Robert Kurkiewicz
Sr. Vice President, Regulatory Affairs
(800) 818-4555 x 4105
Robert.Kurkiewicz@sunpharma.com

URGENT: DRUG RECALL

Felodipine Extended-Release Tablets, 2.5 mg, 5 mg, 10 mg

July 16, 2015

Dear Trading Partner,

This notice is to inform you of a drug product recall involving,

Drug Product Name: Felodipine Extended-Release Tablets, 2.5 mg, 5 mg, 10 mg

Manufacturer: Sun Pharmaceutical Industries, Inc. (Mutual Pharmaceutical Company, Inc.)

Type of Drug Product: Prescription Only.

Intended Use/ Indications: Felodipine extended-release tablets are indicated for the treatment of hypertension, to lower blood pressure.

Lot Numbers:

Product Name	Lot Number	Pack size	NDC Number	Exp. Date
Felodipine Extended-Release Tablets, 2.5 mg	6669101	100 count	53489-368-01	12/15
	6669201	100 count	53489-368-01	12/15
	6708201	100 count	53489-368-01	8/16
	6708301	100 count	53489-368-01	8/16
Felodipine Extended-Release Tablets, 5 mg	6662801	100 count	53489-369-01	10/15
	6662901	100 count	53489-369-01	10/15
	6689601	100 count	53489-369-01	4/16
	6689701	100 count	53489-369-01	5/16
	6708401	100 count	53489-369-01	9/16
Felodipine Extended-Release Tablets, 10 mg	6667301	100 count	53489-370-01	11/15
	6667401	100 count	53489-370-01	11/15
	6699201	100 count	53489-370-01	6/16

Sun Pharmaceutical Industries, Inc.
270 Prospect Plains Road, Cranbury, NJ 08512
Phone: (609) 495 2800

Reason for Recall

This recall is voluntarily initiated based upon stability results. During the analysis of long-term stability sample, it was noticed that, the largest unknown impurity test result is not meeting the specifications. The unknown impurity was identified as benzophenone, which occurs naturally in foods and consumed every day. The trace amount of benzophenone found in the subject drug product lots is unlikely to cause any significant adverse effects. However, Sun Pharmaceutical Industries, Inc., out of an abundance of caution has decided to initiate recall of all the affected in-date lots of Felodipine Extended-Release Tablets, 2.5 mg, 5 mg, 10 mg.

These lots were distributed between February, 2014 to April, 2015.

This recall has been initiated at Retail level. Immediately examine your inventory and quarantine subject lots to this recall. Please stop distributing these lots immediately. In addition, if you have further distributed this product, please notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall letter.

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

For return of affected product, please email **rxrecalls@inmar.com** or call **800-967-5952**, during Monday to Friday, from 8:00am to 5:00pm (EST). Please complete and return the enclosed response form as soon as possible.

Affected product should be sent to:

Inmar
4332 Empire Road
South Dock
Fort Worth, TX 76155

Sincerely,

Robert Kurkiewicz
Sr. Vice President, Regulatory Affairs

URGENT: DRUG RECALL – RESPONSE FORM

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

We do not have any stock ☐

Or,

Please enter the quantity you shall be returning.

Product Name	Lot Number	Pack size	NDC Number	Exp. Date	Quantity to be returned
Felodipine Extended-Release Tablets, 2.5 mg	6669101	100 count	53489-368-01	12/15	
	6669201	100 count	53489-368-01	12/15	
	6708201	100 count	53489-368-01	8/16	
	6708301	100 count	53489-368-01	8/16	
Felodipine Extended-Release Tablets, 5 mg	6662801	100 count	53489-369-01	10/15	
	6662901	100 count	53489-369-01	10/15	
	6689601	100 count	53489-369-01	4/16	
	6689701	100 count	53489-369-01	5/16	
	6708401	100 count	53489-369-01	9/16	
Felodipine Extended-Release Tablets, 10 mg	6667301	100 count	53489-370-01	11/15	
	6667401	100 count	53489-370-01	11/15	
	6699201	100 count	53489-370-01	6/16	

Name_____ DEA #_____

Company_____

Address_____

City _____State _____ Zip Code_____

Phone #_____

Wholesaler_____ City/State_____

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