Lupin Pharmaceuticals, Inc.

February 21, 2020

MANUFACTURED BY:
Lupin Limited
Pithampur (M. P.) 454 775 INDIA

MANUFACTURED FOR:
Lupin Pharmaceuticals, Inc.
Baltimore, Maryland 21202
United States

Dear Healthcare Partner,

URGENT: DRUG RECALL – RETAIL LEVEL

Memantine Hydrochloride Extended Release Capsules, 21mg

Lupin Pharmaceuticals, Inc. is initiating a voluntary recall of lot **H900330 Expiry November 2020** of Memantine Hydrochloride Extended Release Capsules, 21mg to **Retail** level. As an abundance of caution, this product lot is being recalled due to an out of specification result observed in dissolution test at six-month long-term stability study.

The issue under discussion is not expected to cause any health hazards.

The recalled lot was distributed between March 29, 2019 and July 25, 2019 to wholesalers, distributors, independent and mail order pharmacies nationwide.

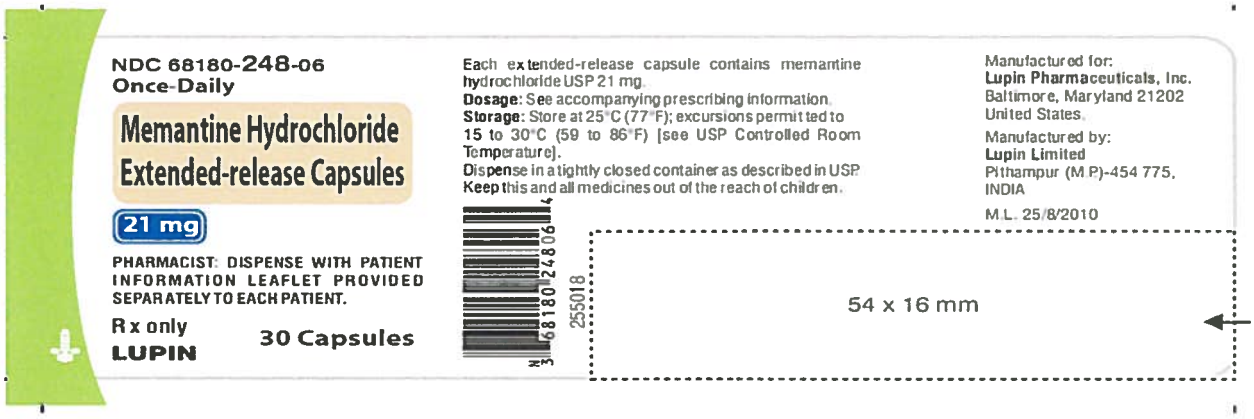
Immediately examine your inventory and quarantine the product lot subject to recall. Wholesalers and distributors should forward this notification to the retailers. Wholesalers and distributors who have the affected product lot in their inventory should contact Inmar Rx Solutions, Inc. at +1-800-967-5952 Monday – Friday 9:00 am to 5:00 pm EST. For reimbursement, please have the recalled lot returned to Inmar Rx Solutions, Inc. on or before May 15, 2020. The lot number can be found on the side of the bottle.

Memantine Hydrochloride Extended Release Capsules are supplied as below:

Strength	Lot No	NDC	Pack Size	Description
21mg	H900330	68180-248-06	30's count	Size '4' Hard Gelatin capsules with white opaque cap and dark green opaque body, with black imprint 'LU' on cap and 'O63' on body and containing white to off-white colored coated pellets.

Lupin Pharmaceuticals, Inc.

Product label:



This recall should be carried out to the **Retail** level.

A COMPLETE PACKAGE OF INFORMATION INCLUDING A REPLY FORM WILL BE MAILED WITHIN (5) BUSINESS DAYS.

Upon receipt of this packet, please take the following actions:

1. **Distributors/Pharmacies –** Immediately examine your inventory, quarantine and discontinue distribution of this lot.
2. **Distributors** – Complete the enclosed Business Response Form even if you do not have any product on hand.
3. **Distributors –** Please pass this Recall Notice on **ONLY** to pharmacies that received this product lot.
4. **Pharmacies –** If you have units of the affected product/lot in inventory, please contact Inmar Pharmaceuticals Services at 800-967-5952 (option 1) to receive a Business Recall Response form or acquire it from clsnetlink.com.
5. Business Recall Response Form can be submitted by any of these methods.
   Fax: 817-868-5362
   Email: rxrecalls@inmar.com
   Address: Inmar, Attn: Recall Coordinator - 635 Vine St, Winston Salem, NC 27101
6. **Distributors/Pharmacies –** Return recalled product to Inmar Pharmaceuticals Services as instructed in recall/return packet.
7. **Pharmacies** – You do not need to contact any patients.

Upon receipt of the completed BRF, a return kit will be sent including an RA form and necessary box labels.

We appreciate your immediate attention to this matter. This recall is being made with the knowledge of the U.S. Food and Drug Administration.

Sincerely,

Anurag Mishra
Digitally signed by Anurag Mishra
Date: 2020.02.21 09:25:45 -05'00'

Anurag Mishra
Associate Director, Quality

RECALL STOCK RESPONSE FORM

RECALL of Memantine Hydrochloride Extended Release Capsules, 21mg
Retail Level
2/21/2020

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand 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_____

Wholesaler Information if not directly purchased from Lupin:

Wholesaler Name: _____

Wholesaler Address: _____

I have checked my stock and:

_____Do not have any stock of the recalled **items**.

OR

I have quarantined and listed in the box below the quantity of recall units and I will be returning to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar, will issue return authorization label(s) Please indicate the # of needed box labels _____.

Item Description	NDC	Lot #	Qty returning
Memantine Hydrochloride Extended Release Capsules, 21mg	68180-248-06	H900330	

If you have any questions regarding this form or product return please contact Inmar at 1-800-967-5952. Office hours 9am to 5pm EST Mon thru Fri.

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