



URGENT DRUG RECALL

April 20, 2026

Dear Customer,

Acella Pharmaceuticals, LLC is initiating a voluntary, retail/pharmacy level recall for two lots of Naproxen Oral Suspension, USP, 125 mg/5 mL. This recall is being conducted with the knowledge of the Food and Drug Administration. The impacted lot numbers can be found in the table below:

Product Description	NDC Number	Lot Number	Exp. Date	Distribution Dates
Naproxen Oral Suspension, USP, 125 mg/5 mL	42192-619-16	23F02	05/2026	06/21/2023 – 03/17/2025
Naproxen Oral Suspension, USP, 125 mg/5 mL	42192-619-16	25A37	01/2028	03/18/2025 – 10/20/2025

The product is being recalled because product testing found levels of lead and lithium in the product above the International Council for Harmonisation (ICH) established permitted daily exposure limits.

Exposure to low levels of lead may not elicit any symptoms. High levels of exposure to lead in utero, infancy, and early childhood can lead to neurological effects such as learning disabilities, behavior difficulties, and lowered IQ. The very young are particularly vulnerable to the potential harmful effects from lead exposure because of their smaller body sizes and rapid metabolism and growth. For adults, chronic lead exposure is associated with kidney dysfunction, hypertension, and neurocognitive effects.

Exposure to lithium may result in increased risk of reduced urinary concentrating ability, hypothyroidism, hyperparathyroidism, and weight gain.

The lots were distributed by Acella Pharmaceuticals, LLC from **06/21/2023 and 10/20/2025**.

Acella Pharmaceuticals, LLC requests that you immediately take the following actions:

- Examine your inventory immediately for the lots listed above and immediately discontinue distribution and sales of the product lot being recalled. Please quarantine the affected lot of this product.
- If you, as a wholesaler/distributor, have further distributed this product, please identify your customers and notify them of this product Recall.
- Promptly complete the attached Recall Business Response Form even if you have **NO** product to return.

Completed Recall Business Response form can be submitted by any of the below methods:

Phone: 877-836-6221

Fax: 817-868-5362

E-mail: RXrecalls@inmar.com



Upon receipt of your Recall Business Response Form a "Return Kit" will be sent to you. This kit will include:

- Pre-paid shipping label(s)
- Processing labels
- Shipping instructions

If you have any general questions regarding the return of this product, please contact Inmar Rx Solutions at 1-877-836-6221. Their office hours are 9:00 am – 5:00 pm ET Monday thru Friday (excluding holidays).

If you have any medical questions regarding this recall, please contact Acella Pharmaceuticals, LLC at 1-470-550-1551 (Monday through Thursday from 9:00 am to 5:00 pm or Friday from 9:00 am to 12:30 pm ET).

We regret any inconvenience and appreciate your immediate cooperation.

Becky Clasper
Senior Director – Global Quality and Compliance
For Acella Pharmaceuticals, LLC.

See below for product container label:

DO NOT USE IF TAMPER-EVIDENT SEAL IS SEPARATED OR MISSING

Pharmacist: Dispense in light resistant container.

Store at 25°C (77°F); excursions permitted to 15°C - 30°C (59°F - 86°F).

[see USP Controlled Room Temperature]

Avoid excessive heat above 40°C (104°F).

Usual dosage: For dosage recommendations and other important information, including the Medication Guide, read accompanying prescribing information.



MADE IN CANADA
Distributed by:
Acella Pharmaceuticals, LLC
Alpharetta, GA 30005
1-800-541-4802
L 0293 Rev 1020 01

NDC: 42192-619-16

**NAPROXEN
ORAL SUSPENSION, USP
125 mg/5 mL**

FOR ORAL ADMINISTRATION ONLY.
SHAKE WELL BEFORE USING.

PHARMACIST:
Dispense a Medication Guide with each prescription.

Rx only

16 fl. oz. (473 mL)





**URGENT DRUG RECALL
BUSINESS RESPONSE FORM**

April 20, 2026

Recall # RCL082-26, N131461

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.

Table 1: Product Lots Associated with the Recall

Product Description	NDC #	Lot #	Exp. Date	Distribution Dates
Naproxen Oral Suspension, USP, 125 mg/5 mL	42192-619-16	23F02	05/2026	06/21/2023 – 03/17/2025
Naproxen Oral Suspension, USP, 125 mg/5 mL	42192-619-16	25A37	01/2028	03/18/2025 – 10/20/2025

Customer Name				DEA Number	
Address					
City		State		Zip Code	
Contact Name (Printed)				Email Address	
Telephone #				Fax #	
Contact Signature				Date	

Please check the box to indicate your agreement with the following statements:	
<input type="checkbox"/>	I have read and understand the recall instructions provided in the letter.
<input type="checkbox"/>	I have identified and notified my customers that were shipped this product.



Please check your inventory stock and indicate whether you have any recalled units:	
<input type="checkbox"/>	I do not have any stock of the recalled items.
<input type="checkbox"/>	I have quarantined the quantity of recall units indicated in the table below to return to Inmar Rx Solutions. Upon receipt of this completed response form, Inmar will issue a return authorization, shipping label, and instruction sheet.

NDC	Lot Number	Bottle Quantity Returned	
		Sealed	Open
42192-619-16	23F02		
42192-619-16	25A37		

If you did not purchase the product directly from the Manufacturer, please complete the section below:		
Purchased From	Wholesaler Name	
	Wholesaler Address	
	Wholesaler DEA #	

Have you been informed of any adverse events associated with recalled product?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If yes, please provide details:		

Please fax this form to: 1-817-868-5362 or E-mail: RXrecalls@inmar.com

Once this form is received, a Return Authorization will be initiated and a Return Kit will be sent to you that will contain shipping instructions and a pre-paid shipping label.

If you have any questions regarding this form or product return, please contact Inmar Rx Solutions at 1-877-836-6221.
Office hours: 9:00 am – 5:00 pm ET Monday thru Friday (excluding holidays).