

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

Corporate Office&R&D Center
 MedOne House, B-75, Road No. 33,
 Wagle Estate, Thane - 400 604,
 Maharashtra, India
 Tel: 91-22-61414000/50414000
 Fax: 91-22-61414021
 CIN: U73100MH1999PTC119744

Manufacturing Plant-I
 K-30/4 & 30/5, Additional M.I.D.C.,
 Ambarnath, Thane - 421 506
 Maharashtra, India
 Tel: 0251-7139500 / 3501240
 Fax: 0251-7139575
 Email: rubicon@rubicon.co.in

Manufacturing Plant-II
 J-4/2, Additional M.I.D.C.,
 Satara - 415 004,
 Maharashtra, India
 Tel: 02162-240309 / 240463
 Fax: 02162-240331
 Website: www.rubicon.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.
Ambarnath, 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

Corporate Office & R&D Center
MedOne House, B-75, Road No. 33,
Wagle Estate, Thane - 400 604,
Maharashtra, India
Tel: 91-22-61414000 / 504 14000
Fax: 91-22-614 14021
CIN: U73100MH1999PTC119744

Manufacturing Plant-I
K-30/4 & 30/5, Additional M.I.D.C.,
Ambarnath, Thane - 421 506
Maharashtra, India
Tel: 0251-7139500 / 350 1240
Fax: 0251-7139575
Email: rubicon@rubicon.co.in

Manufacturing Plant-II
J-4/2, Additional M.I.D.C.,
Satara - 415 004,
Maharashtra, India
Tel: 02162-240309 / 240463
Fax: 02162-240331
Website: www.rubicon.co.in

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

Digitally signed
by Shailesh
Kulkarni
Date: 2024.04.25
18:54:44 +05'30'

General Manager - Quality Assurance
Rubicon Research Pvt. Ltd.

Rubicon Research Private Limited

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

<p>Each film-coated tablet contains: Tramadol hydrochloride USP50 mg</p>	<p>NDC 72888-080-00</p>	<p>Distributed by: Advagen Pharma Limited, 666 Plainsboro Road Suite 605, Plainsboro, NJ, 08536, USA</p>	
<p>Dispense in a tight container.</p>		<p>Manufactured by: Rubicon Research Private Limited Ambemath, Dist. Thane, 421506 India</p>	
<p>Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). [see USP Controlled Room Temperature]</p>		<p>Mfg Lic No.: KD-682 21206</p>	
<p>Keep out of the reach of children.</p>	<p>Rx Only 1000 Tablets</p>	<p style="text-align: center;">Overprinting Area 55 x 30 mm</p>	
<p>Usual Dosage: For dosage and other prescribing information, see accompanying package insert.</p>			
<p>Rev 01, 09/21</p>			

120% Enlarged Size Artwork

<p>Each film-coated tablet contains: Tramadol hydrochloride USP50 mg</p>	<p>NDC 72888-080-00</p>	<p>Distributed by: Advagen Pharma Limited, 666 Plainsboro Road Suite 605, Plainsboro, NJ, 08536, USA</p>	
<p>Dispense in a tight container.</p>		<p>Manufactured by: Rubicon Research Private Limited Ambemath, Dist. Thane, 421506 India</p>	
<p>Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). [see USP Controlled Room Temperature]</p>		<p>Mfg Lic No.: KD-682 21206</p>	
<p>Keep out of the reach of children.</p>	<p>Rx Only 1000 Tablets</p>	<p style="text-align: center;">Overprinting Area 55 x 30 mm</p>	
<p>Usual Dosage: For dosage and other prescribing information, see accompanying package insert.</p>			
<p>Rev 01, 09/21</p>			

130 mm x 70 mm (Actual Size)

Pharma Code 21206

Col.:	Pantone 2925 C
	Black
Font :	Times New Roman
	Overprinting Area

Label Revision
New Itemcode and Pharmcode