URGENT DRUG RECALL
Tretinoin Capsules 10 mg
Initiated 01/10/2022

Teva Pharmaceuticals USA, Inc.

NDC	Lot	Exp. Date	Bottle Size
0555-0808-02	100022970	08/2022	100 Count

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (Teva USA) is voluntarily recalling the above references lot of **Tretinoin Capsules 10 mg** to the **Retail Level**. The affected product lot was distributed under the label of Teva Pharmaceuticals USA, Inc. Please take the following actions as given below.

This recall has been initiated because the assay dissolution results for the specified lot are below specification limit at 13-months from date of manufacture. It should be noted that at the time of product release of this lot, all test results, including assay, were within specification limits. Tretinoin Capsules are indicated for the induction of remission in patients with acute promyelocytic leukemia (APL), or who have relapsed from, anthracycline chemotherapy, or for whom anthracycline based chemotherapy is contraindicated. The main safety concern that may arise from the low capsule dissolution is decreased efficacy of the product due to lower bioavailability that may result in an exacerbation of the underlying disease and progression of APL. Nevertheless, to date, Teva has not received reports of adverse events or product complaints for the lot in this recall.

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 lot.
- 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 06/30/2021 - 08/30/2021.
- 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: Contact Inmar at 855-319-5715 (Hours of Operation: 9 am to 5 pm Eastern Time) Recall Stock Response Forms - Contact Inmar at 855-319-5715 or acquire forms from clsnetlink.com.
Medical-related Questions or to report an Adverse Event: Contact Medical Information at: 888-838-2872, option 3, then, option 4 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: Contact 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
Customer Service-related Questions: Contact Teva Customer Service: 888-838-2872, option 3 then, option 2 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: 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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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.

NDC	Lot	Exp. Date	Bottle Size	# of Bottles to Return (Count Partial Bottles as 1)
0555-0808-02	100022970	08/2022	100 Count	

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