



Sun Pharmaceutical Industries, Inc

URGENT: DRUG RECALL
Sumatriptan and Naproxen Sodium Tablets, 85mg/500 mg
WHOLESALE LEVEL

October 23, 2026

Dear Valued Customer,

This notice is to inform you of a product recall involving, **Sumatriptan and Naproxen Sodium Tablets, 85mg/500 mg**; see enclosed product label for ease in identifying the product at the **wholesale** level.

(This is a marketed product under the Sun Pharmaceutical label and NorthStar label).

Product Name	Package Description	NDC#	Lot#	Expiration Date
Sumatriptan and Naproxen Sodium Tablets	85mg/500 mg; 9 in 1 bottle	16714-891-01	DNG0559A	5/31/2027
Sumatriptan and Naproxen Sodium Tablets	85mg/500 mg; 9 in 1 Bottle	47335-410-22	DNG0559B	5/31/2027

This recall has been initiated in response to Out of Specification, (OOS), result for dissolution, during analysis at the 12- month long term stability station, at, (25°C, 60%RH).

The Health Hazard Evaluation concluded “*considering that the product is indicated for the acute treatment of migraine and is not intended for the management of conditions with severe outcomes, any subtherapeutic clinical response can generally be managed by the treating physician through appropriate dose adjustment. Furthermore, all other critical quality attributes were found to be within their respective specification limits. Therefore, the use of impacted tablets with low dissolution values is expected to pose a minor risk to patients, other than the known safety profile of the drug.*”

The lots complied with all of the established product quality specifications at the time the product was released for distribution and with dissolution requirements at the initial, 3-month, 6-month, and 9-month stability intervals.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on 9/3/2025.

Immediately examine your inventory and quarantine product subject to the recall. In addition, if you have further distributed this product, please identify your **wholesale** customers and notify them at once of this product recall. Your notification to your **wholesale** customers may be enhanced by including a copy of this recall letter.



Please complete and return the enclosed response form as soon as possible. After receipt of the response form, a return kit will be provided so the affected product can be sent to:

Inmar Rx Solutions
3845 Grand Lakes Way
Grand Prairie, TX 75050

If you have any questions or return the enclosed response form contact Inmar, Inc. at Rxrecalls@Inmar.com or call **844-940-8050** Monday to Friday from 8:30 am to 5:00 pm (EST).

This recall should be carried out to the **wholesale** level.

Your assistance is appreciated and necessary to prevent patient harm.

For adverse reactions or quality problems experienced with the use of this product, contact firm's website or to the FDA's Med Watch Adverse Event Reporting program either online, by regular mail or by fax.

Complete and submit the report Online: www.fda.gov/medwatch/report.htm

Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800- 332-1088 to request a reporting form, then complete and return to the address on the pre- addressed form, or submit by fax to 1-800-FDA-0178

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

Regards,
Aster Amanuel

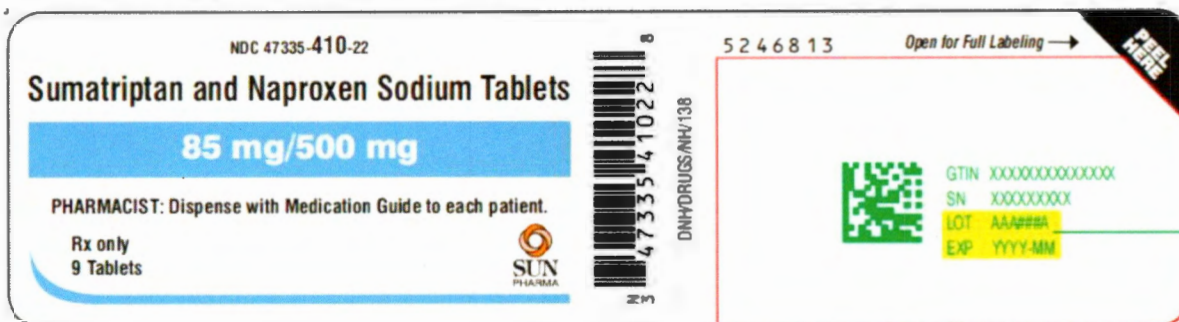
Signed by:  10/23/2026
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Sun Pharmaceutical Industries, Inc.
Manager, Quality Compliance

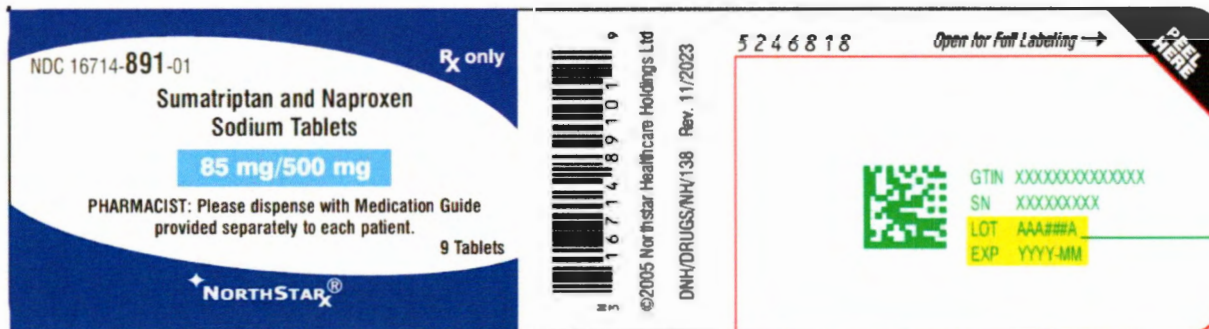
For return of affected product, please email Rxrecalls@Inmar.com or call **844-940-8050**

Enclosure:Product Label:

Sumatriptan and Naproxen Sodium Tablets, Sun Parma Label: NDC#: 47335-410-22



Sumatriptan and Naproxen Sodium Tablets, NorthStar Label, NDC 16714-891-01





Sun Pharmaceuticals Industries, Inc.

URGENT: DRUG RECALL RESPONSE FORM

Sumatriptan and Naproxen Sodium Tablets, 85mg/500 mg

(This is a marketed product under the Sun Pharmaceutical label and NorthStar label).

Wholesale Level

10/23/2026

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.

Customer Name:

DEA#:

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

Address:

City:

State:

Zip:

Contact Name (Please Print):

Telephone#:

Email:

Contact Signature:

Date:

DEBIT MEMO# (If unsure, leave blank):

Wholesaler Information if not directly purchased from Sun Pharma:

Wholesaler Name:

DEA#:

City:

State:

Zip:

I have checked my stock and communicated to my customers at the appropriate level:

- ☐ I confirm that all locations that received the impacted products have been notified to the **Wholesale level** _____ (Initial and date)
- ☐ I do not have any stock of the recalled items. **OR**
- ☐ I have quarantined and listed in the box below the quantity of recalled units and I will be returning to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar, will issue return authorization label(s). Please indicate the # of needed box labels _____.

Product Name	Package Description	NDC#	Lot#	Expiration Date	Input total number of units to return
Sumatriptan and Naproxen Sodium Tablets	85mg/500 mg; 9 in 1 bottle	16714-891-01	DNG0559A	5/31/2027	
Sumatriptan and Naproxen Sodium Tablets	85mg/500 mg; 9 in 1 Bottle	47335-410-22	DNG0559B	5/31/2027	

If you have any questions regarding this form or product return please contact Inmar Inc. at Rxrecalls@Inmar.com or call **844-940-8050** Monday to Friday from 8:30 am to 5:00 pm (EST).

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