



URGENT DRUG RECALL - Update
Cartia XT® 120 mg Capsules USP
Update 11/09/2021 – Retail Level

Teva Pharmaceuticals USA, Inc.

Cartia XT® (Diltiazem HCl Extended-Release Capsules, USP) 120 mg				
NDC	Lot #	Labeled Exp. Date	Size	Dates Distributed
62037-597-90	100023805	05/2023	90 Count Bottles	07/27/2021 through 09/13/2021

Dear Valued Customer:

On 10/27/2021, Teva Pharmaceuticals USA, Inc. (Teva USA) initiated a voluntary recall of the above drug product to the Wholesale Level. This voluntary recall is now being extended to the Retail Level. Please take the following actions given below. Teva USA also wishes to advise its customers that affected Lot # 100023805 was distributed under the label of Teva Pharmaceuticals USA, Inc. and not under the Actavis Pharma Inc.

As stated in our 10/27/2021 recall letter, Lot # 100023805 is being recalled because it was packaged with an incorrect expiration date of 05/2023. The correct expiration date is 01/2023. Based on the health hazard assessment, exposure to the product of concern could lead to mild adverse events although the likelihood of occurrence is remote. The expiration date of drug product represents the final day that the manufacturer guarantees the full potency and safety of a medication. The main safety concern is a possible lack of efficacy or a decreased efficacy. A patient might experience an exacerbation of the treating conditions (hypertension and angina). Patients treated for hypertension might experience increases in blood pressure. For patients treated for angina, possible lack of efficacy or a decreased efficacy might mean increased chances of suffering acute angina attacks.

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 Lot # 100023805 of Cartia XT® (Diltiazem HCl Extended-Release Capsules, USP) 120 mg NDC 62037-597-90.
- Quarantine and cease distribution of the product lot affected by this recall.
- Teva USA distribution records indicate Lot # 100023805 of Cartia XT® 120 mg Capsules, USP was shipped to its customers from 07/27/2021 through 09/13/2021.
- 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 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 AND CREDIT
Product Returns: Contact Inmar at: 855-825-1447 (Hours of Operation: 9 am to 5 pm Eastern Time) Recall Stock Response Forms - Contact Inmar at: 855-825-1447 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.



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 #	Labeled Exp. Date	Size	Quantity to Return (Count Partial Bottles as 1)
62037-597-90	100023805	05/2023	90 Count Bottles	

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