Robert Kurkiewicz
Sr. Vice President, Regulatory Affairs
(800) 818-4555 x 4105
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URGENT DRUG RECALL
VENLAFAXINE HCl ER TABLETS, 37.5 MG

September 29, 2014

Dear Trading Partner,

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

Drug Product Name: Venlafaxine Hydrochloride Extended-Release Tablets, 37.5 mg

Manufacturer: Sun Pharmaceutical Industries, Ltd.

NDC Number: 41616-760-83 (30 CRC) and 41616-760-81 (90 CRC).

Dosage Form: Extended Release Tablet

Route of Administration: Oral

Type of Drug Product: Prescription

Intended Use/ Indications: Indicated for the treatment of major depressive disorder.

Package Type and Number of Doses/Sizes: 30 tablets packed in HDPE bottles closed with Child Resistant Caps (CRC) and 90 tablets packed in HDPE bottles closed with Child Resistant Caps (CRC).

Lot Numbers

Product Name	Lot No.	Pack Size	Mfg. Date	Exp. Date
Venlafaxine Hydrochloride Extended-Release Tablets, 37.5 mg	JKM3855A	30 count CRC pack	06/2013	05/2015
	JKM3855B	90 count CRC pack	06/2013	05/2015
	JKM7265A	30 count CRC pack	12/2013	11/2015
	JKM7265B	90 count CRC pack	12/2013	11/2015

Reason for Recall

This recall is voluntarily initiated based upon stability results. The product may not meet the drug release specification throughout its expiry period. As a Precaution, Sun is voluntarily recalling these batches of Venlafaxine Hydrochloride Extended-Release Tablets, 37.5 mg.

Immediately examine your inventory and quarantine subject lots to this recall. Please stop distributing these lots immediately.

This recall has been initiated to the retail level (Recall Class II). In addition, if you have further distributed this product, please notify your retail customers 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 **recallnotice@inmar.com** or call **800-967-5952**. 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

If there are any further questions, please feel free to contact me at 800-818-4555 x 4105.

Sincerely,

Robert Kurkiewicz
Sr. Vice President, Regulatory Affairs

URGENT: DRUG RECALL – RESPONSE FORM

Please Complete Form and Fax to: 817-868-5362 or Email to: recallnotice@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
Venlafaxine Hydrochloride Extended-Release Tablets, 37.5 mg	JKM3855A	30 count	41616-760-83	05/2015	
	JKM3855B	90 count	41616-760-81	05/2015	
	JKM7265A	30 count	41616-760-83	11/2015	
	JKM7265B	90 count	41616-760-81	11/2015	

Name_____ DEA #_____

Company_____

Address_____

City _____State _____ Zip Code_____

Phone Number_____ Email_____

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