Cipla

URGENT: DRUG RECALL UPDATE (Retail Level)

01/15/2019

Smith Drug
9098 Fairforest Rd
Spartanburg SC 29301-1134

Dear Valued Customer:

This is to inform you of a product recall update by Cipla USA, Inc. [being conducted by InvaGen Pharmaceuticals, Inc. (A Cipla Subsidiary)] for a single lot of Nevirapine Extended Release Tablets 400 mg. The start date of distribution was March 2018. The product is labeled for and marketed by Cipla USA, Inc. bearing the NDC Number 69097-403-02.

Nevirapine Extended Release Tablets 400 mg (R_X)

NDC Number: 69097-403-02

Lot Number: GG80257 (Expiry 12/2019)

Please see enclosed product label to facilitate the identification of the drug product found in **ANNEXURE-1.o**

This recall has been initiated due to failure of dissolution test at the 3-month long-term stability interval. Use of this product is not likely to have any impact on the consumer. Use of this product is not likely to have any adverse impact on the consumer, however it may not consistently achieve drug concentrations needed to suppress HIV replication.

Recall Instructions:

Please examine your inventory immediately and return all bottles of the Nevirapine Extended Release Tablets 400 mg lot as mentioned above. Please quarantine / discontinue the distribution of this lots promptly and return a completed response form to the authorized agent listed below. A return kit will be issued to you for the return of affected drug product. If you have any questions regarding product return, call Inmar at 800-967-5952 (Fax # 817-868-5362)

Drug product covered by this recall should be returned to the following authorized agent:

INMAR – South Dock
c/o Cipla USA
4332 Empire Road
Fort Worth, TX 76155
1-800-967-5952 (Customer Service toll free)

This recall should be carried out to the **retail level**. Please notify your customers down to the retail level and provide them the attached response form so they may return any affected product in their possession. Your assistance is appreciated and necessary to prevent unnecessary risk to the consumer.

Please complete and return the enclosed response form as soon as possible.

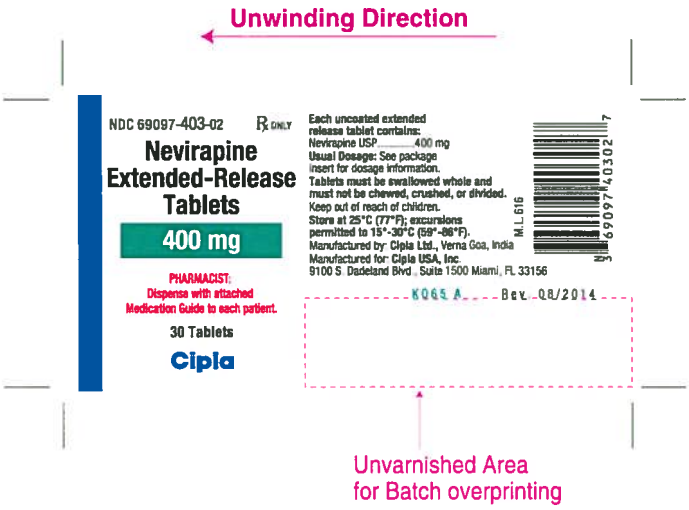
If you have any questions, please call or contact:

Suneel Chhatre
Director, Quality & Compliance
Tel: (631) 231-3233 Ext: 529
Fax: 516-493-5329
Email: Suneel.chhatre@Cipla.com

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

Thank you.

Annexures(s)



DO NOT PRINT UP NO & SUPPLIER LOGO

PACKAGING DEVELOPMENT

Product Name: Nevirapine Extended-Release Tablets 400mg	**Item Code:** KO65 A	**Version:** 01	**Item:** Label	**Date:** 24-11-2015
Co-ordinator: Yogita	**Artist:** Atish	**Software:** Illustrator CC		
Fonts: ——				
Colours: BLUE WOOL TEST VALUE 5-8 (LIGHT FASTENING DATA)	PANTONE 2945 C	PANTONE 3275 C		
	PANTONE 199 C	Black		
INK: UV-Flexo Printing ink - UV SICURA FLEX 39-10 LM (LMLO) From Siegwerk				
Spectro-Densitometer Delta-E reading (△E) for colour: NOT MORE THAN dE2.5	**Glossmeter reading (for white surface):** NOT LESS THAN 80 %			
Supersedes / Reference:	**Screen : #**	**Unwinding Direction:** As indicated in Artwork		
Links: NA				
Pharmacode:		**Design:** Roll Form		
Material: 80 gsm Fasson FasPrint NG paper/Adhesive Fasson HITAC/ Release liner Fasson PET23 (PTA2450 from Avery Dennison) with adhesive NLT 15 gsm and release liner NLT 28 gsm or 23 micron ±10 %		**Varnish:** Benzophenone free UV varnish Prisco E-cure 712 (except unvarnished area)		
Actual Size: 75 x 38 mm				
Grain Direction : Parallel to length				
Instructions for Printer • Avoid contamination of **Benzophenone free varnish** at all stages of printing activities, printing material usage, printing equipment and system etc. • COA should have all the details of printed label paper/ink/varnish.				
Reference / Instructions / Remark: NA				
Artwork Print Size: ☐ actual ☐ scaled				
Path : PC: D:\ATISH\Pratima\CIPLA ANDA\NEVIRAPINE ER TABLETS 400 MG\KO65 A NEVIRAPINE ER TABLETS 400 MG 30's Lbl				

Checked by	Artist	Cordinator	Section Head	File Copied by	file loaded in BCT HO
Pharma Code	☐	☐			
2D Code	☐	☐			
Barcode	☐	☐			
Artwork	☐	☐			
Spell check	☐	☐		Date:	

NOTE TO THE PRINTER :

- Colour scheme must be as approved by packaging development co-ordinator.
- Any deviation must be brought to the notice of packaging development co-ordinator immediately.
- For any clarification, please contact packaging development co-ordinator immediately.
- The final sample set (shade card, multi-up sheet and samples as per CIPLA Standards) should be sent FOR CIPLA'S Approval and it should be signed and dated, and also be accompanied with one multi up which is approved by Supplier's QA/QC with sign and date and should have Stamped with " Copy matter and colour checked for all the multi ups" on the multi up sheet.

InvaGen
Pharmaceuticals, Inc.
A Cipla Subsidiary

RECALL RESPONSE FORM

Extended Release Tablets 400 mg (RX)
Lot Number: GG80257 (Expiry 12/2019)
(Retail Level)

VOLUNTARY RECALL UPDATE 01/15/19

Please fill out this form completely and return it immediately via the instructions below. By doing so, you acknowledge that you have read and understood the recall instructions and have taken the appropriate action.

Customer Name _____ DEA #_____

DEA # is required, if it is not provided, the processing of your form will be delayed.

Address_____

City_____ State_____ Zip_____

Contact Name (please print)_____ Telephone #_____

Contact Signature _____ Date_____

I have checked my stock and: (MARK ONE)

○ Do not have any stock of the recalled drug product referenced above.

OR

○ Have quarantined and listed below the quantity of withdrawn bottles. I will return the drug product to Inmar, as soon as possible. Upon receipt of this recall Response Form, Inmar, will issue return authorization label(s). Please indicate the number of return authorization label(s) required. _____.

Item Description	NDC	Lot #	Qty returning
Nevirapine Extended Release Tablets 400 mg	**69097-403-02**	**GG80257**	

If you did not purchase the product directly from the Manufacturer please complete the below section.

Purchased From: Wholesaler Name _____

City_____ State_____

Wholesaler DEA#_____

If you have any questions regarding this form or product return, please contact Inmar Customer Service (1-800-967-5952 during the hours of 9am to 5pm EST, Monday through Friday.

Please fax this form to: 1-817-868-5362, or E-mail to: rxrecalls@inmar.com