



## **URGENT: DRUG RECALL**

**BromSite™ (bromfenac 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](mailto: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.

A handwritten signature in black ink, appearing to read "Kristy Zielny".

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

For return of affected product, please email [rxrecalls@inmar.com](mailto: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](mailto: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:

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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](mailto:rxrecalls@inmar.com) or call 1-800-967-5952.