

**URGENT MARKET RECALL - RETAIL LEVEL - INITIATED 08/05/2021****BLEOMYCIN FOR INJECTION, USP., 15 units/vial**

Dear Customer:

Hikma Pharmaceuticals USA Inc. (formerly West-Ward Pharmaceuticals) is voluntarily initiating a drug recall of one lot of **Bleomycin Injection, USP, 15 units/mL vial** at the **retail level**. This recall is being conducted with the knowledge of the Food and Drug Administration.

| Item Description                        | NDC          | Lot    | Expiration Date |
|---|--------------|--------|-----------------|
| Bleomycin 15 Units/vial (1 vial/carton) | 0143-9240-01 | BL0018 | 10/2022         |

**Reason for Recall:**

This recall is being conducted due to print discrepancy on the unit carton (secondary label). The unit vial label has the correct product NDC and strength information.

**Important Basic Information:**

This recall is limited to one lot number listed above. **No other Hikma products or lots are impacted by this recall.** 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 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 required **even if there is no affected product/lot in your inventory**.

**If you have Recalled 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 recalled 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, Inc. Attn: Recall Coordinator 635 Vine St. Winston-Salem, NC 27101**. 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. If you are NOT a Direct Customer of Hikma a credit should be requested from your WHOLESALER.

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

By mail: Inmar Rx Solutions, Inc. Attn: Recall Coordinator 635 Vine St. Winston-Salem, NC 27101

By email address: [HikmaEvent@inmar.com](mailto:HikmaEvent@inmar.com).

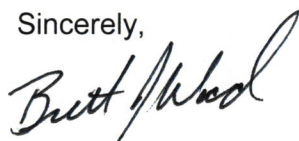
By FAX: 1-817-868-5362

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 – 7:00pm EST, Monday through Friday, or email at [usrecall@hikma.com](mailto: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](mailto:us.hikma@primevigilance.com).
- For additional information regarding the return of the product, call Inmar Rx Solutions, Inc. at 855-768-0769.
- Further note that within the upcoming weeks you will receive an Effectiveness Check form that will be used 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. It is important that you complete this form and return in a timely manner.

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,



Brett Wood  
Senior Director of Quality and Technical Operations

Unit carton print Label:







Hikma Pharmaceuticals USA Inc.

**Recall Return Response Form**  
**Retail Level – 8/5/2021****Bleomycin for Injection, USP., 15 Units/vial**

**Please complete and return this form immediately by FAX 1-817-868-5362 or email to [HikmaEvent@inmar.com](mailto:HikmaEvent@inmar.com).**

**Please check ALL appropriate boxes:**

- ☐ I have read and understand the instructions provided in the enclosed **Bleomycin for Injection, USP, 15 Units/ vial** 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.
- ☐ I **have** informed all my customers of the Retail Level Recall

**Recalled Product: Bleomycin for Injection USP., 15 units/ vial**

| Lot No. | Exp. Date | Product Packaging | NDC No.      | Ship Dates             | Total Full unit cartons (sealed) | Total Partial Units (opened) |
|---------|-----------|-------------------|--------------|------------------------|----------------------------------|------------------------------|
| BL0018  | 10/2022   | 15units/ vial     | 0143-9240-01 | 07/14/2021- 07/26/2021 |                                  |                              |

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 (formerly known as West-Ward) 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 1- 855-768-0769 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](mailto:HikmaEvent@inmar.com).
- Please include a copy in the box with your returns to ensure proper credit.