nationwide recall of *the above one (1) lot* of Trazodone Hydrochloride Tablets USP, 50mg to the RETAIL LEVEL. The product in this recall is distributed under the Teva Pharmaceuticals USA, Inc. label. This lot is being recalled as a safety precaution because, to date, a single Buspirone Hydrochloride Tablet, USP (15 mg) was discovered in each of two individual sealed bottles of Trazodone Hydrochloride Tablets USP, 50mg lot 1394026. The clinical concern regarding use of the recalled lot is lack of effect or lack of efficacy and/or potential for an adverse event(s). To date, TEVA has received no relevant complaints for drug ineffectiveness, lack of effect or lack of efficacy. Teva's health hazard assessment concluded that use of the subject product lot of concern may result in, at most, mild and transient self-limiting effects following administration of a product other than that prescribed. However, because hypersensitivity to the mixed-up drug cannot be excluded, the potential severity was assessed as severe. The likelihood of harm is considered negligible, as there is a low probability that the product would reach the patient, and even if it did, the defect could be readily identified visually by the patient or healthcare professional. Consequently, the overall risk of harm to the patient population is considered low.

This recall is being conducted to the retail level.
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 Trazodone Hydrochloride Tablets USP, 50mg lot # 1394026.
- Immediately discontinue distribution of and quarantine Trazodone Hydrochloride Tablets USP, 50mg lot # 1394026 being recalled.
- TEVA's records indicate that the recalled lot was commercially distributed/shipped to its direct customers from 04/14/2026 through 06/30/2026.
- **If you have further distributed Trazodone Hydrochloride Tablets USP, 50mg lot # 1394026, 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 in its entirety 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. 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 888-302-6077 (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: 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.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.

RCL242-26