Robert Kurkiewicz
Sr. Vice President, Regulatory Affairs
(800) 818-4555 x 4105
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URGENT: DRUG RECALL

Clonidine Hydrochloride Tablets, USP, 0.1 mg, 0.2 mg, 0.3 mg

July 09, 2015

Dear Trading Partner,

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

Drug Product Name: Clonidine Hydrochloride Tablets, USP, 0.1 mg, 0.2 mg, 0.3 mg

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

Type of Drug Product: Prescription Only.

Intended Use/ Indications: Clonidine hydrochloride tablets USP are indicated in the treatment of hypertension. Clonidine hydrochloride tablets USP may be employed alone or concomitantly with other antihypertensive agents.

Lot Numbers:

Product Name	Lot Number	Pack size	NDC Number	Exp. Date
Clonidine Hydrochloride Tablets, USP, 0.1mg	6624001	100 count	53489-215-01	2-16
	6624002	1000 count	53489-215-10	2-16
	6624201	1000 count	53489-215-10	2-16
	6630501	100 count	53489-215-01	3-16
	6630601	1000 count	53489-215-10	3-16
	6668901	1000 count	53489-215-10	12-16
	6669001	100 count	53489-215-01	12-16
	6676001	1000 count	53489-215-10	1-17
	6676101	1000 count	53489-215-10	1-17
	6676201	100 count	53489-215-01	1-17
	6679401	1000 count	53489-215-10	2-17
	6679501	1000 count	53489-215-10	2-17
	6680701	100 count	53489-215-01	2-17

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

Product Name	Lot Number	Pack size	NDC Number	Exp. Date
Clonidine Hydrochloride Tablets, USP 0.2 mg	6643901	100 count	53489-216-01	5-16
	6677101	1000 count	53489-216-10	1-17
	6677201	100 count	53489-216-01	1-17
Clonidine Hydrochloride Tablets, USP, 0.3 mg	6676701	100 count	53489-217-01	1-17
	6676801	100 count	53489-217-01	1-17

Reason for Recall

Clonidine hydrochloride drug substance lot used in manufacturing of drug products was dispensed in the unauthorized rooms by drug substance manufacturer. The analysis performed by contract laboratory found no contamination in the drug substance lot; the extent of contamination, if any, was too little to be detected and this 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 Clonidine hydrochloride tablets, USP, 0.1 mg, 0.2 mg, and 0.3 mg.

These lots were distributed during April, 2013 to June, 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
Clonidine Hydrochloride Tablets, USP, 0.1mg	6624001	100 count	53489-215-01	2-16	
	6624002	1000 count	53489-215-10	2-16	
	6624201	1000 count	53489-215-10	2-16	
	6630501	100 count	53489-215-01	3-16	
	6630601	1000 count	53489-215-10	3-16	
	6668901	1000 count	53489-215-10	12-16	
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	6679501	1000 count	53489-215-10	2-17	
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Clonidine Hydrochloride Tablets, USP 0.2 mg	6643901	100 count	53489-216-01	5-16	
	6677101	1000 count	53489-216-10	1-17	
	6677201	100 count	53489-216-01	1-17	
Clonidine Hydrochloride Tablets, USP, 0.3 mg	6676701	100 count	53489-217-01	1-17	
	6676801	100 count	53489-217-01	1-17	

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