URGENT: DRUG RECALL - REVISED

Sumatriptan Succinate Tablets, 50 mg and 100 mg

January 13, 2020

Dear Customer,

This notice is to inform you of a product recall involving:

Product Name	Package Description	Lot Number	NDC Number	Expiration Date
Sumatriptan Succinate Tablets, 50 mg	100 Count Bottle	JKT4175A	62756-521-88	11/2020
Sumatriptan Succinate Tablets, 50 mg	9 (1 x 9) Unit-of-use Tablets	JKU1939A	62756-521-69	04/2022
Sumatriptan Succinate Tablets, 50 mg	9 (1 x 9) Unit-of-use Tablets	JKU1940A	62756-521-69	04/2022
Sumatriptan Succinate Tablets, 50 mg	9 (1 x 9) Unit-of-use Tablets	JKU1940B	62756-521-69	04/2022
Sumatriptan Succinate Tablets, 100 mg	9 (1 x 9) Unit-of-use Tablets	JKT4174A	62756-522-69	11/2021
Sumatriptan Succinate Tablets, 100 mg	9 (1 x 9) Unit-of-use Tablets	JKU0622A	62756-522-69	01/2022
Sumatriptan Succinate Tablets, 100 mg	9 (1 x 9) Unit-of-use Tablets	JKU1308A	62756-522-69	02/2022

The depth of the recall was revised to the retail level.

See enclosed product labeling.

This recall has been initiated in response to related substance results that were reported near or above the specification limit.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on March 29, 2019.

Immediately examine your inventory and quarantine product subject to recall. In addition, if you have further distributed this product, please identify your retail customers and notify them at once of

this product recall. Your notification to your retail customers may be enhanced by including a copy of this recall notification 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, Inc.
4332 Empire Road
South Dock
Fort Worth, TX 76155

If you have any questions, contact Inmar, Inc. at rxrecalls@inmar.com or call 1-800-967-5952, Monday to Friday from 8:30 am to 5:00 pm (EST).

This recall should be carried out to the retail level.

Your assistance is appreciated and necessary to prevent patient harm.

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

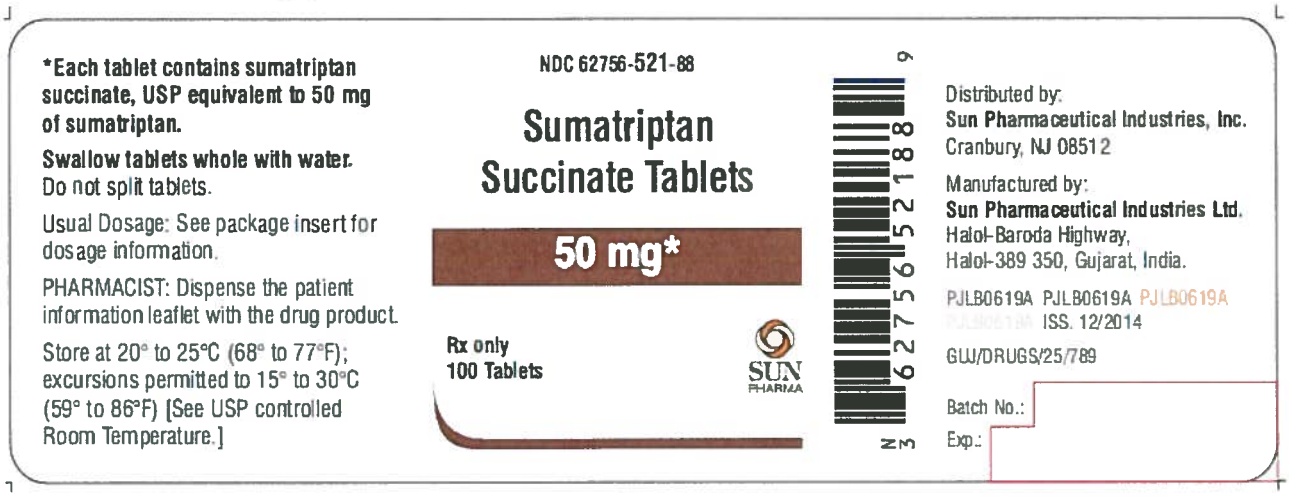
Aimee Albanese 01-13-2020

Aimee Albanese
Sun Pharmaceutical Industries, Inc.
Associate Director, Cluster Quality Support

Enclosure

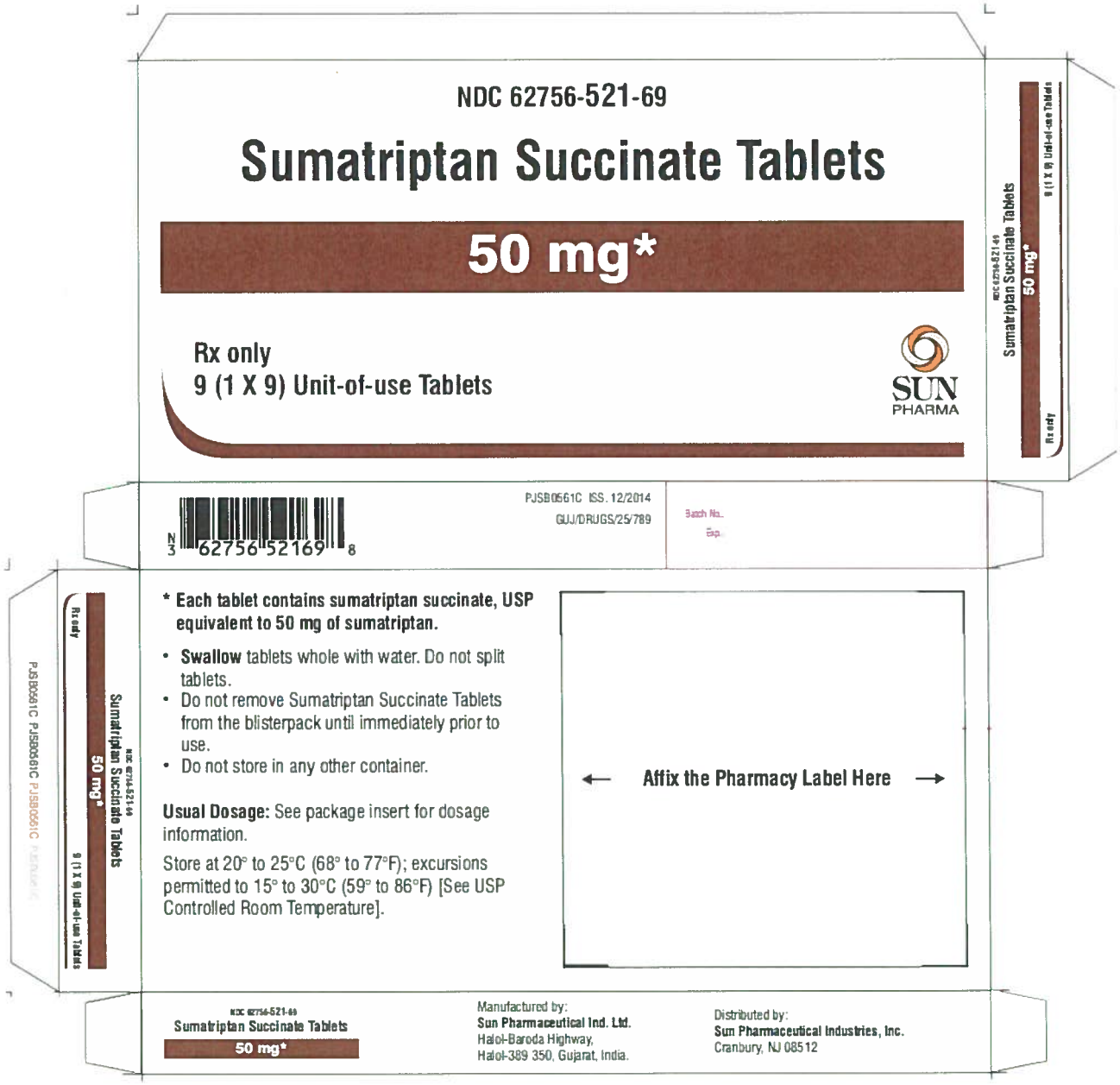
For return of affected product, please email rxrecalls@inmar.com or call 1-800-967-5952.

Enclosures:
Sumatriptan Succinate Tablets, 50 mg (100 Count Bottle) Labeling



For return of affected product, please email rxrecalls@inmar.com or call 1-800-967-5952.

Sumatriptan Succinate Tablets, 50 mg (9 Unit-of-use Tablets) Labeling



For return of affected product, please email rxrecalls@inmar.com or call 1-800-967-5952.

Sumatriptan Succinate Tablets, 100 mg (9 Unit-of-use Tablets) Labeling

For return of affected product, please email rxrecalls@inmar.com or call 1-800-967-5952.

URGENT: DRUG RECALL – RESPONSE FORM

Please Complete This Form and Fax to: 817-868-5362
or Email to: rxrecalls@inmar.com

Product Name	Package Description	Lot Number	NDC Number	Expiration Date
Sumatriptan Succinate Tablets, 50 mg	100 Count Bottle	JKT4175A	62756-521-88	11/2020
Sumatriptan Succinate Tablets, 50 mg	9 (1 x 9) Unit-of-use Tablets	JKU1939A	62756-521-69	04/2022
Sumatriptan Succinate Tablets, 50 mg	9 (1 x 9) Unit-of-use Tablets	JKU1940A	62756-521-69	04/2022
Sumatriptan Succinate Tablets, 50 mg	9 (1 x 9) Unit-of-use Tablets	JKU1940B	62756-521-69	04/2022
Sumatriptan Succinate Tablets, 100 mg	9 (1 x 9) Unit-of-use Tablets	JKT4174A	62756-522-69	11/2021
Sumatriptan Succinate Tablets, 100 mg	9 (1 x 9) Unit-of-use Tablets	JKU0622A	62756-522-69	01/2022
Sumatriptan Succinate Tablets, 100 mg	9 (1 x 9) Unit-of-use Tablets	JKU1308A	62756-522-69	02/2022

Please check ALL appropriate boxes.

□ I have read and understand the recall instructions provided in the January 13, 2020 letter.

□ I have checked our stock and have quarantined inventory consisting of _____ units.

□ Indicate disposition of recalled product:

□ returned (**specify quantity, date and method**)/held for return;

Number of Labels Required for Return to Inmar: _____

□ previously destroyed (**specify quantity, date and method**);

□ I have identified and notified my retail customers that were shipped or may have been shipped this product by (**specify date and method of notification**); or

□ Attached is a list of retail customers who received/may have received this product. Please notify my customers.

For return of affected product, please email rxrecalls@inmar.com or call 1-800-967-5952.

URGENT: DRUG RECALL – RESPONSE FORM

Please Complete This Form and Fax to: 817-868-5362
or Email to: rxrecalls@inmar.com

Product Name	Affected Lots
Sumatriptan Succinate Tablets, 50 mg	JKT4175A, JKU1939A, JKU1940A, and JKU1940B
Sumatriptan Succinate Tablets, 100 mg	JKT4174A, JKU0622A, and JKU1308A

Any adverse events associated with recalled product? □ Yes □ No
If yes, please explain: _____

Please check the appropriate box(es) to describe your business

□ wholesaler/distributor
□ grocery corporate headquarters
□ repacker
□ pharmacy
□ retailer
□ hospital pharmacies
□ hospital/medical facility
□ Other:

Customer Name: _____ Title: _____

Company: _____ DEA Number: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone Number: _____

Customer Debit Memo Number: _____

Wholesaler: _____ City\State: _____

Wholesaler DEA Number: _____

For return of affected product, please email rxrecalls@inmar.com or call 1-800-967-5952.

Taro Pharmaceuticals U.S.A., Inc.

January 15, 2020

URGENT: DRUG RECALL - CONSUMER LEVEL

Lamotrigine Tablets USP, 100 mg

Lot #	Exp. Date	Size	NDC	Dates Distributed
331771	June 2021	100 count bottles	**51672-4131-1**	August 23 to August 30, 2019

Dear Valued Customer,

This is to notify you that Taro Pharmaceuticals U.S.A., Inc. is initiating a **Voluntary Recall** of one (1) lot of Lamotrigine Tablets USP, 100 mg, 100 count bottles, Lot # 331771. This recall is being initiated because an investigation determined that Lot # 331771 was inadvertently cross-contaminated with a small quantity of another drug, Enalapril maleate, at the same facility. Enalapril maleate is indicated for hypertension and congestive heart failure. Chronic exposure may impact users, particularly small children or pregnant women. It is associated with risk of birth defects in developing fetus. This recall is being conducted with the knowledge of the FDA.

Distributors/Pharmacies/Wholesalers:
Please examine your inventory **immediately** to determine if you have units of Lot # 331771 in stock. Please discontinue distributing this lot, remove it from your stock, and promptly return all units to our distribution center according to the following instructions:

(1) Please fill out the attached Recall Response Form completely
(2) Return the completed form via Fax to **914-470-4946** ….. or mail the completed form to:
Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive
Hawthorne, New York 10532
Attention: Richard Lewellyn
(3) Taro will provide return authorization/call tag to ship any returned merchandise to our distribution center at:
Taro Pharmaceuticals U.S.A., Inc.
1 Commerce Drive
Cranbury, New Jersey 08512
Attn: RETURNED GOODS - RECALL – Lamotrigine Tablets 100 mg
(4) Please contact all of your customers to ensure product return.

NOTE: Please return the form even if you do not have any inventory of the impacted lots.
We appreciate your prompt attention in looking through your inventory, discontinuing distribution of the affected lot and returning all units. If you have any questions about the content of this letter, please contact Richard Lewellyn at 1-800-544-1449 ext. 6334 or via email to richard.lewellyn@taro.com, or me at 914-345-9001 ext. 6216.
For any stock returned by Consumers, please contact Inmar at 866-705-1553 for product returns.

Consumers:
Please contact Inmar at 866-705-1553 for return information and reimbursement or contact the pharmacy where you purchased the product and return directly to them.

Taro apologizes for any inconvenience this may have caused.

Sincerely,

Scott P. Keenan

Scott Keenan
Manager, Quality Compliance

Enclosure: Recall Response Form – Lamotrigine Tablets USP, 100 mg

Taro Pharmaceuticals U.S.A., Inc.

RECALL RESPONSE FORM – Consumer Level

Lamotrigine Tablets USP, 100 mg

Lot #	Exp. Date	Size	NDC	Dates Distributed
331771	June 2021	100 count bottles	**51672-4131-1**	August 23 to August 30, 2019

Please enter the following information, completely:

Pharmacy/Retailer

Name of Business: _____ Phone: _____

Address: _____

_____

Wholesale Supplier/Distributor

Name: _____ Phone: _____

Address/Location: _____

Wholesaler/Distributor Account Number: _____

Please check ALL that apply:

- ☐ I have read and understood the instructions provided in the recall letter
- ☐ I have checked my inventory for any stock of lot # 331771
- ☐ **Check here IF YOU DO NOT have any inventory**, and please return this form
- ☐ Check here if you **DO** have inventory from lot #331771 and enter the quantity to be returned below:

Lot #	Exp. Date	Quantity
331771	**June 2021**	

Please FAX a copy of the completed response form to Richard Lewellyn at: 914-470-4946

...or return a copy of this form BY MAIL to: Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive
Hawthorne, New York 10532
Attention: Richard Lewellyn

A call tag will be issued to you for any returned merchandise, once Taro receives the response form. Please include a copy of this form with your return shipment, with the Return Authorization Number entered below.

Return Authorization Number: _____