

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



URGENT: DRUG RECALL
Ergoloid Mesylates Tablets, USP, 1 mg

March 10, 2015

Dear Trading Partner,

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

Drug Product Name: Ergoloid Mesylates Tablets, USP, 1 mg

Manufacturer: Mutual Pharmaceutical Company, Inc.

NDC Number: 53489-281-01

Dosage Form: Tablets

Route of Administration: Oral

Type of Drug Product: Prescription

Intended Use/ Indications: A proportion of individuals over sixty who manifest signs and symptoms of an idiopathic decline in mental capacity (i.e., cognitive and interpersonal skills, mood, self-care, apparent motivation) can experience some symptomatic relief upon treatment with ergoloid mesylates preparations.

Package Type and Size: 100 tablets in a bottle.

Lot Numbers:

Product Name	Lot No.	Pack Size	Exp. Date
Ergoloid Mesylates Tablets, USP, 1 mg	6557301	100 count bottle	03-15
	6557401	100 count bottle	03-15
	6557501	100 count bottle	03-15
	6656301	100 count bottle	10-16
	6687701	100 count bottle	04-17

Sun Pharmaceutical Industries, Inc.
270 Prospect Plains Road, Cranbury, NJ 08512
Phone: (609) 495 2800 • FAX: (609) 495 2711

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 specification limit.

These lots were distributed during July, 2012 to March, 2015

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 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 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
Ergoloid Mesylates Tablets, USP, 1 mg	6557301	100 count bottles	53489-281-01	03-15	
	6557401	100 count bottles	53489-281-01	03-15	
	6557501	100 count bottles	53489-281-01	03-15	
	6656301	100 count bottles	53489-281-01	10-16	
	6687701	100 count bottles	53489-281-01	04-17	

Name _____ DEA # _____

Company _____

Address _____

City _____ State _____ Zip Code _____

Phone Number _____ Email _____

Wholesaler _____ City\State _____

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