

URGENT DRUG RECALL



<i>Product</i>	<i>NDC Number</i>	<i>Lot</i>
Ondansetron Inj., USP 4 mg/2 mL (2 mg/mL) 2 mL iSecure™ Syringe	0409-1120-62	01695LL; 03820LL; 79610LL; 82610LL; 84515LL; 86665LL; 88585LL; 94795LL; 95640LL
Diazepam Inj., USP 10 mg/2 mL (C-IV) (5 mg/mL) 2 mL iSecure™ Syringe	0409-1273-05	90575LL
Heparin Sodium Inj., USP 5,000 USP Units/0.5 mL 0.5 mL iSecure™ Syringe	0409-1316-25	01595LL; 04750LL; 88650LL; 89695LL; 90580LL; 91540LL; 92540LL; 93575LL; 94775LL; 96545LL
Ketorolac Tromethamine Inj., USP 30 mg (30 mg/mL) 1 mL iSecure™ Syringe	0409-2287-21	90720LL; 94655LL
Ketorolac Tromethamine Inj., USP 60 mg (30 mg/mL) 2 mL iSecure™ Syringe	0409-2287-22	88690LL
Midazolam Inj., USP 2 mg/2 mL (C-IV) (1 mg/mL) 2 mL iSecure™ Syringe	0409-2306-22	85610LL
Midazolam Inj., USP 5 mg/mL (C-IV) 1 mL iSecure™ Syringe	0409-2307-21	80680LL; 90735LL

July 8, 2011

Dear Valued Customer:

Hospira, Inc. is voluntarily recalling the iSecure Syringe products identified above to address complaints about cracks in some lots of the syringes. These cracks, which have only been found in the original iSecure syringes with the white plunger rod, have resulted in low filled, unfilled or leaking products and present the potential for contamination of the solution. iSecure products with the purple plunger rod are not affected.

These lots were distributed September 2009 through June 2011.

Hospira has initiated an investigation to determine the cause and preventive actions. We have not received any adverse events associated with this issue at this time. This recall is being conducted as a precautionary measure. Hospira has notified the U.S. Food and Drug Administration.

Please check your inventory and immediately quarantine any affected product. Complete the attached Reply Form and return it to the number 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. Alternately, you may call Stericycle at 1-800-871-6145 and supply them a consignee list to have them contact your accounts directly.

2455_01_01AD
Hospira, Inc.
275 North Field Drive
Lake Forest, IL 60045
(224) 212-2000
www.hospira.com

FA106-02 (3)



Return affected product to Stericycle using the label provided with this letter. Call Stericycle at 1-800-871-6145 if you have not received a return label 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.

For medical inquiries, please call Hospira Medical Communications at 1-800-615-0187.

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,

A handwritten signature in black ink, appearing to read "Janet Stevens", with a large, stylized flourish at the end.

Janet Stevens
Vice President, Parenteral Quality Operations

Urgent Drug Recall Reply Form – Response Required
iSecure™ Syringes



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.

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 below.)

I have affected product (fill out and return both pages of the form to Stericycle via the fax/email below 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)

Fax the completed form to 1-866-551-2713 or e-mail the completed form to hospira2455@stericycle.com.
To obtain return labels or if you have questions about this form call Stericycle at 1-800-871-6145.

2455_01_02AS
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 275 North Field Drive
 Lake Forest, IL 60045
 (224) 212-2000
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«Consignee_Id»/«Sequence_Number»

Urgent Drug Recall Reply Form – Response Required
iSecure™ Syringes



Business Name _____

NDC Number	Lot	Expiration Date	Quantity of Syringes to be Returned
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Ondansetron Inj., USP			
0409-1120-62	01695LL	1JAN2013	
	03820LL	1MAR2013	
	79610LL	1JUL2011	
	82610LL	1OCT2011	
	84515LL	1DEC2011	
	86665LL	1FEB2012	
	88585LL	1APR2012	
	94795LL	1OCT2012	
	95640LL	1NOV2012	

Diazepam Inj., USP			
0409-1273-05	90575LL	1DEC2011	

Heparin Sodium Inj., USP			
0409-1316-25	01595LL	1JUL2012	
	04750LL	1OCT2012	
	88650LL	1OCT2011	
	89695LL	1NOV2011	
	90580LL	1DEC2011	
	91540LL	1JAN2012	
	92540LL	1FEB2012	
	93575LL	1MAR2012	
	94775LL	1APR2012	
	96545LL	1JUN2012	

Ketorolac Tromethamine Inj., USP			
0409-2287-21	90720LL	1DEC2011	
	94655LL	1APR2012	
0409-2287-22	88690LL	1OCT2011	

Midazolam Inj., USP			
0409-2306-22	85610LL	1JAN2012	
0409-2307-21	80680LL	1AUG2011	
	90735LL	1JUN2012	

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