

Attached is a list of customers who received/ may have received this product. Please

notify my customers.

Product Name	Package Description	NDC#	Lot#	Expiration Date	Input Total Number of Tablets to Return	

Any adverse events associated with recalled product? □ Yes □ No	
If yes, please explain: Not applicable	
Please check the appropriate box(es) to describe your business wholesaler/distributor retailer grocery corporate headquarters food service/restaurant repacker manufacturer pharmacy - retail hospital/medical facility hospital pharmacies medical laboratory	
Other: Name: Inmar Rx Solutions	
Title: Recall co-ordinator Tel. number: 1-877-861-3809	
PLEASE SEND RESPONSE TO: rxrecalls@inmar.com or call 1-877-861-3809	
Monday to Friday from 9:00 am to 5:00pm (EST).	
Event Id: RCL107-24/N131160	

Rubicon Research Private Limited

Corporato Offico&R&D Confor MedOne House, B-75, Road No. 33, Wagle Estate, Thane – 400 604, Maharashtra, India Tel: 91-22-61414000/50414000 Fax: 91-22-61414021 CRX: U73100MH1999PTC119744 Manufacturing Plant-I K-30/4 & 30/5, Additional M.L.D.C., Ambernath, Thane - 421 506 Maharashtra, India Tel: 0251-7139500 / 3501240 Fax: 0251-7139575 Email: subleon@rubleon.co.in Manutacturing Plant-II J-4/2, Additional M.I.D.C., Satara - 415 004, Maharashira, India Tel: 02162-240309 / 240463 Fax 02162-240331 Website: www.nabicon.co.in



URGENT: DRUG PRODUCT RECALL

25 April 2024

Shailesh Kulkarni Rubicon Research Pvt. Ltd. Plot No. K 30/4 & 30/5, Additional M.I.D.C. Ambernath, Dist. Thane, Maharashtra

Zip Code: 421 506

Dear Customer:

This is to inform you of a product recall involving:

Tramadol Hydrochloride Tablets, USP 50 mg

Batch No.	NDC code	Description	Pack size	Mfg. Date	Exp. Date
230774H1	72888-080- 00	White to off white, capsule shaped film coated tablet debossed with "018" on one side and scored on other side.	1000	May 2023	Apr 2026

See enclosed product label for ease in identifying the product at retail level. This recall has been initiated due to a potential mix-up of the lot. A pharmacist reported that they observed a round tablet of Baclofen Tablets USP, 10 mg in a bottle of 1000's count of Tramadol Hydrochloride Tablets USP 50 mg which happens to be oval shaped.

We began shipping this product on 03 Aug 2023.

Immediately examine your inventory and quarantine Tramadol Hydrochloride Tablets, USP 50mg subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

This recall should be carried out to the retail level.

Your assistance is appreciated and necessary to prevent patient harm.

Rubicon Research Private Limited

Email: rub/cor/@rub/cor.co. n



Please complete and return the enclosed response form as soon as possible. After receipt of the response form, a return kit will be provided, or product will be picked up from the store so the affected product can be sent to:

Inmar Rx Solutions 3845 Grand Lakes Way, Grand Prairie, TX 75050

If you have any questions, contact Inmar, Inc. at rxrecalls@inmar.com or call 1-877-861-3809

Monday to Friday from 9:00 am to 5:00pm (EST).

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

Enclosures:

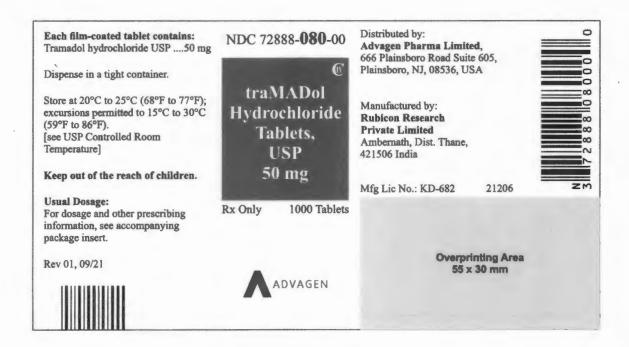
- 1. Bottle Label Tramadol Hydrochloride Tablets, USP 50 mg
- 2. Return Response form

Shailesh by Shailesh Kulkarni Date: 2024.04.25

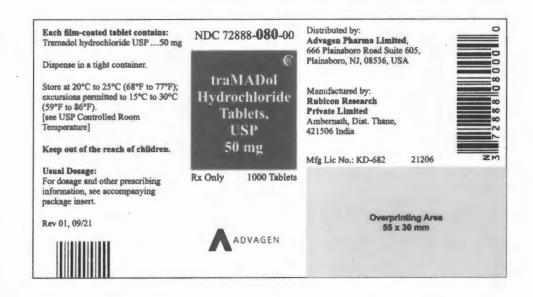
General Manager - Quality Assurance Rubicon Research Pvt. Ltd.

CIN: U731D0MH1999PTC119744

Tramadol Hydrochloride Tablets USP, 50 mg - 1000's Tablets

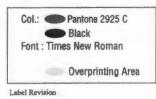


120% Enlarged Size Artwork



130 mm x 70 mm (Actual Size)

Pharma Code 21206



New itemcode and Pharmacode