



Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL
Clonidine Transdermal System, USP
0.1, 0.2, 0.3 mg/day
March 19, 2026

<i>Clonidine Transdermal System, USP 0.1 mg/day</i>				
Carton NDC	Pouch NDC	Lot #	Exp. Date	Size
0591-3508-04	0591-3508-54	100060315	04/2026	4 pouch/carton
0591-3508-04	0591-3508-54	100068644	01/2027	4 pouch/carton

<i>Clonidine Transdermal System, USP 0.2 mg/day</i>				
Carton NDC	Pouch NDC	Lot #	Exp. Date	Size
0591-3509-04	0591-3509-54	100060002	07/2026	4 pouch/carton
0591-3509-04	0591-3509-54	100066802	05/2027	4 pouch/carton

<i>Clonidine Transdermal System, USP 0.3 mg/day</i>				
Carton NDC	Pouch NDC	Lot #	Exp. Date	Size
0591-3510-04	0591-3510-54	100053892	04/2026	4 pouch/carton
0591-3510-04	0591-3510-54	100057899	05/2026	4 pouch/carton
0591-3510-04	0591-3510-54	100062704	02/2027	4 pouch/carton

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (Teva USA) is initiating a voluntary nationwide recall of the above seven (7) lots of **Clonidine Transdermal System, USP, 0.1, 0.2 and 0.3 mg/day** to the **RETAIL LEVEL**. The product in this recall is distributed under the Actavis Pharma Inc. label. The reason for the recall is due to use of an unapproved raw material (CoTran 9728 Membrane) in the manufacture of Clonidine Transdermal System, USP 0.1, 0.2, 0.3 mg/day. The primary health concern associated with this recall is due to a lack of extractable and leachable data for the unapproved raw material to establish safety of the drug product. Teva's toxicological evaluation and health hazard assessment concluded that the severity of the hazard was assessed as no adverse health consequences and the overall risk of harm in the patient population is considered as 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 seven (7) lots Clonidine Transdermal System, USP, 0.1, 0.2 and 0.3 mg/day listed above.
- Immediately discontinue distribution of and quarantine the seven (7) lots Clonidine Transdermal System, USP, 0.1, 0.2 and 0.3 mg/day listed above.
- TEVA's records indicate that the recalled lots were commercially distributed/shipped to its direct customers from 07/02/2024 through 11/07/2025.
- **If you have further distributed the seven (7) lots Clonidine Transdermal System, USP, 0.1, 0.2 and 0.3 mg/day listed above, 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.
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.



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CONTACT INFORMATION AND CREDIT

Product Returns:

Contact Inmar at 877-249-6203 (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, 9:00 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, 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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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 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.

Carton NDC #	Pouch NDC #	Size	Lot #	Expiry	# of Cartons to Return (Count Partial as 1)
00591-3508-04	00591-3508-54	4 pouch/carton	100060315	04/2026	
00591-3508-04	00591-3508-54	4 pouch/carton	100068644	01/2027	
00591-3509-04	00591-3509-54	4 pouch/carton	100060002	07/2026	
00591-3509-04	00591-3509-54	4 pouch/carton	100066802	05/2027	
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00591-3510-04	00591-3510-54	4 pouch/carton	100057899	05/2026	
00591-3510-04	00591-3510-54	4 pouch/carton	100062704	02/2027	



Teva Pharmaceuticals USA, Inc.

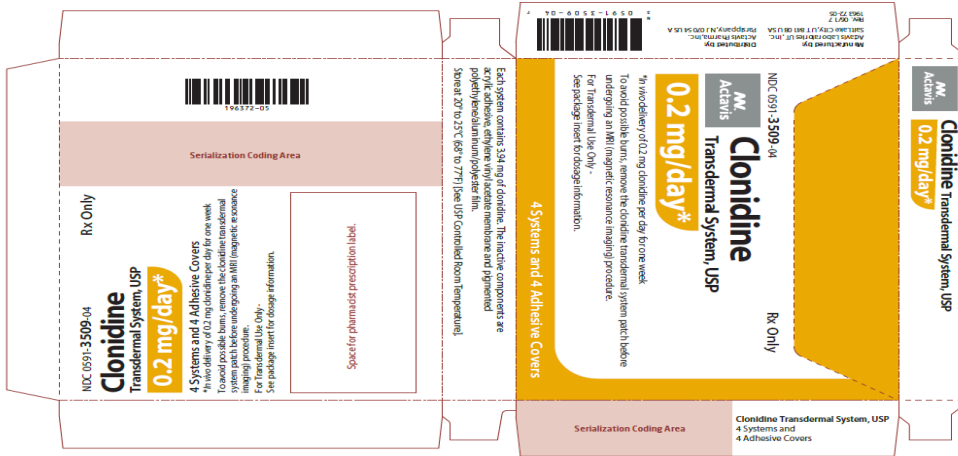
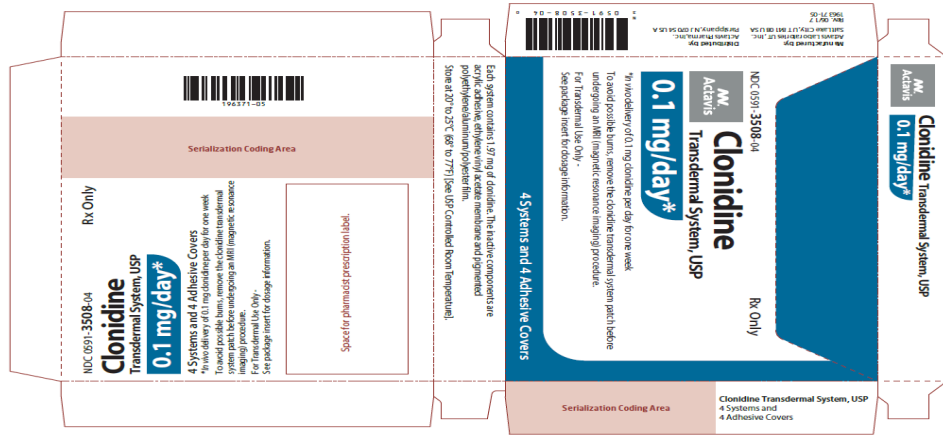
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Image Shown Has Not Been Reproduced to Scale of Actual Label



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