COMPANY ANNOUNCEMENT

B. Braun Medical Inc. Issues Voluntary Nationwide Recall of One (1) Lot of Ceftazidime for Injection USP and Dextrose Injection USP (50 mL), Duplex Container Due to Out-of-Specification Results for High Molecular Weight Polymers

Summary

Company Announcement Date:

April 17, 2020

FDA Publish Date:

April 20, 2020

Product Type:

Drugs

Reason for Announcement:

Out-of-Specification Results for High Molecular Weight Polymers

Company Name:

Braun Medical Inc

Brand Name:

B. Braun

Product Description:

Ceftazidime for Injection USP (2g) and Dextrose for Injection USP (50 ml) in Duplex® Container

Company Announcement

Braun Medical Inc. (B. Braun) is voluntarily recalling one (1) lot of 2g Ceftazidime for Injection USP (2g) and Dextrose for Injection USP (50 ml) in Duplex® Container to the hospital/user level.. During stability testing of Batch H8J812, test results were found to exceed the

specification limits for High Molecular Weight Polymers (HMWP) at the nineteen (19) month [82 week] stability interval.

Elevated levels of High Molecular Weight Polymers have been shown to cause kidney damage and liver issues in animal studies. While the impact of HMWP in humans is unknown, B. Braun 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 this product lot.

Ceftazidime for Injection USP and Dextrose Injection USP is a cephalosporin antibacterial indicated in the treatment of the following infections caused by susceptible isolates of the designated microorganisms: Lower respiratory tract infections; skin and skin-structure infections; bacterial septicemia; bone and joint infections; gynecologic infections; intra-abdominal infections; and central nervous system infections.

Ceftazidime for Injection USP and Dextrose Injection USP in the DUPLEX® Container is a flexible dual chamber container containing approximately 50 mL of 5% Dextrose Injection in the diluent chamber and ceftazidime in the drug powder chamber. After reconstitution, the concentration is equivalent to 2 g ceftazidime. Ceftazidime for Injection USP and Dextrose Injection USP is packaged in 24 DUPLEX® Containers per case. The affected recalled product includes the following lot number and expiration date:

NDC	ref	Dose/Volume	Impacted Batch	Expiration Date
0264-3145-11	3145-11	2 g per 50 mL	H8J812	31 Jul 2020

Product was distributed Nationwide within the United States to domestic distributors. Pictures of the product and product labeling follow this press release.

B. Braun is notifying its distributors and customers by an official recall notice sent via certified registered mail and is arranging for return of all recalled products. Facilities and distributors that have product which is being recalled should **discontinue use immediately** and contact the B. Braun Medical Inc. Customer Support Department at 800-227-2862 Monday through Friday, 8 a.m. – 6 p.m. EST to arrange for product return.

Facilities with questions regarding this recall can contact B. Braun by phone at 800-227-2862 Monday through Friday, 8 a.m. – 6 p.m. EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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 (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) 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 recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

About B. Braun

B. Braun Medical Inc., a leader in infusion therapy and pain management, develops, manufactures, and markets innovative medical products and services to the healthcare industry. Other key product areas include nutrition, pharmacy admixture and dialysis. The company is committed to eliminating preventable treatment errors and enhancing patient, clinician and environmental safety. B. Braun Medical is headquartered in Bethlehem, PA and is part of the B. Braun Group of Companies in the U.S., which includes B. Braun Interventional Systems, Aesculap® and CAPS®.

Globally, the B. Braun Group of Companies employs more than 64,000 employees in 64 countries. Guided by its Sharing Expertise® philosophy, B. Braun continuously exchanges knowledge with customers, partners and clinicians to address the critical issues of improving care and lowering costs. To learn more about B. Braun Medical, explore our website.

Company Contact Information

Consumers:

B. Braun Medical Inc. Customer Support Department

800-227-2862

Media:

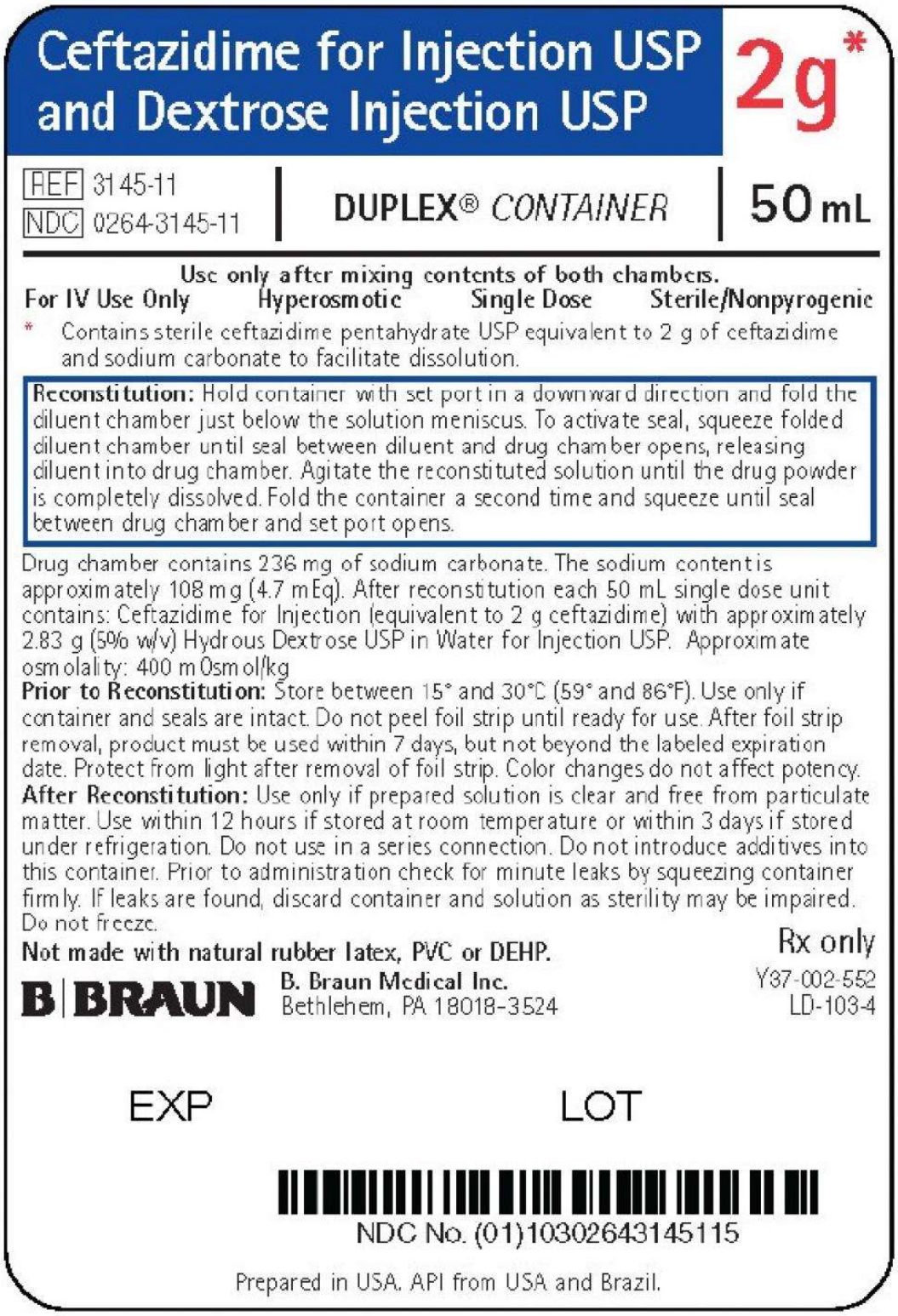
Allison Longenhagen

484-523-9801

allison.longenhagen@bbraunusa.com (mailto:allison.longenhagen@bbraunusa.com)

Product Photos


Ceftazidime for Injection USP
and Dextrose Injection USP
2g*
DUPLEX®
DRUG DELIVERY SYSTEM
50 mL
B|BRAUN
Made in USA



Ceftazidime for Injection USP and Dextrose Injection USP

2g*

REF 3145-11
NDC 0264-3145-11

DUPLEX® *CONTAINER*

50 mL

Use only after mixing contents of both chambers.

For IV Use Only **Hyperosmotic** **Single Dose** **Sterile/Nonpyrogenic**

* Contains sterile ceftazidime pentahydrate USP equivalent to 2 g of ceftazidime and sodium carbonate to facilitate dissolution.

Reconstitution: Hold container with set port in a downward direction and fold the diluent chamber just below the solution meniscus. To activate seal, squeeze folded diluent chamber until seal between diluent and drug chamber opens, releasing diluent into drug chamber. Agitate the reconstituted solution until the drug powder is completely dissolved. Fold the container a second time and squeeze until seal between drug chamber and set port opens.

Drug chamber contains 236 mg of sodium carbonate. The sodium content is approximately 108 mg (4.7 mEq). After reconstitution each 50 mL single dose unit contains: Ceftazidime for Injection (equivalent to 2 g ceftazidime) with approximately 2.83 g (5% w/v) Hydrous Dextrose USP in Water for Injection USP. Approximate osmolality: 400 mOsmol/kg

Prior to Reconstitution: Store between 15° and 30°C (59° and 86°F). Use only if container and seals are intact. Do not peel foil strip until ready for use. After foil strip removal, product must be used within 7 days, but not beyond the labeled expiration date. Protect from light after removal of foil strip. Color changes do not affect potency.

After Reconstitution: Use only if prepared solution is clear and free from particulate matter. Use within 12 hours if stored at room temperature or within 3 days if stored under refrigeration. Do not use in a series connection. Do not introduce additives into this container. Prior to administration check for minute leaks by squeezing container firmly. If leaks are found, discard container and solution as sterility may be impaired. Do not freeze.

Not made with natural rubber latex, PVC or DEHP.

Rx only

B BRAUN

B. Braun Medical Inc.
Bethlehem, PA 18018-3524

Y37-002-552
LD-103-4

EXP LOT

NDC No. (01)10302643145115

Prepared in USA. API from USA and Brazil.

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