

Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 01/30/2020

traMADOL Hydrochloride Tablets USP CIV 50 mg

RECALLED BY:

Teva Pharmaceuticals USA, Inc., Parsippany, NJ 07054

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling specific lots within expiry of traMADOL Hydrochloride Tablets USP CIV 50 mg packaged in 100 and 500 count bottles, NDCs 0093-0058-01 and 0093-0058-05, respectively. Refer to Attachment I that accompanies this letter for the lots in this recall. This recall is being carried out to the **RETAIL Level**. The lots in this recall were sold under the **Teva Pharmaceuticals USA, Inc.** label.

Teva USA is initiating this recall because a section in specific versions of the patient leaflets for the specified lots (Rev. AC 12/2016, Rev. AD 9/2017, Rev. AE 10/2018, or Rev. AF 4/2019) contains language relative to a 25 mg dosing titration that necessitates the use of a scored 50 mg tablet. However, Teva's traMADOL Hydrochloride Tablets USP CIV 50 mg for the lots in this recall are not scored. This dosing titration language is not intended for use with an unscored tablet.

Based on available literature, dividing unscored tablets could potentially give rise to dose irregularities as unscored tablets can be difficult to divide in two equal halves. The use of unscored Tramadol HCl 50 mg tablets in a 25 mg dosing titration regimen might potentially contribute to decreased treatment effect or delay in the onset of analgesic effect in some patients; although, the extent of the effect would be temporary or reversible, and the risk of significant adverse health consequence is considered low.

Please perform the following activities that are necessary for this recall:

- Immediately examine your inventory for the specified lots of traMADOL Hydrochloride Tablets USP CIV 50 mg – refer to the Attachment I that accompanies this letter.
- Immediately discontinue distribution of product lots affected by the recall.
- Our records indicate that Teva USA shipped the specified lots to its customers from 4/9/2018 through 12/03/2019.
- **Carry out a SUB-RECALL to your Retail / Direct Accounts (sub-accounts). Please use this Recall Notification and Stock Response Form as a basis for your SUB-RECALL letter.**
- Even if there is **no** recalled product to return, 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: tevarecalls@inmar.com

FAX: 817-868-5362.

Inmar will send a Return Goods Authorization label and shipping label, if requested on your SRF. Appropriate credit for product returns, plus handling and shipping expenses, will be issued upon receipt of product with the Return Goods Authorization form. All recalled product returned without a Return Goods Authorization label 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	
<u>Product Returns:</u>	
Contact Inmar at: 855-267-6250. (Hours of Operation: 9 am to 5 pm Eastern Time)	
Recall Stock Response forms Contact Inmar at: 855-267-6250 or acquire it from clsnetlink.com .	
<u>Medical-related Questions or to report an Adverse Event:</u>	
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	
<u>Product Quality Complaint-related Questions:</u>	
Contact Quality Assurance Services: 888-838-2872, option 3, then, option 3	
Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week	
<u>Customer Service-related Questions:</u>	
Contact Teva Customer Service: 888-838-2872, option 2	
Live calls received: M - F, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week	
<u>FDA contact information for reporting adverse events/quality complaints:</u>	
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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traMADOL Hydrochloride Tablets USP CIV 50 mg

STOCK RESPONSE FORM – Page 1 of 1

Refer to Attachment I for the List of Product Lots in this recall.

Even if there is no recalled product to return, promptly complete this recall Stock Response Form and return by mail, email, or FAX to Inmar:

FAX to: 817-868-5362 or EMAIL to tevarecalls@inmar.com or MAIL to: Inmar, Attn: Recall Coordinator, Inmar, 635 Vine Street, Winston Salem, NC 27101

Please fill out completely

Date: _____

Does this response include **all** your DC locations?

☐ YES ☐ NO

Customer/Store Name: _____

*DEA #: _____

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

Address: _____

City: _____ State: _____ Zip: _____

Contact Name (please print): _____ Telephone #: _____

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.

Indicate Number of Forms being submitted with this Stock Response: _____

traMADOL Hydrochloride Tablets USP CIV 50 mg in 100 or 500 count bottles			
NDC	Lot Number	Exp. Date	Number of Bottles to be Returned

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.

Please send me _____ shipping box labels

NON DIRECT CUSTOMERS ONLY: Please complete the following:

Purchased From (Wholesaler name): _____ DEA #: _____

City: _____ State: _____

Inmar/MedTurn Use Only:

Scan	Labels	Store	Kit	D.B
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Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 01/30/2020

traMADOL Hydrochloride Tablets USP CIV 50 mg

Attachment I of I				
Lots	Exp. Date	Product Description	Bottle Size	NDC
100005876	02/2020	traMADOL Hydrochloride Tablets 50 mg	100 Count	0093-0058-01
100008310	07/2020	traMADOL Hydrochloride Tablets 50 mg	100 Count	0093-0058-01
100008311	07/2020	traMADOL Hydrochloride Tablets 50 mg	100 Count	0093-0058-01
100008638	09/2020	traMADOL Hydrochloride Tablets 50 mg	100 Count	0093-0058-01
100008639	09/2020	traMADOL Hydrochloride Tablets 50 mg	100 Count	0093-0058-01
100011763	02/2021	traMADOL Hydrochloride Tablets 50 mg	100 Count	0093-0058-01

Attachment I of I				
Lot	Exp. Date	Product	Bottle Size	NDC
100005418	01/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005419	01/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005420	01/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005421	01/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005877	01/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005878	01/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005879	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005880	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005881	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005882	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005883	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005884	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005885	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005886	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005887	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005888	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005889	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005890	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005891	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005892	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005893	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005894	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005895	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005896	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005897	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005898	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005899	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005900	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005901	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005902	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100005903	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100006588	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100006718	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100006719	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100006720	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100006721	02/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100006722	03/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100006724	03/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100006725	03/2020	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05

traMADOL Hydrochloride Tablets USP CIV 50 mg[illegible]

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Attachment I of I

[illegible]

traMADOL Hydrochloride Tablets USP CIV 50 mg

[illegible]

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Attachment I of I				
Lot	Exp. Date	Product	Bottle Size	NDC
100011900	03/2021	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100011901	03/2021	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100011902	04/2021	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100011903	04/2021	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100011904	04/2021	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100011905	04/2021	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100011906	04/2021	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100011907	04/2021	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100011908	04/2021	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100011909	04/2021	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100011910	04/2021	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100011911	04/2021	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100011912	04/2021	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100011913	04/2021	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100011914	04/2021	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05
100011918	04/2021	traMADOL Hydrochloride Tablets 50 mg	500 count	0093-0058-05