

URGENT: RETAIL LEVEL MARKET WITHDRAWAL - INITIATED 09/19/2025
LORAZEPAM INJECTION USP, 2MG/ML and 4MG/ML CIV
ATIVAN (LORAZEPAM INJ. USP) 2MG/ML and 4MG/ML CIV

Dear Customer:

Hikma Pharmaceuticals USA Inc. is voluntarily initiating a market withdrawal of thirteen (13) lots of Lorazepam Injection, USP and Ativan (Lorazepam Inj. USP) 2mg/mL and 4mg/mL, 1mL fill vials at the retail level. This market withdrawal is being conducted with the knowledge of the Food and Drug Administration.

NDC	Item Description	Lot	Exp. Date	First Ship Date	Last Ship Date
0641-6001-25	ATIVAN (LORAZEPAM INJ.) 2MG/ML VIAL X 25	D24100Z	Apr-26	6/10/2024	6/11/2024
0641-6001-25	ATIVAN (LORAZEPAM INJ.) 2MG/ML VIAL X 25	D24106Z	Apr-26	6/4/2024	6/11/2024
0641-6003-25	ATIVAN (LORAZEPAM INJ.) 4MG/ML VIAL X 25	G24103Z	Jul-26	9/16/2024	4/7/2025
0641-6044-25	LORAZEPAM 2MG/ML VIAL X 25	C24099	Mar-26	5/24/2024	6/3/2024
0641-6044-25	LORAZEPAM 2MG/ML VIAL X 25	D24098	Apr-26	6/4/2024	6/13/2024
0641-6044-25	LORAZEPAM 2MG/ML VIAL X 25	D24104	Apr-26	6/13/2024	6/17/2024
0641-6044-25	LORAZEPAM 2MG/ML VIAL X 25	D24115	Apr-26	6/17/2024	6/25/2024
0641-6045-25	LORAZEPAM 4MG/ML VIAL X 25	G24103	Jul-26	9/16/2024	12/2/2024
0641-6048-25	LORAZEPAM NOVA+ 2MG/ML VIAL X 25	H24079Z	Aug-26	10/3/2024	11/18/2024
0641-6049-25	LORAZEPAM NOVA+ 4MG/ML VIAL X 25	G24103Y	Jul-26	9/16/2024	4/21/2025
72572-380-25	LORAZEPAM CIVICA 2MG/ML VIAL X 25	B24072Z	Feb-26	3/22/2024	3/22/2024
72572-380-25	LORAZEPAM CIVICA 2MG/ML VIAL X 25	C24097Z	Mar-26	5/22/2024	5/22/2024
72572-380-25	LORAZEPAM CIVICA 2MG/ML VIAL X 25	D24102Z	Apr-26	5/29/2024	5/29/2024

Reason for withdrawal:

This market withdrawal is being conducted as a precautionary measure. This is being executed out of abundance of caution as the product may exceed the total related compound specification prior to end of shelf-life.

Important Basic Information:

This market withdrawal is limited to the lot numbers listed above. No other Hikma products or lots are impacted by this market withdrawal. We have received no Adverse Events complaints for the subject lots to date. The services of Inmar Rx Solutions, Inc. have been enlisted to facilitate the market withdrawal.

Labeling:

Please see attachments for Product Labels that will assist in identifying the products.

Action Required:

- Stop distributing these lots immediately and segregate any product remaining in your inventory for return.
- Immediately copy and forward this letter and the Return Response Form to any of your direct retail or distributor consignees to whom these affected product lots were distributed.
- Promptly complete a physical count and record this data on the enclosed Return Response Form included with this letter. Complete the Return Response Form indicating that you have contacted your consignees and return to Inmar Rx Solutions, Inc. An immediate response to complete the Return Response Form is required **even if there is no affected product/lot in your inventory**.

If you have Product to Return:

- Once the Return Response Form is sent to Inmar Rx Solutions, Inc., Inmar will send a return kit and prepaid shipping label for your market withdrawal product return.
- Once you receive a shipping label and a return kit, immediately ship market withdrawal product to **Inmar Rx Solutions, Inc.** Do not include any other products/lots in this return shipment. Return of the market withdrawal product must be separate from all other returns and returned only to **Inmar RX Solutions, 3845 Grand Lakes Way, Grand Prairie, TX 75050**. All market withdrawal product returned without a return kit may delay the issuance of your credit. Hikma will issue a credit for the quantity of returned product to direct customers of Hikma. If you are NOT a Direct Customer of Hikma, a credit should be requested from your WHOLESALE.

Completed Return Response Form can be submitted by mail, email, or FAX to Inmar Rx Solutions, Inc.

By mail: Inmar RX Solutions Attn: Retail Coordinator, One West Fourth Street, Winston Salem, NC 27101

By email address: HikmaEvent@Inmar.com or by FAX: 1-817-868-5362

For information regarding this market withdrawal, please reference the following contact information:

- For information regarding the market withdrawal process, call Hikma at 1-800-631-2174 between 8:00am - 6:00pm EST, Monday through Friday, or email at usrecall@hikma.com.
- For medical or technical product information or to report an Adverse Event call Hikma at 1-877-233-2001 between 9:00am – 7:00pm EST, Monday through Friday or email us.hikma@primevigilance.com.
- For additional information regarding the return of the product, call Inmar Rx Solutions, Inc. at (866) 479-7682.

We are committed to supplying our customers with quality products. We apologize for this inconvenience and thank you for your time and continued support. Your cooperation and compliance with the requests in this letter are appreciated.

Sincerely,

A handwritten signature in blue ink, appearing to read "Georgiy Guralnik". The signature is stylized with a large initial "G" and a long horizontal stroke.

Georgiy Guralnik
Sr. Director, Quality Operations

Lorazepam/ Ativan Vial and Shelf-Pack/Carton print Label for the presentations listed above:

NDC 0641-6001-01

Ativan ^{IV}
Injection
(lorazepam inj., USP)
2 mg/mL

For IM use
Dilute for IV use
Protect from light
Refrigerate
1 mL Vial ^{Rx only}
Mfd. by Hikma

Lot:
Exp:

Lot:
Exp:
To open—Cut seal along dotted line.

NDC 0641-6001-25 ^{Rx only}

Ativan Injection
(lorazepam injection, USP)
2 mg/mL ^{IV}

For Intramuscular use
For Intravenous use, dilution required; see insert.
Refrigerate
25 x 1 mL Vials 462-155-02 **hikma.**

Each mL contains 2 mg lorazepam, 0.18 mL polyethylene glycol 400 in propylene glycol with 2% benzyl alcohol as preservative.
Usual Dosage: See insert. Do not use if solution is discolored or contains a precipitate.
Protect from light; Store in carton.
Manufactured by Hikma Berkeley Heights, NJ 07922

NDC 0641-6003-01

Ativan ^{IV}
Injection
(lorazepam inj., USP)
4 mg/mL

For IM use
Dilute for IV use
Protect from light
Refrigerate
1 mL Vial ^{Rx only}
Mfd. by Hikma

Lot:
Exp:

Lot:
Exp:
To open—Cut seal along dotted line.

NDC 0641-6003-25 ^{Rx only}

Ativan Injection
(lorazepam injection, USP)
4 mg/mL ^{IV}

For Intramuscular use
For Intravenous use, dilution required; see insert.
Refrigerate
25 x 1 mL Vials 462-157-02 **hikma.**

Each mL contains 4 mg lorazepam, 0.18 mL polyethylene glycol 400 in propylene glycol with 2% benzyl alcohol as preservative.
Usual Dosage: See insert. Do not use if solution is discolored or contains a precipitate.
Protect from light; Store in carton.
Manufactured by Hikma Berkeley Heights, NJ 07922

NDC 0641-6044-01

Lorazepam ^{IV}
Injection, USP
2 mg/mL

For IM use
Dilute for IV use
Protect from light
Refrigerate
1 mL Vial ^{Rx only}
Mfd. by Hikma

Lot:
Exp:

Lot:
Exp:
To open—Cut seal along dotted line.

NDC 0641-6044-25 ^{Rx only}

Lorazepam Injection, USP
2 mg/mL ^{IV}

For Intramuscular use
For Intravenous use, dilution required; see insert.
Refrigerate
25 x 1 mL Vials 462-164-02 **hikma.**

Each mL contains 2 mg lorazepam, 0.18 mL polyethylene glycol 400 in propylene glycol with 2% benzyl alcohol as preservative.
Usual Dosage: See insert. Do not use if solution is discolored or contains a precipitate.
Protect from light; Store in carton.
Manufactured by Hikma Berkeley Heights, NJ 07922

NDC 0641-6045-01

Lorazepam 
Injection, USP

4 mg/mL

For IM use
Dilute for IV use
Protect from light
Refrigerate
1 mL Vial Rx only
Mfd. by Hikma
Lot: [Redacted]
Exp: [Redacted]

Lot: [Redacted]
Exp: [Redacted] To open—Cut seal along dotted line.

NDC 0641-6045-25 Rx only

Lorazepam 
Injection, USP

4 mg/mL

For intramuscular use
For intravenous use, dilution required; see insert.
Refrigerate
25 x 1 mL Vials 462-166-02

Each mL contains 4 mg lorazepam, 0.18 mL polyethylene glycol 400 in propylene glycol with 2% benzyl alcohol as preservative.
Usual Dosage: See insert. Do not use if solution is discolored or contains a precipitate.
Protect from light: Store in carton.
Manufactured by Hikma, Berkeley Heights, NJ 07922
hikma.

NDC 0641-6048-01

Lorazepam 
Injection, USP

For IM use
Dilute for IV use
2 mg/mL

Protect from light
Refrigerate
1 mL Vial Rx ONLY
Mfd. by Hikma
novaplus+
Lot: [Redacted]
Exp: [Redacted]

Lot: [Redacted]
Exp: [Redacted] To open—Cut seal along dotted line.

NDC 0641-6048-25 Rx ONLY

Lorazepam 
Injection, USP

2 mg/mL

For intramuscular use
For intravenous use, dilution required; see insert.
Refrigerate
25 x 1 mL Vials **novaplus+** 402-373-02

Each mL contains 2 mg lorazepam, 0.18 mL polyethylene glycol 400 in propylene glycol with 2% benzyl alcohol as preservative.
Usual Dosage: See insert. Do not use if solution is discolored or contains a precipitate.
Protect from light: Store in carton.
Manufactured by Hikma, Berkeley Heights, NJ 07922
402-373-02

NDC 0641-6049-01

Lorazepam 
Injection, USP

For IM use
Dilute for IV use
4 mg/mL

Protect from light
Refrigerate
1 mL Vial Rx ONLY
Mfd. by Hikma
novaplus+
Lot: [Redacted]
Exp: [Redacted]

Lot: [Redacted]
Exp: [Redacted] To open—Cut seal along dotted line.

NDC 0641-6049-25 Rx ONLY

Lorazepam 
Injection, USP

4 mg/mL

For intramuscular use
For intravenous use, dilution required; see insert.
Refrigerate
25 x 1 mL Vials **novaplus+** 462-375-02

Each mL contains 4 mg lorazepam, 0.18 mL polyethylene glycol 400 in propylene glycol with 2% benzyl alcohol as preservative.
Usual Dosage: See insert. Do not use if solution is discolored or contains a precipitate.
Protect from light: Store in carton.
Manufactured by Hikma, Berkeley Heights, NJ 07922
462-375-02

NDC 72572-380-01 Rx Only

LORazepam 
Injection, USP

2 mg/mL

For IM use
Dilute for IV use
Protect from light
Refrigerate
1 mL Vial
Mfd. for: Civia, Inc.
Lot: [Redacted]
Exp: [Redacted]

Lot: [Redacted]
Exp: [Redacted] To open—Cut seal along dotted line.

NDC 72572-380-25 Rx Only

LORazepam 
Injection, USP

2 mg/mL

For intramuscular use
For intravenous use, dilution required; see insert.
Refrigerate
25 x 1 mL Vials 462-876-00

Each mL contains 2 mg lorazepam, 0.18 mL polyethylene glycol 400 in propylene glycol with 2% benzyl alcohol as preservative.
Usual Dosage: See insert. Do not use if solution is discolored or contains a precipitate.
Protect from light: Store in carton.
Mfd. for: Civia, Inc., Labi, UT 84043
Mfd. by Hikma, Cherry Hill, NJ 08003



Return Response Form
Retail Level Market Withdrawal- Initiated 09/19/2025
LORAZEPAM INJECTION USP, 2MG/ML and 4MG/ML CIV
ATIVAN (LORAZEPAM INJ. USP) 2MG/ML and 4MG/ML CIV

Please complete and return this form immediately by FAX 1-817-868-5362 or email to HikmaEvent@inmar.com.

Please check ALL appropriate boxes:

- I have read and understand the instructions provided in the enclosed Lorazepam Injection, USP and Ativan (Lorazepam Inj. USP)- 2mg/mL and 4mg/mL, 1mL fill vials market withdrawal packet.
I have checked my stock of the product listed below and have quarantined inventory and will be returning the number of units shown below. Upon receipt of this Return Response Form, Inmar Rx Solutions, Inc., will issue return authorization shipping label(s) and a return kit. Please indicate the number of needed box labels.
I do not have any stock of the below market withdrawal products and will not be making a return.
I have informed all my customers of the Retail Level market withdrawal

Market Withdrawal Product: Lorazepam Injection, USP and Ativan (Lorazepam Inj. USP)-2mg/mL and 4mg/mL, 1mL fill vials

Table with 8 columns: NDC, Item Description, Lot, Exp. Date, First Ship Date, Last Ship Date, Total Full unit cartons (sealed), Total Partial Units (opened cartons). Rows list various NDCs and their corresponding lot and shipping dates.

Company Name: _____ DEA# _____

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

Address: _____ City: _____

State _____ Zip _____ Phone Number: _____

Fax Number: _____ Email Address: _____

Contact Name: (please print) _____

Contact Name Signature: _____ Date: _____

If you did not purchase the product directly from Hikma Pharmaceuticals, please complete the below section:

Purchased From: Wholesaler Name _____ DEA # _____

City _____ State _____ Zip _____

- If you have any questions regarding this form or product return, please contact Inmar Rx Solutions, Inc. at (866) 479-7682 during office hours from 9:00am to 5:00pm EST, Monday through Friday.
Please send this form to Inmar Rx Solutions, Inc. by FAX: 1-817-868-5362 or E-mail: HikmaEvent@inmar.com.
Please include a copy in the box with your returns to ensure proper credit.