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Hikma Injectables USA Inc.

URGENT DRUG RECALL – HOSPITAL/MEDICAL CENTER LEVEL - INITIATED 04/29/2024

EPHEDRINE SULFATE 50MG/5ML (10MG/ML) IN 0.9% SODIUM CHLORIDE INJECTION, PRESERVATIVE FREE 5ML SYRINGE (503B)

Dear Customer:

Hikma Injectables USA Inc. is voluntarily initiating a drug recall of one (1) lot ePHEDrine Sulfate 50mg/5mL (10 mg/mL) in 0.9% Sodium Chloride Injection at the **Hospital/Medical center level.** This recall is being conducted with the knowledge of the Food and Drug Administration.

Item Description	Potency	Unit of sale	NDC	Lot	Use By Date	Ship Dates
Ephedrine Sulfate in 0.9% Sodium Chloride Injection	10mg/mL	25 syringes/ shipper	63037-123-25	240310003D	06/04/2024	03/28/2024-04/08/2024
Phenylephrine in 0.9% Sodium Chloride Injection **(incorrect label)**	100mcg/mL	25 syringes/ shipper	63037-123-25	240310003D	06/04/2024	03/28/2024-04/08/2024

Reason for Recall:
This recall is being conducted due to a portion of the lot being labeled with the incorrect unit label. A portion of the lot has syringes that were labeled with the Ephedrine variable lot data printed on the **Phenylephrine** label instead of the correct Ephedrine label.

Important Basic Information:
This recall is limited to the lot number listed above. **No other Hikma 503B products or lots are impacted by this recall.** We have received no Adverse Events complaints for the subject lot to date. The services of **Inmar Rx Solutions, Inc.** have been enlisted to facilitate the product recall.

Labeling:
Please see attachment for Product Labels that will assist in identifying the recalled product.

Action Required:
☐ Stop using this lot immediately and segregate any product remaining in your inventory for return.

☐ Promptly complete a physical count and record this data on the enclosed Return Response Form included with this letter. Complete the Return Response Form 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 recall product return.

☐ Once you receive a shipping label and a return kit, immediately ship recalled product to **Inmar Rx Solutions, Inc.** Do not include any other products/lots in this return shipment. Return of the recalled product must be separate from all other returns and returned only to Inmar RX Solutions, **Attention Recall Coordinator, 3845 Grand Lakes Way, Grand Prairie, TX 75050**. All recalled 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.

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, Suite 500, Winston Salem, NC 27101
By email address: HikmaEvent@Inmar.com or by FAX: 1-817-868-5362

For information regarding this recall, please reference the following contact information:

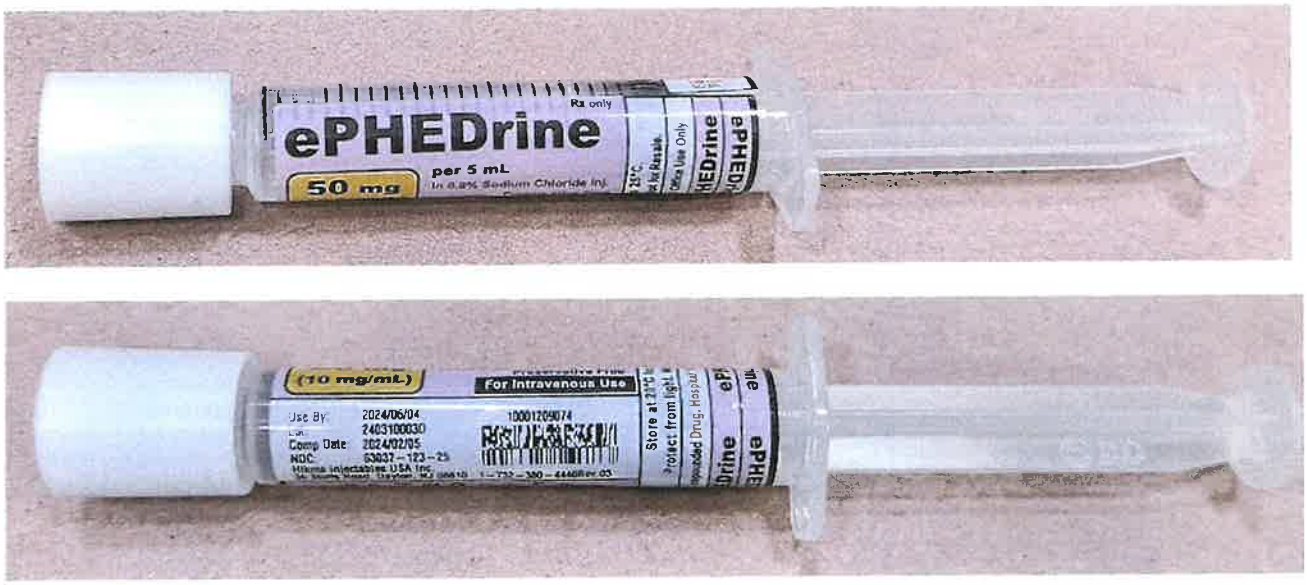
- For information regarding the recall process, call Hikma at 1-800-631-2174 between 8:00am – 6:00pm EST, Monday through Friday, or email at usrecall@hikma.com.
- For medical or technical product information or to report an Adverse Event call Hikma at 1-877-233-2001 between 9:00am – 7:00pm EST, Monday through Friday or email us.hikma@primevigilance.com.
- For additional information regarding the return of the product, call Inmar Rx Solutions, Inc. at 877-861-8968
- Further note that within the upcoming weeks you will receive an Effectiveness Check follow-up notification to verify the efficacy of this recall. The purpose of the audit is to determine that all customers have received the initial notification of the recall and the appropriate actions have been taken to remove the affected product from the market.

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.

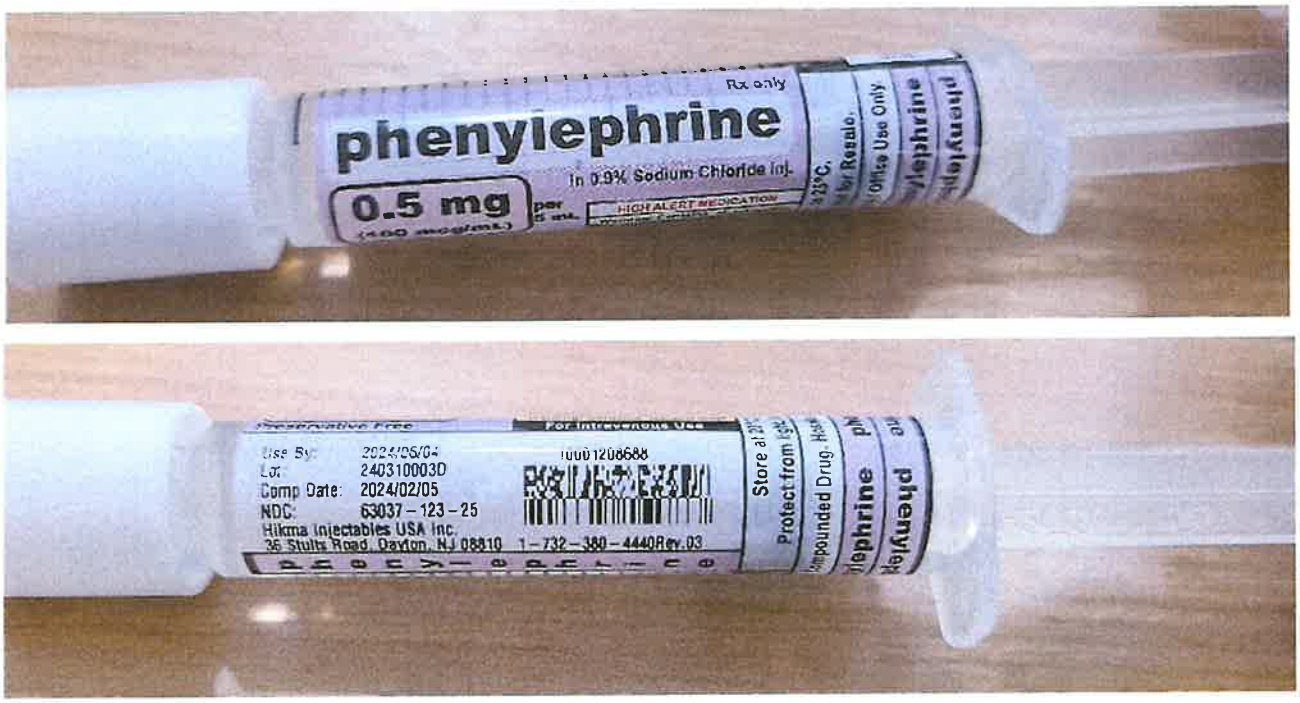
Sincerely,

Junan Guo, Associate VP,
Quality Operations, for R&D, 3rd Party and 503B

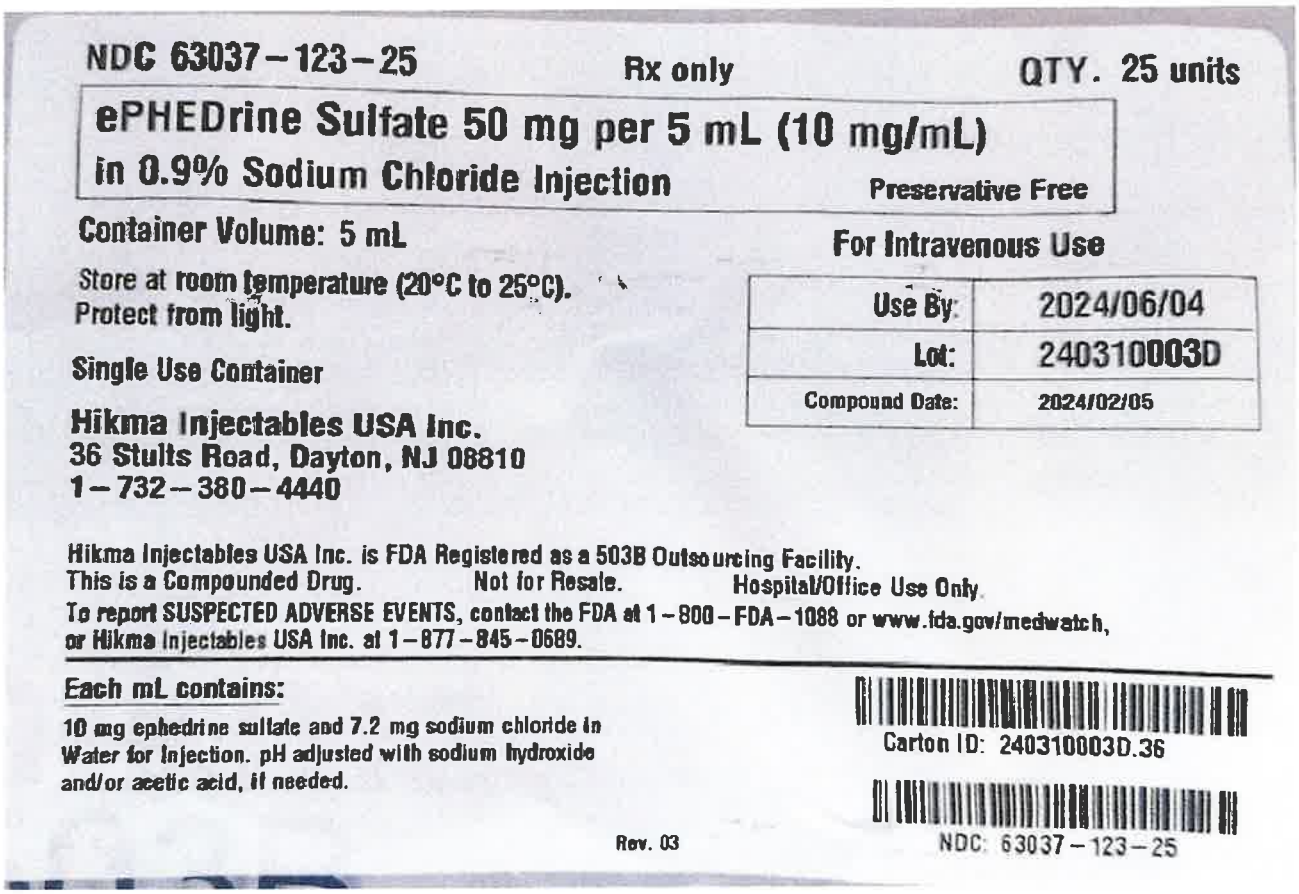
Correct Ephedrine unit label for lot 240310003D:



Incorrect Ephedrine unit label for lot 240310003D:



Correct Shipper label for Ephedrine lot 240310003D:



NDC 63037–123–25 Rx only QTY. 25 units

ePHEDrine Sulfate 50 mg per 5 mL (10 mg/mL)
in 0.9% Sodium Chloride Injection Preservative Free

Container Volume: 5 mL

For Intravenous Use

Store at room temperature (20°C to 25°C).
Protect from light.

Use By:	2024/06/04
Lot:	240310003D
Compound Date:	2024/02/05

Single Use Container

Hikma Injectables USA Inc.
36 Stults Road, Dayton, NJ 08810
1–732–380–4440

Hikma Injectables USA Inc. is FDA Registered as a 503B Outsourcing Facility.
This is a Compounded Drug. Not for Resale. Hospital/Office Use Only.
To report SUSPECTED ADVERSE EVENTS, contact the FDA at 1–800–FDA–1088 or www.fda.gov/medwatch,
or Hikma Injectables USA Inc. at 1–877–845–0689.

Each mL contains:

10 mg ephedrine sulfate and 7.2 mg sodium chloride in Water for Injection. pH adjusted with sodium hydroxide and/or acetic acid, if needed.

Carton ID: 240310003D.36

Rev. 03

NDC: 63037–123–25

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Hikma Injectables USA Inc.

Recall Return Response Form - Hospital/Medical Center Level – 04/29/2024

EPHEDRINE SULFATE 50MG/5ML (10MG/ML) IN 0.9% SODIUM CHLORIDE INJECTION PRESERVATIVE FREE 5ML SYRINGE (503B)

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 **ePHEDrine 50mg/5mL (10 mg/mL) in 0.9% Sodium Chloride Injection** at the **Hospital/Medical center level** recall packet.

☐ I **have** checked my stock of the recalled 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 recalled product and will not be making a return.

Recalled Products:
ePHEDrine Sulfate 50mg/5mL (10 mg/mL) in 0.9% Sodium Chloride Injection, 5mL syringe and Phenylephrine 0.5mg/5mL (100mcg/mL) in 0.9% Sodium Chloride Injection **(incorrect label)**

Lot No.	Product Name	Use By Date	Product Packaging	NDC No.	Ship Dates	Total Full unit cartons (sealed)	Total Partial Units (opened cartons)
240310003D	ePHEDrine Sulfate	06/04/2024	50mg/5mL (10mg/mL), 5mL syringe (25 syringes /Shipper)	63037-123-25	03/28/2024-04/08/2024		
240310003D	Phenylephrine	06/04/2024	0.5mg/5mL (100mcg/mL) 5mL syringe (25 syringes /Shipper)	63037-123-25	03/28/2024-04/08/2024		

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 have any questions regarding this form or product return please contact **Inmar Rx Solutions, Inc.** at 877-861-8968 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.