

May 03, 2019

URGENT DRUG RECALL

Dear Customer:

This official communication is to notify you that Zydus Pharmaceuticals USA Inc., is voluntarily recalling multiple lots of Anastrozole Tablets, USP, 1mg at **RETAIL LEVEL**. Detail of lots being recalled is provided in annexure-I as an attachment to this letter.

Product	NDC Number	Count	Distribution Start Date	Distribution End Date
Anastrozole Tablets, USP, 1mg	68382-209-06 & 68382-209-10	30's Bottle & 1000's Bottle	For 1000's count: 17-Jul-17 to 23-Mar-19 For 30's count: 01-Sep-17 to 30-Apr-19	

In view of an ongoing USFDA inspection and an associated FDA observation at our Moraiya manufacturing site, Zydus Pharmaceuticals USA Inc has decided to proactively initiate a voluntary recall of multiple lots of the above referenced drug product. This recall is being initiated as a precautionary measure as though no evidence has been found in any product testing, we cannot rule out at this time cross contamination due to a GMP cleaning procedure failure in the Fluid Bed Dry Processor area.

While we continue to do a thorough investigation on this FDA observation, and in an effort to always provide the highest quality product, we have decided to recall these batches at a **RETAIL LEVEL**.

Zydus Pharmaceuticals USA Inc. advises its customers that have this product in stock to discontinue use/dispense/distribution and return it to Inmar Pharmaceuticals Services as per the details below.

Through this communication, at our cost, we request you to organize to return the above referenced drug product in your possession. To facilitate this recall, please do the following actions:

1. Examine your available stock for the presence of recalled lot of Anastrozole Tablets, USP, 1mg, 30's & 1000's bottles
2. If you have the concerned lot number of the drug product in your stock, please discontinue further distribution, quarantine the affected product and return all units to: Inmar Pharmaceutical Service, South Dock, 4332 Empire Rd, Fort Worth, TX 76155. A credit memo will be issued covering the quantity of your return to Inmar.

3. Please complete the enclosed "PRODUCT RECALL RESPONSE FORM" and fax it to us at **1-817-868-5362** or email it to rxrecalls@inmar.com. Even if you do not possess any inventory of the lot being recall, then also we appreciate if you fill out and return the "PRODUCT RECALL RESPONSE FORM"

4. If you have further distributed this product, please notify your customers at once of this product recall. Your notification to your 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.

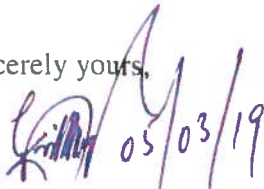
If you have any questions about the Logistic and other issues, then please call Recall Services at 1-800-967-5952 during Monday – Friday (excluding holidays), 9 am to 5 pm EST.

If you have any questions about product safety concerns, then please call Zydus Pharmaceuticals Drug Safety/ Medical Affairs at 1-877-993-8779 Option# 2 during Monday – Friday (excluding holidays), 9 am to 5 pm EST.

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

We apologize for any inconvenience this voluntary recall may have caused you. Your assistance is appreciated and necessary to prevent further product usage.

Sincerely yours,



Srinivas Gurram (Srini)
Vice President & Head of RA & QA- North America
Zydus Pharmaceuticals (USA) Inc.

Attachment: Lot Details of Anastrozole Tablets, USP, 1mg



Lot Details of Anastrozole Tablets, USP, 1mg, 30's Bottle, NDC: 68382-209-06

Lot No.	Exp Date	Lot No.	Exp Date	Lot No.	Exp Date	Lot No.	Exp Date
M706674	Jun-19	M805195	Mar-20	M805959	Apr-20	M818121	Nov-20
M706676	Jun-19	M805196	Mar-20	M812457	Jul-20	M818274	Oct-20
M707685	Jun-19	M805197	Mar-20	M812458	Aug-20	M818635	Nov-20
M711219	Sep-19	M805199	Apr-20	M812459	Aug-20	M819270	Dec-20
M711220	Sep-19	M805202	Apr-20	M813912	Aug-20	M819861	Dec-20
M711221	Sep-19	M805944	Apr-20	M813913	Aug-20	M819862	Dec-20
M711222	Sep-19	M805945	Apr-20	M813914	Aug-20	M900921	Jan-21
M711269	Sep-19	M805948	Apr-20	M813915	Aug-20	M900922	Jan-21
M801027	Dec-19	M805951	Apr-20	M813916	Aug-20	M900923	Jan-21
M801028	Jan-20	M805953	Apr-20	M815768	Oct-20	M900924	Jan-21
M801029	Jan-20	M805956	Apr-20	M815769	Oct-20	M900925	Jan-21
M801030	Jan-20	M805957	Apr-20	M818119	Nov-20	M902634	Feb-21
M802206	Feb-20	M805958	Apr-20	M818120	Nov-20	M902635	Feb-21

Lot Details of Anastrozole Tablets, USP, 1mg, 1000's Bottle, NDC: 68382-209-10

Lot No.	Exp Date	Lot No.	Exp Date	Lot No.	Exp Date	Lot No.	Exp Date
M708570	Jun-19	M711270	Sep-19	M802207	Feb-20	M812460	Aug-20



PRODUCT RECALL RESPONSE FORM

URGENT DRUG RECALL-RETAIL LEVEL

Please complete the required information and fax to **1-817-868-5362**
 or email to rxrecalls@inmar.com

To the Attention of Drug Safety/ Recall Services-Zydus Pharmaceuticals USA Inc.

**Product Details: Anastrozole Tablets, USP, 1mg, 30's Bottle
 NDC: 68382-209-06**

Lot No.	Exp Date	No. of Bottle Purchased	No of Bottles consumed	No. of bottles in Possession	No of Bottles to be returned	Lot No.	Exp Date	No. of Bottle Purchased	No of Bottles consumed	No. of bottles in Possession	No of Bottles to be returned
M706674	Jun-19					M805959	Apr-20				
M706676	Jun-19					M812457	Jul-20				
M707685	Jun-19					M812458	Aug-20				
M711219	Sep-19					M812459	Aug-20				
M711220	Sep-19					M813912	Aug-20				
M711221	Sep-19					M813913	Aug-20				
M711222	Sep-19					M813914	Aug-20				
M711269	Sep-19					M813915	Aug-20				
M801027	Dec-19					M813916	Aug-20				
M801028	Jan-20					M815768	Oct-20				
M801029	Jan-20					M815769	Oct-20				
M801030	Jan-20					M818119	Nov-20				
M802206	Feb-20					M818120	Nov-20				
M805195	Mar-20					M818121	Nov-20				
M805196	Mar-20					M818274	Oct-20				



Lot No.	Exp Date	No. of Bottle Purchased	No of Bottles consumed	No. of bottles in Possession	No of Bottles to be returned	Lot No.	Exp Date	No. of Bottle Purchased	No of Bottles consumed	No. of bottles in Possession	No of Bottles to be returned
M805197	Mar-20					M818635	Nov-20				
M805199	Apr-20					M819270	Dec-20				
M805202	Apr-20					M819861	Dec-20				
M805944	Apr-20					M819862	Dec-20				
M805945	Apr-20					M900921	Jan-21				
M805948	Apr-20					M900922	Jan-21				
M805951	Apr-20					M900923	Jan-21				
M805953	Apr-20					M900924	Jan-21				
M805956	Apr-20					M900925	Jan-21				
M805957	Apr-20					M902634	Feb-21				
M805958	Apr-20					M902635	Feb-21				

**Product Details: Anastrozole Tablets, USP, 1mg, 1000's Bottle
 NDC: 68382-209-10**

Lot No.	Exp Date	No. of Bottle Purchased	No of Bottles consumed	No. of bottles in Possession	No of Bottles to be returned	Lot No.	Exp Date	No. of Bottle Purchased	No of Bottles consumed	No. of bottles in Possession	No of Bottles to be returned
M708570	Jun-19					M802207	Feb-20				
M711270	Sep-19					M812460	Aug-20				

No. of Returns kit required: _____

Please mark as applicable

___ We currently do not have any inventory of the above listed Lot/bottles



We are notifying our customers

We have identified and notified my customers that were shipped or may have been shipped this product by _____;

Attached is the list of customers who received/ may have received this product. Please notify my customers.

Any adverse event associated with recalled product? Yes No

If yes, please explain:

Please check appropriate box to describe your business

Wholesaler/Distributor

Retailers

Repackager

Manufacturer

Pharmacy- Retail

Hospital/ Medical Facility

Hospital Pharmacies

Medical Laboratory

Other: _____

Name: _____

Title: _____

Tel Number: _____

Firm Name: _____ DEA# _____

www.zydususa.com



Address: _____

City/ State: _____

If you have not purchased, the concerned lot directly from Zydus Pharmaceuticals USA Inc., then please provide details of your wholesaler: _____ (Name, City) DEA# _____

Signature: _____

Date: _____