



URGENT DRUG RECALL

<i>Product</i>	<i>NDC Number</i>	<i>Lot</i>
Tazicef® (Ceftazidime for Injection, USP) equivalent to 1 gram ceftazidime ADD-Vantage™ Vial	0409-5092-16	020098M; 020108M; 030368M; 860158M; 860168M; 860178M; 890288M; 890298M; 920098M; 940068M; 960018M
Tazicef® (Ceftazidime for Injection, USP) equivalent to 1 gram ceftazidime ADD-Vantage™ Vial (NOVAPLUS®)	0409-5092-52	020098M; 030368M; 860148M; 860158M; 890298M; 920088M; 920098M; 940068M; 960018M
Tazicef® (Ceftazidime for Injection, USP) equivalent to 2 grams ceftazidime ADD-Vantage™ Vial	0409-5093-11	020118M; 020128M; 030378M; 820298M; 820308M; 860188M; 860198M; 860208M; 860218M; 890268M; 890278M; 920118M; 920128M; 940078M; 960028M; 960038M
Tazicef® (Ceftazidime for Injection, USP) equivalent to 2 grams ceftazidime ADD-Vantage™ Vial (NOVAPLUS®)	0409-5093-51	860188M; 890278M; 920108M; 920118M; 960038M; 020118M

September 30, 2011

Dear Valued Customer:

Hospira, Inc. is voluntarily recalling the lots of Tazicef (Ceftazidime for Injection, USP) identified above due to out-of-specification results first discovered during routine stability testing. Further testing of retain samples of on market lots resulted in certain lots being out-of-specification for one or more of the following attributes: sub-visible particulate, related substances, pyridine content and Ceftazidime assay.

These lots were distributed March 2010 through August 2011. Hospira has not received any reports of adverse events associated with this issue. This recall is being conducted as a precautionary measure. Hospira has notified the U.S. Food and Drug Administration.

These lots were manufactured by Sandoz GmbH for Hospira. Sandoz has initiated an investigation to determine the root cause and corrective and preventive actions.

Please check your inventory and immediately quarantine any affected product. Complete the attached Reply Form and return it to the fax number or e-mail address on the form, even if you do not have the affected product. Inform healthcare professionals in your organization of this recall.

This recall is being conducted to the medical facility level. Therefore, **if you have distributed the product further, notify your accounts that received the product identified above** of this recall and ask them to fax the reply form to the number on the form and follow the instructions provided on the form for returning product.

2493_01_01AS
Hospira, Inc.
275 North Field Drive
Lake Forest, IL 60045
(224) 212-2000
www.hospira.com



Return affected product to Stericycle using the label provided with this letter. Call Stericycle at 1-888-843-0253 if you need a reply form, have not received return labels or require additional labels for returning the affected product. To ensure proper and timely credit, follow the instructions on the reply form for returning the product, include your Hospira customer number (if applicable) and information about your wholesaler/distributor from whom you purchased the affected product (if applicable), and include a copy of your PO, Debit Memo or Invoice showing the purchase price on the outside of the package being shipped (e.g. case, pallet).

Replacement product is available in alternate packaging configurations. Please contact Hospira Customer Care at 1-877-946-7747 or your Hospira representatives to order replacement product in fliptop vials.

For clinical inquiries, please contact Hospira using the information provided below.

Hospira Contact	Contact Information	Areas of Support
Hospira Global Product Safety and Complaints	1-800-441-4100 (8am-5pm CST, M-F) (ProductComplaintsPP@hospira.com)	To report adverse events or product complaints
Hospira Medical Communications	1-800-615-0187 (Available 24 hours a day/7 days per week)	Medical inquiries

Any adverse events experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by:

- Linking to the MedWatch website at www.fda.gov/medwatch
- Calling 1-800-FDA-1088
- Faxing at 1-800-FDA-0178
- Mailing to MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD, 20852-9787

Hospira is committed to providing our customers with the highest level of service and product quality. We appreciate your cooperation, and we regret any inconvenience this action may cause.

Sincerely,

Grace Breen
Vice President, Commercial Quality

2493_01_02AS

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**Urgent Drug Recall Reply Form – Response Required
Tazicef (Ceftazidime for Injection, USP – ADD-Vantage® Vial)**



Check your inventory and complete the information below, even if you do not have the affected product.
Failure to complete all sections of this page may result in improper, delayed or denied credit.

Fax the completed form to **1-866-608-3939** or e-mail the completed form to **hospira2493@stericycle.com**.
To obtain return labels or if you have questions about this form call Stericycle at **1-888-843-0253**.

Required Information	
Business Name	Phone Number
Address/City/State/Zip	DEA #
Hospira Customer Number (ship to #) if applicable	Your reference # (e.g. PO, Debit Memo or Invoice #)
Completed by: Printed Name/Signature/Date	

I have **NO** affected product (fill out and return this page to Stericycle at the fax/e-mail above.)

I have affected product (fill out and return all pages of the form to Stericycle via the fax/e-mail above and return the product per instructions below.)

If you did not purchase the product directly from Hospira, complete the information below to receive credit:

Lot Number	Wholesaler/Distributor Name <small>If you purchased from Wholesalers/Distributors include name, address, city, state, zip, quantity from each, name, and invoice number. If you purchased directly from Hospira leave this section blank.</small>	QTY	PO, Debit memo or Invoice)
	1.		
	2.		
	1.		
	2.		
	1.		
	2.		

If affected product is not being returned, please explain:

✓ Have you distributed the product further to the retail level? YES___ NO___

✓ If yes, have you notified your retail customers? YES___ NO___ (if no, explain)

2493_01_03AS

CID/SEQ

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Urgent Drug Recall Reply Form – Response Required
Tazicef (Ceftazidime for Injection, USP – ADD-Vantage® Vial)



Business Name _____ Hospira Customer No. _____

Lot	Expiration Date	Qty of vials to be returned	Lot	Expiration Date	Qty of vials to be returned
NDC 0409-5092-16 Tazicef® (Ceftazidime for Injection, USP) equivalent to 1 gram ceftazidime					
020098M	2/1/2013		890288M	5/1/2012	
020108M	2/1/2013		890298M	5/1/2012	
030368M	3/1/2013		920098M	8/1/2012	
860158M	2/1/2012		940068M	10/1/2012	
860168M	2/1/2012		960018M	12/1/2012	
860178M	2/1/2012				
NDC 0409-5092-52 Tazicef® (Ceftazidime for Injection, USP) equivalent to 1 gram ceftazidime (NOVAPLUS®)					
020098M	2/1/2013		920088M	5/1/2012	
030368M	3/1/2013		920098M	5/1/2012	
860148M	2/1/2012		940068M	10/1/2012	
860158M	2/1/2012		960018M	12/1/2012	
890298M	5/1/2012				
NDC 0409-5093-11 Tazicef® (Ceftazidime for Injection, USP) equivalent to 2 grams ceftazidime					
020118M	2/1/2013		860218M	2/1/2012	
020128M	2/1/2013		890268M	5/1/2012	
030378M	3/1/2013		890278M	5/1/2012	
820298M	10/1/2011		920118M	8/1/2012	
820308M	10/1/2011		920128M	8/1/2012	
860188M	2/1/2012		940078M	10/1/2012	
860198M	2/1/2012		960028M	12/1/2012	
860208M	2/1/2012		960038M	12/1/2012	
NDC 0409-5093-51 Tazicef® (Ceftazidime for Injection, USP) equivalent to 2 grams ceftazidime (NOVAPLUS®)					
020118M	2/1/2013		920108M	8/1/2012	
860188M	2/1/2012		920118M	8/1/2012	
890278M	5/1/2012		960038M	12/1/2012	

Return Instructions:

Direct Customer (purchased directly from Hospira) <i>Credit will be issued by Hospira</i>	Indirect Customer (purchased from a wholesaler/distributor) <i>Credit will be issued through the wholesaler/distributor</i>
<ul style="list-style-type: none"> • Include a PO, Debit Memo or Invoice showing the purchase price on the outside of the package being shipped (e.g. case, pallet). • Ship only the <i>affected product</i> to Stericycle using the prepaid return label. 	<ul style="list-style-type: none"> • Supply information for each wholesaler/distributor. • Include a PO, Debit Memo or Invoice showing the purchase price on the outside of the package being shipped (e.g. case, pallet). • Ship only the <i>affected product</i> to Stericycle using the prepaid return label.

2493_01_04AS

CID/SEQ

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