URGENT DRUG RECALL
Metoclopramide Tablets USP 10mg
May 23, 2025

Teva Pharmaceuticals USA, Inc.

Metoclopramide Tablets USP 10mg			
NDC	Lot #	Exp. Date	Size
0093-2203-01	5420094	09/2027	100 count bottle

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (TEVA) is initiating a voluntary nationwide recall of *the above one (1) lot* of Metoclopramide Tablets USP 10 mg to the CONSUMER 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 Torsemide Tablet (20 mg) was discovered in each of three individual sealed bottles of Metoclopramide Tablets USP, 10 mg lot 5420094. 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 could potentially lead to severe adverse health consequences outside the known safety profile of Metoclopramide if a Torsemide Tablet (20mg) is ingested, although the likelihood of occurrence is remote/unlikely as Metoclopramide Tablets are dispensed from the original packaging, divided at pharmacy level and dispensed in smaller quantities for patient use, where the difference in tablets is likely to be noticed by the pharmacist.

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 Metoclopramide Tablets USP, 10 mg lot # 5420094.
- Immediately discontinue distribution of and quarantine Metoclopramide Tablets USP, 10 mg lot # 5420094 being recalled.
- TEVA's records indicate that the recalled lot was commercially distributed/shipped to its direct customers from 12/16/2024 through 01/27/2025.
- **If you have further distributed Metoclopramide Tablets, USP 10 mg lot # 5420094, 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 855-243-4880 (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.

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RECALL BUSINESS REPLY FORM

Date Form Completed _____

Fill out this form completely. If this form is not filled out correctly and, in its entirety, it will delay the issuance of credit. 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 # ***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: _____

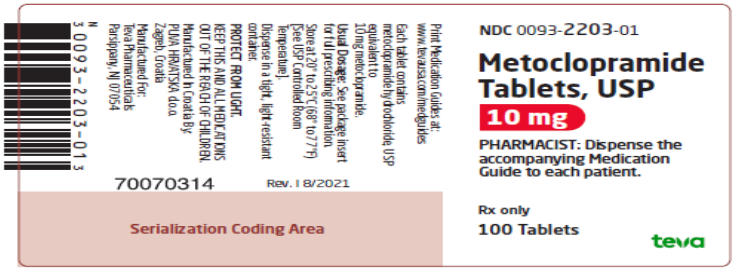
Name of Your Wholesaler/Distributor and Location

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	Bottle Size	Quantity of Product to Return (Count Partial Bottles as 1)
0093-2203-01	5420094	09/2027	100	

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