URGENT DRUG RECALL
Budesonide Extended-Release Tablets, 9 mg
January 08, 2024

Teva Pharmaceuticals USA, Inc.

Budesonide Extended-Release Tablets				
Lot #	Exp. Date	Strength	Bottle size	NDC
100047273	07/2025	9 mg	30 Count	0591-2510-30

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (TEVA USA) is initiating a voluntary nationwide recall of the above referenced drug product to the **RETAIL LEVEL.** The product in this recall is distributed to TEVA USA direct customers under the Actavis Pharma, Inc. label. The reason for the recall is test results for dissolution were above approved product specifications for the subject lot. The main health consequences arising from this is a potential overdose due to a higher amount of active substance being released. For systemic glucocorticosteroid effects of excessive doses for prolonged periods, the medical consequences could be hypercorticism and adrenal suppression. The review of the Teva Global Safety Database did not identify any cases potentially related to the incident (i.e., none of the case reports described symptoms of overdose). TEVA's health hazard assessment concluded that no adverse health consequences (outside the known safety profile of the product) are expected for the recalled lot.

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 recall lot.
- Immediately discontinue distribution of the specific lot being recalled.
- TEVA's records indicate that the specified lot was commercially distributed/shipped to its direct customers from 9/5/2023 through 11/20/2023.
- **If you have further distributed the recall lot, 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 877-810-1775 (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.

URGENT DRUG RECALL
Budesonide Extended-Release Tablets, 9 mg
January 08, 2024

Teva Pharmaceuticals USA, Inc.

RECALL BUSINESS REPLY FORM

Date Form Completed _____

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
Repackagers/Relabelers – Use Section 3 on the next page

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.

Budesonide Extended-Release Tablets, 9 mg, 30 Count			
Lot #	NDC	*Enter # of Bottles to Return (count partial bottles as 1)*	*Enter the # of shipping labels that you need to return the recalled product(s):*
100047273	0591-2510-30		

URGENT DRUG RECALL
Budesonide Extended-Release Tablets, 9 mg
January 08, 2024

Teva Pharmaceuticals USA, Inc.

RECALL BUSINESS REPLY FORM

Section 3 – Repackagers/Relabelers – Quantity of Product to Return
Wholesalers/Distributors/Retailers – Use Section 2

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

Name of Repackager/Relabeler: _____ ***Location:*** _____

Budesonide Extended-Release Tablets, 9 mg			
Teva (Actavis) Labeled Product	Lot #100047273 NDC 0591-2510-30	*Enter # of Bottles to Return (count partial bottles as 1)*	*Enter # of shipping labels that you need to return the recalled product(s):*
Repackager/Relabeler	*Enter Lot #:* _____ *Enter NDC:* _____	*Enter # of Bottles to Return (count partial bottles as 1)*	*Enter the number of shipping labels that you need to return the recalled product(s):*
Attach a Copy of the Relabeled Product:			

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