

Urgent Drug Recall



<i>Product</i>	<i>NDC Number</i>	<i>Lot / Expiration</i>
Lorazepam Inj., USP (C-IV) 2 mg/mL iSecure™ Syringe	NDC 0409-1985-05	79-690-LL / 1JUL2011 83-606-LL / 1NOV2011 91-660-LL / 1JUL2012

March 9, 2011

Dear Valued Customer:

Hospira is voluntarily recalling three lots of Lorazepam Injection, USP in the iSecure Syringe identified above. Hospira has initiated this voluntary recall because there is a discrepancy in the storage statement on the Hospira shipping container (corrugate). The side of the corrugate is preprinted in black letters with "STORE AT CONTROLLED ROOM TEMPERATURE. AVOID EXCESSIVE HEAT. PROTECT FROM FREEZING." The end of the corrugate bears a white label just under the product identification label which says in red letters "STORE UNDER REFRIGERATION". The refrigerated storage label is the correct label – **the product must be stored under refrigeration**. If stored improperly, the product does not meet approved specifications and may not be efficacious.

These lots were distributed in between August 2009 and December 2010.

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. Please 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.

Return affected product to Stericycle using the labels provided with this letter. Call Stericycle at 1-855-201-4334 if you 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 and include your Hospira customer number (if applicable) and information about your wholesaler/distributor from whom you purchased the affected product (if applicable).

Hospira has not received any reports of adverse events related to this issue. This recall is being conducted as a precautionary measure. Hospira has notified the U.S. Food and Drug Administration.

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 long horizontal flourish extending to the right.

Janet Stevens
Vice President, Parenteral Quality Operations

Hospira, Inc.
275 North Field Drive
Lake Forest, IL 60045
(224) 212-2000
www.hospira.com
2363_01_01AS

FA101-01(7)

**Urgent Drug Recall Reply Form – Response Required
 Lorazepam Inj., USP (C-IV) 2 mg/mL iSecure™ Syringe
 NDC 0409-1985-05**



Check your inventory and complete the information below, even if you do not have the affected product.

To ensure proper and timely credit be sure to include your Hospira customer number (if applicable) and provide information about your wholesaler/distributor from whom you purchased the affected product. *Failure to complete all sections of this page may result in improper, delayed or denied credit.*

Fax the completed form to Stericycle at 1-855-201-4336.

To obtain a return kit or if you have questions about this form call Stericycle at 1-855-201-4334.

I have **NO** affected product (fill out and return the form to Stericycle at the fax number above)

I have affected product (fill out and return the form to Stericycle via fax and contact them if you need return labels using the appropriate numbers above)

If yes, indicate quantity of stock on hand to be returned:

<i>Lot</i>	<i>Lot / Quantity</i>		
79-690-LL	_____syringes	_____cartons	_____cases
83-606-LL	_____syringes	_____cartons	_____cases
91-660-LL	_____syringes	_____cartons	_____cases

If affected product is not being returned, please explain

✓ Did you receive this affected product from a wholesaler or distributor? YES ___ NO ___

✓ If yes, **you must** provide your wholesaler or distributor name and address below in order to receive credit.

 Wholesaler or Distributor Name

 Address/City/State/Zip (required for indirect customers)

✓ 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)

Required Information:

_____ Business Name	_____ Phone Number
_____ Address/City/State/Zip	
_____ Hospira Customer Number (ship to #) if applicable	_____ DEA Number
_____ Completed by: Printed Name/Signature/Date	

- Once the return labels are received, package only the *affected product*, this completed reply form, and PO, Debit Memo or Invoice showing the purchase price and then return the product to Stericycle.
- **Direct Hospira customers** who purchased the product directly from Hospira must supply their Hospira customer number and reference # (e.g. PO, Debit Memo or Invoice #). Credit will be issued by Hospira.
- **Indirect customers** who purchased the product from a wholesaler or distributor must supply their wholesaler/distributor information and reference # (e.g. PO, Debit Memo or Invoice #). Credit will be issued through the wholesaler/distributor.

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