URGENT DRUG RECALL
Clonidine Transdermal System, USP 0.1 mg/day
INITIATED 10/28/2021

Teva Pharmaceuticals USA, Inc.

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling one lot of Clonidine Transdermal System, USP 0.1 mg/day to the Retail Level. The lot in this recall was distributed under the Actavis Pharma Inc., label. Detailed information for the lot in this recall is given in the table below.

Carton NDC	Carton Lot#	TDS (Patch) NDC	TDS (Patch) Lot#	Exp. Date	Size
0591-3508-04	1369117B	0591-3508-54	1369117	11/2021	4 Patches / Carton

This recall is being initiated because Lot # 1369117B exceeded the stability specification limit for related substances. Teva's Toxicological Analysis of this Clonidine related substance determined it to be non-mutagenic and does not pose any health risks to the patient. In addition, Teva's Health Hazard Assessment concluded exposure to the related substance is unlikely to result in any adverse health consequences or impact the efficacy of the drug. As such, the overall risk of harm is considered to be low.

This recall is being made with the knowledge of the Food and Drug Administration.

Please *promptly* perform the following actions that are necessary for this recall:

- Examine your inventory for product lot affected by this recall.
- Quarantine and cease distribution of the product lot affected by this recall.
- Teva USA distribution records show that the product lot affected by this recall was shipped to its customers from 01/22/2020 through 12/16/2020.
- 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 lot 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
Product Returns: Contact Inmar at: 855-826-5624 (Hours of Operation: 9 am to 5 pm Eastern Time) Recall Stock Response Forms - Contact Inmar at: 855-826-5624 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.

URGENT DRUG RECALL

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Teva Pharmaceuticals USA, Inc.

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.

Clonidine Transdermal System, USP 0.1 mg/day						
Carton NDC	**Carton Lot#**	**TDS (Patch) NDC**	**TDS (Patch) Lot#**	**Exp. Date**	**Size**	**Number of Patches to Return**
0591-3508-04	1369117B	0591-3508-54	1369117	11/2021	4 Patches / Carton	

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