



Teva Pharmaceuticals USA, Inc.

**URGENT DRUG RECALL**

**Claravis™ (Isotretinoin Capsules USP), 10 mg**

**April 06, 2026**

Claravis™ (Isotretinoin Capsules USP), 10 mg				
NDC Carton (Outer)	NDC Wallet (Inner)	Lot	Exp. Date	Size
0555-1054-56	0555-1054-60	100067507	07/2026	100 Capsules (10 x 10 Blister Packs)
0555-1054-86	0555-1054-60	100067508	07/2026	30 Capsules (3 x 10 Blister Packs)

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (Teva USA) is initiating a voluntary nationwide recall of the above two (2) lots of **Claravis™ (Isotretinoin Capsules USP), 10mg** to the **RETAIL LEVEL**. The products in this recall were distributed under the Teva Pharmaceuticals USA Inc. label. The reason the two (2) lots listed in the table above are being recalled is due to out of specification result for the specified impurity Tretinoin. The specification limit (not more than [NMT]) for the specified impurity Tretinoin is an NMT of 3.5% and the reported result was 3.8%. Teva’s health hazard assessment concluded that the above-mentioned incident is clinically irrelevant, therefore the exposure to the product of concern is not expected to lead to any adverse health consequences beyond the known safety profile of Claravis™ Capsules. Consequently, the overall risk of harm in patient population is considered to be not applicable.

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 the two (2) lots of Claravis™ (Isotretinoin Capsules USP), 10mg listed in the table above.
- Immediately discontinue distribution of and quarantine the specified lots being recalled.
- TEVA’s records indicate that the recalled lots were commercially distributed/shipped to its direct customers between 02/04/2025 and 07/14/2025.
- **If you have further distributed the recall lots, 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, Attention: Recall Coordinator, by any one of these means:**

MAIL: Inmar, One West Fourth Street, Suite 500, Winston Salem, NC 27101  
 EMAIL: [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com).  
 FAX: 817-868-5362

**Please note: the Recall BRF must be filled out. If the Recall BRF form is not filled out correctly and, in its entirety, no credit will be issued.**

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
<p><b>Product Returns:</b>            Contact Inmar at 877-406-1419 (Hours of Operation: M – F, 9.00 am to 5.00 pm Eastern Time) for Recall Stock Response forms or acquire from: <a href="http://clsnetlink.com">clsnetlink.com</a></p>
<p><b>Medical-related Questions or to report an Adverse Event:</b>            Contact Teva 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 or by email at <a href="mailto:druginfo@tevapharm.com">druginfo@tevapharm.com</a></p>
<p><b>Product Quality Complaint-related Questions:</b>            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 <a href="mailto:QAS.QAS@tevapharm.com">QAS.QAS@tevapharm.com</a></p>
<p><b>Customer Service-related Questions:</b>            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</p>



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**FDA contact information for reporting adverse events/quality complaints:**

Online at [www.fda.gov/medwatch/report.htm](http://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 \_\_\_\_\_

**This form must be filled out completely. If this form is not filled out correctly and, in its entirety, no credit will be issued. 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](mailto: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 #:

\*Debit Memo #:

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

*\*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 Carton (Outer)	NDC Wallet (Inner)	Lot	Exp. Date	Strength	Quantity of product to return (count partial cartons as 1)
0555-1054-56	0555-1054-60	100067507	07/2026	10 mg	
0555-1054-86	0555-1054-60	100067508	07/2026	10 mg	

**Please indicate the number of shipping labels that you need to return the recalled product(s): \_\_\_\_\_**

**See the following page for images of the product carton label**



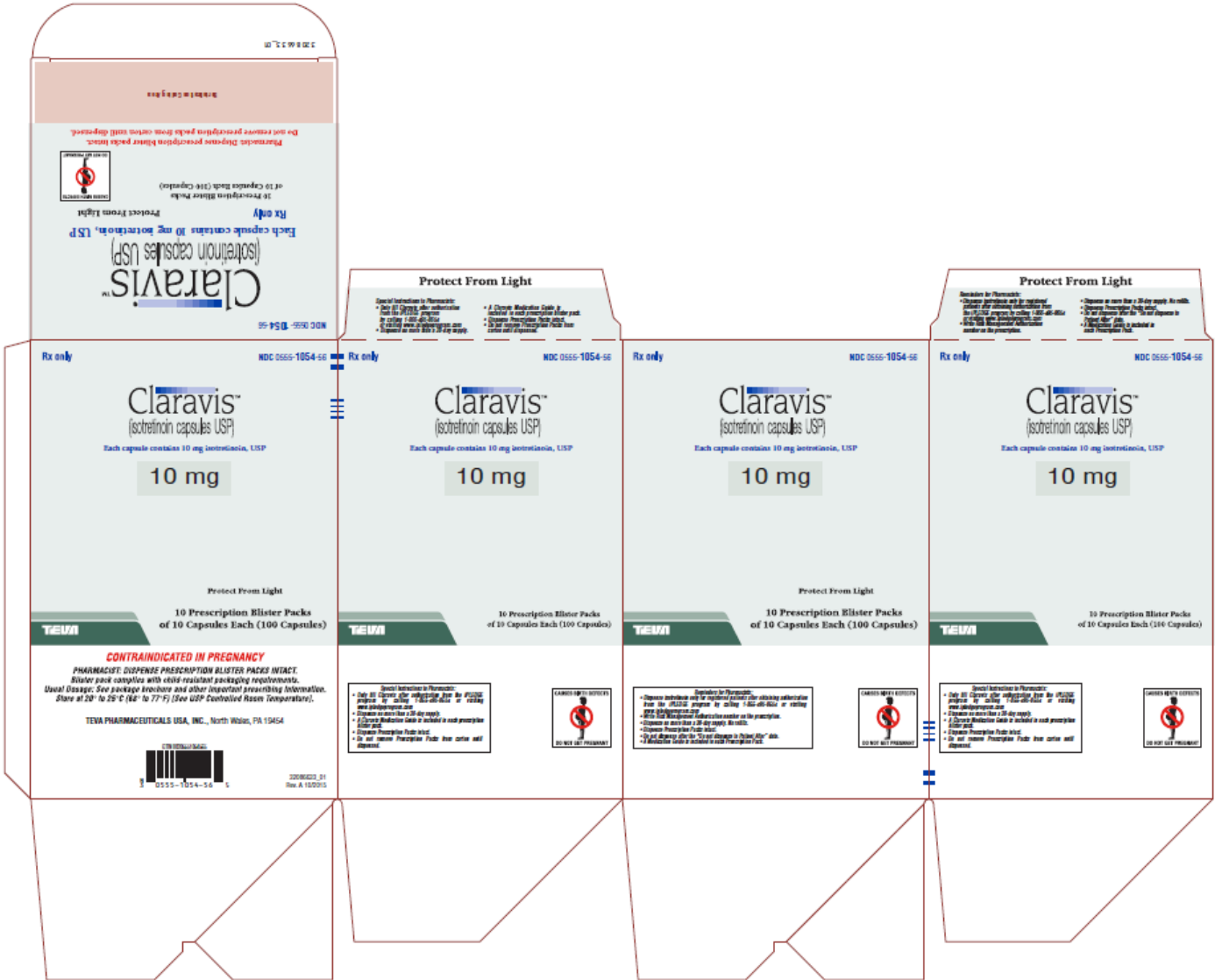
Teva Pharmaceuticals USA, Inc.

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Images Shown Have Not Been Reproduced to Scale of Actual Product Carton



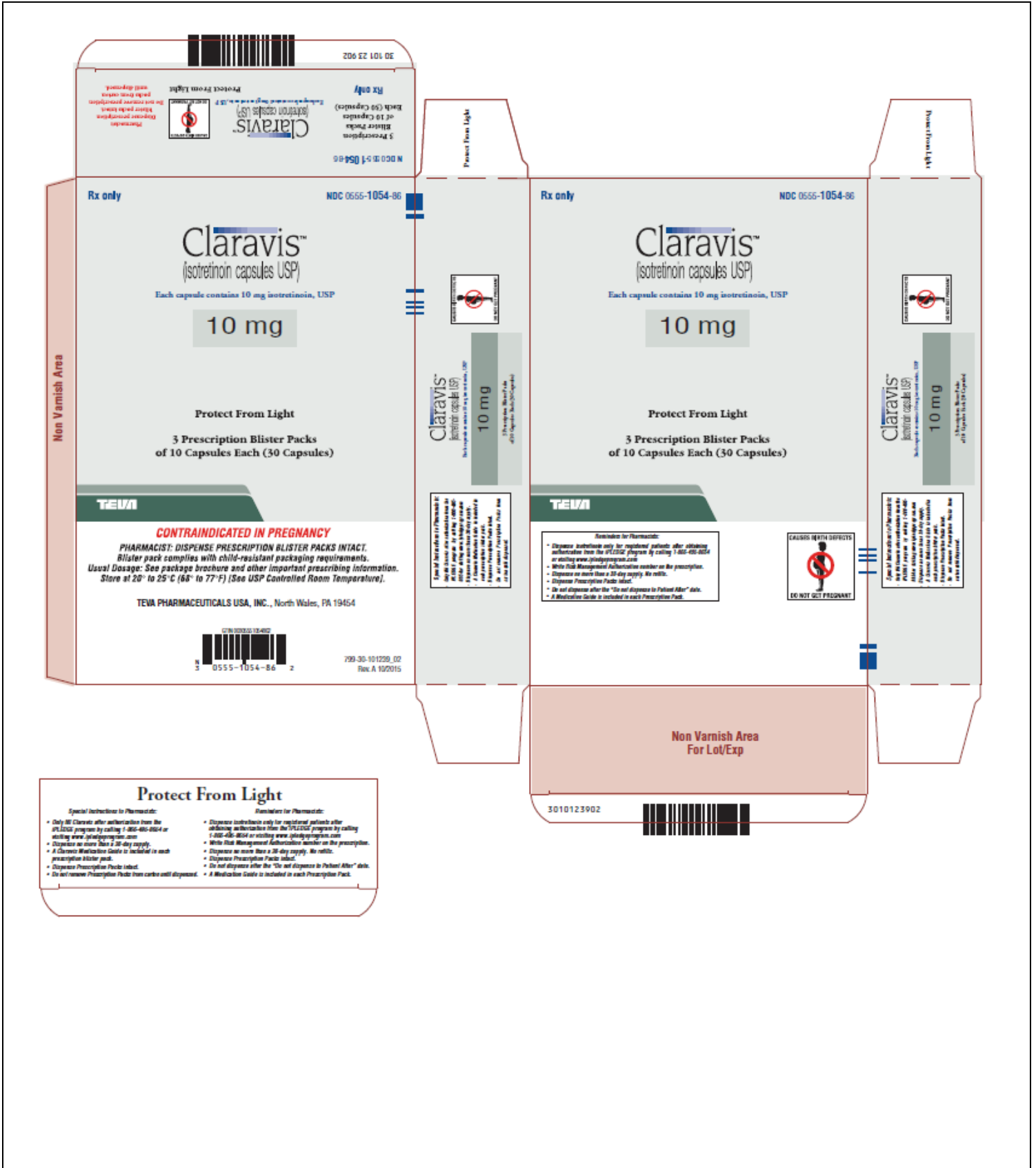


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Inmar/MedTurn Use Only:				
Scan	Labels	Store	Kit	D.B