

URGENT RECALL NOTICE

25 April 2019

Dear Valued Customer

The purpose of this letter is to advise you that B. Braun Medical Inc. (BBMI) is voluntarily recalling one (1) batch of product due to a failure in ongoing stability data.

Affected Product and Distribution Information:

This voluntary product recall is being initiated for the following product catalog number and affected batch number:

Product Catalog Number	Product Description	Batch Number	Distribution Date Range	Expiration Date
3145-11 (NDC: 00264-3145-11)	2g Ceftazidime for Injection USP (2g) and Dextrose for Injection USP (50 ml), Duplex Container	H8A832	28 Feb 2018 – 05 Mar 2018	31 Jan 2020

Reason for Recall:

During stability testing of Batch H8A832, one (1) test result was found to exceed the specification limits for High Molecular Weight Polymers (HMWP) at the 52 week stability interval. Additional test results for the batch also indicated levels that were out-of-trend when compared with prior stability data.

Risk to Health:

Elevated levels of High Molecular Weight Polymers have been shown to cause acute nephrotoxicity in rabbits and mice and phagocytic deposits of the foreign material in the Kupffer liver cells of dogs after repeated elevated doses. While the impact of HMWPs in humans is unknown, BBMI is initiating this voluntary recall out of an abundance of caution to prevent any risks of adverse reactions due to the elevated HMWP levels. To date there have been no complaints or reports of adverse reactions associated with the product.

Actions to be taken by the Customer/User:

1. Review the Product Recall Notification in its entirety and ensure that all users in your organization and other concerned persons are informed about this voluntary recall and the affected product(s).
2. If you are a distributor, please forward this recall notification to your customers. Under the FDA recall enforcement policy, you are legally obligated to notify your customers of drug recalls such as this one. It is highly recommended that you determine your customers' inventory levels and request the return of these lots to you. Please combine your customers' inventory with your own inventory and return all affected product to B. Braun Medical Inc. at one time.
3. Determine your current inventory of the affected lot(s) within your facility. Do not destroy any affected product.
4. Utilizing the attached "Product Recall Acknowledgement" form, record the total number of individual units (within partial cases) and the number of full unopened cases. If you have no inventory remaining, please enter zero (0) on the form.
5. Return the completed "Product Recall Acknowledgement" form to B. Braun Medical Inc. Quality Assurance department by utilizing the enclosed self-addressed envelope or via fax to (610) 849-5430 within two (2)

weeks of receipt, even if the total inventory in your possession is zero (0). It is important this form is returned so B. Braun Medical Inc. can meet regulatory requirements of the United States Food and Drug Administration.

6. If you have any full cases, partial cases or unused individual units of the affected product, please call B. Braun Medical Inc. Customer Support Department at 1-800-227-2862 to arrange for return and replacement product. A Customer Support Representative will provide you with instructions for handling affected product. We will arrange for all affected product to be returned to B. Braun Medical Inc. for proper disposition.

Should you experience any adverse reactions or quality problems with the product, please report the event promptly to BBMI by contacting our Medical Affairs Department at 1-800-854-6851. Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Additionally, adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This product recall is being performed with the knowledge of the United States Food and Drug Administration.

We apologize for the inconvenience that this issue may have caused you and your facility, but we appreciate your understanding of our commitment to assuring our products are safe and effective for both health care professionals and patients.

Sincerely,



Kahina Hadjaz

Director, Quality (Irvine, CA)

Enclosures