URGENT: DRUG RECALL

BromSite™ (brofenac ophthalmic solution), 0.075% (Sterile 5 mL)

January 23, 2019

Dear Customer,

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

Product Name	Brand Name	Lot Number	NDC Number	Expiration Date
Bromfenac Ophthalmic Solution, 0.075% (Sterile 5 mL)	BromSite™	V18E01	49708-754-41	05/2020

See enclosed product labeling.

This recall has been initiated due to an identified equipment issue that caused leaking/damaged bottles, thus there is a possibility of a lack of sterility assurance. Use of this product can possibly pose a risk to patient safety.

Sun Pharma initiated shipment of this product on September 12, 2018.

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.

Kristy Zielny
Sun Pharmaceutical Industries, Inc.
Director, Site Head of Quality, Cranbury
Enclosure

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

Enclosure:

BromSite™ (bromfenac ophthalmic solution), 0.075% (Sterile 5 mL) Carton Labeling

URGENT: DRUG RECALL – RESPONSE FORM

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

Product Name	Brand Name	Lot Number	NDC Number	Expiration Date
Bromfenac Ophthalmic Solution, 0.075% (Sterile 5 mL)	BromSite™	V18E01	49708-754-41	05/2020

Please check ALL appropriate boxes

□ I have read and understand the recall instructions provided in the January 23, 2019 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.

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:

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

URGENT: DRUG RECALL – RESPONSE FORM

SUN PHARMA

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

Product Name	Brand Name	Lot Number	NDC Number	Expiration Date
Bromfenac Ophthalmic Solution, 0.075% (Sterile 5 mL)	BromSite™	V18E01	49708-754-41	05/2020

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.