accord
The Evolution of Generics

URGENT VOLUNTARY RECALL: Retail Level, January 12, 2023

Two Lots of Allopurinol Tablets USP 100 mg (lot # R2200455, R2200456)

Accord Healthcare, Inc. is voluntarily recalling **two lots** of Allopurinol Tablets USP 100 mg, lot # R2200455, R2200456.

This recall has been initiated at the Retail-level. The cause of the recall is a product quality complaint where a pharmacist reported discovering an issue with one of the tablets that was in a sealed and intact 100-count bottle of Allopurinol Tablets USP 100 mg. One of the tablets was reported to have a small piece of green plastic embedded in the crack towards the edge of the tablet, which represents a potential health hazard. The pharmacist reported examining the rest of the tablets in the bottle and not finding any issues. The complaint was made at the pharmacy level and was not distributed to any consumers.

The complaint was received for the lot # R2200456 and this is the first and only complaint of such nature received for the subject lot. However, since two lots were manufactured simultaneously, out of an abundance of caution, Accord is recalling both lots from the market. Based on findings of both preliminary and final investigations carried out at the manufacturing site, Accord believes that no other lots of Allopurinol Tablets are affected.

Please examine your inventory of Accord's Allopurinol Tablets USP 100 mg for lot # R2200455 and R2200456 carefully.

The product label should have the following details:

Item description	NDC #	Lot #	Mfg. Date	Exp. Date
Allopurinol Tablets 100 mg	16729-134-01	R2200455 R2200456	04/2022	05/2025

Retailers - Please perform the following activities:

- Examine your inventory immediately for listed lots of Allopurinol Tablets USP 100 mg (Lot R2200455, R2200456).
- Immediately discontinue distribution of Allopurinol Tablets USP 100 mg (Lot R2200455, R2200456).
- Promptly complete the attached recall stock response form and reply even if you have **NO** Product to return.
- If you do have Product to return, complete the attached recall stock response form, quarantine the stock and follow the instructions on such form.
- If you have further distributed any of the Lots R2200455, R2200456, please immediately contact your accounts, advise them of the recall and have them return their outstanding recalled stock to you. Return this stock as per the instructions on the attached recall stock response form.

Your assistance is appreciated and necessary to prevent any potential health risk to the consumer. Please complete and return the attached response recall stock response form as soon as possible, but no later than five business days from receipt of this letter.

Accord is working with Inmar Inc. to complete this recall. This recall is being made with the knowledge of the Food & Drug Administration. Your cooperation and prompt response to this notice is much appreciated.

Accord Healthcare Inc.
Phone: 877-515-9862 · Fax: 817-868-5362 · rxrecalls@inmar.com

Completed Recall Stock Response form should be mailed, emailed, or sent via FAX to INMAR, Attn: Recall Coordinator, One West Fourth Street, Suite 500 Winston Salem, NC 27101. INMAR Email: rxrecalls@inmar.com. FAX: 817-868-5362.

INMAR will send you a Return Goods Authorization and shipping label. Appropriate credit for returned product plus handling and shipping expenses will be issued to you upon receipt of the recalled product with the completed Return Goods Authorization. All recalled product returned without a Return Goods Authorization may delay the issuance of your credit.

We appreciate your assistance in this matter.

Sincerely,

Sabita Nair, RAC, ASQ-CPGP
Vice President – Regulatory Affairs
Accord Healthcare, Inc.
1009 Slater Road, Suite 210-B
Durham, NC 27703
United States

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RECALL RESPONSE FORM

Product Recall Date: January 12, 2023 **Voluntary Recall: Retail Level**

Item description	NDC	Lot	Quantity Returning (In bottles)
Allopurinol Tablets 100 mg	16729-134-01	R2200455 R2200456	

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the recall instructions and have taken the appropriate action.

Distributor Name _____ DEA # * _____

**DEA # is required, if not provided the processing of your form will be delayed.*

Address _____

City _____ State _____

Zip _____

Contact Name (please print) _____ Telephone # _____

Contact Signature _____ Date _____

If you did not purchase the product directly from the Manufacturer please complete the following section.

Purchased from: Name _____ DEA # _____

Address _____

City _____ State _____

Zip _____

Please check all appropriate boxes:

☐ I have read and understand the recall instructions provided in the letter.
☐ I have checked my stock and have quarantined inventory consisting of _____ bottles/units.

Any adverse events associated with recalled product?

☐Yes ☐ NO If yes, please explain: _____

Please describe your business: _____

I have checked my stock and:

_____Do not have any stock of the recalled **items**.

OR

_____Have quarantined and listed in the box above the quantity of bottles/units of **Allopurinol Tablets 100 mg** and will be returning them to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar will issue return authorization label(s).

Please indicate the number of box labels needed: _____

Please fax this form to 1-817-868-5362 or E-mail at: rxrecalls@inmar.com. Questions - 877-515-9862.