



## MARKET WITHDRAWAL

Product	NDC Number	Lots*	Expiration Date
Amidate™ (Etomidate Injection, USP) 40 mg/20 mL (2 mg/mL), 20 mL Single-dose, Lifeshield™ Abboject Glass Syringe	0409-8060-29	42-257-DK	1JUN2016
		49-426-DK	1JAN2017
		51-394-DK	1MAR2017
		53-228-DK	1MAY2017

\*Note: The lot number may be followed by numbers from 01 to 99.

March 22, 2016

Dear Valued Customer:

Hospira, Inc., a Pfizer company, is proactively withdrawing from the market the lots of Amidate™ Etomidate Injection, USP identified above, due to the potential for the product to not meet specification (OOS) prior to expiry. Hospira has chosen to withdraw the product from market out of an abundance of caution.

The impacted lots were distributed January 2015 through February 2016. To date, Hospira has not received reports of any adverse events associated with this issue for these lots. Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

**Please check your inventory and immediately stop use and 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 market withdrawal.

Return affected product to Stericycle using the label provided with this letter. **All returns are requested to be completed within six months of this notice date.** To ensure proper and timely credit, follow the instructions on the return label for returning the product. *The return label provided in this notification is for single use only, please DO NOT reproduce.* Please visit <http://expertezlabel.com> to request additional labels for returning affected product. If you have not received a return label or require additional assistance, contact Stericycle at 1-888-965-6072 (M-F, 8am to 5pm ET).

This market withdrawal is being carried out to the hospital/retail level. Please instruct entities that may have received the market withdrawal product from you that if they have redistributed the product, they should notify their accounts, locations or facilities of the market withdrawal to the hospital/retail level. If additional copies of the letter and/or reply form are needed, please contact Stericycle at 1-888-965-6072 (M-F, 8am to 5pm ET).

Please contact Hospira Customer Care at 1-877-946-7747 (M-F, 7am to 6pm CT) or your Hospira representative regarding product availability and for questions regarding this field action.

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Hospira, Inc., a Pfizer company  
275 North Field Drive  
Lake Forest, IL 60045  
(224) 212-2000  
[www.hospira.com](http://www.hospira.com)



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

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

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](http://www.fda.gov/medwatch/report.htm)
- **Regular Mail or Fax**: Download form [www.fda.gov/MedWatch/getforms.htm](http://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 market withdrawal is being executed with the knowledge of the U.S. Food and Drug Administration.

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,

Shane Ernst  
Vice President, Quality  
Rocky Mount, North Carolina

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275 North Field Drive  
Lake Forest, IL 60045  
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**Market Withdrawal Reply Form – Response Required**  
**Amidate™ Etomidate Injection, USP, Lifeshield™ Abboject Glass Syringe**  
**Potential Out of Specification**  
**March 22, 2016**



**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 1-888-965-6074 or e-mail the completed form to [Hospira3097@stericycle.com](mailto:Hospira3097@stericycle.com).**  
**All returns are requested to be completed within six months of this notice date.** *The return label provided in this notification is for single use only, please DO NOT reproduce.* Please visit <http://expertezlabel.com> to request additional labels for returning product. If you have not received a return label or require additional assistance contact Stericycle at **1-888-965-6072** (M-F, 8am to 5pm ET).

<b>Required Information</b>	
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 form to Stericycle at the fax/e-mail above).

**YES**, I have affected product (fill out and return this form to Stericycle via the fax/e-mail above and return the product per the instructions on the return label).

- If yes, do you intend to return the affected product?      YES\_\_\_ NO\_\_\_

If affected product is not being returned, please explain:

- Have you distributed the product further?    YES\_\_\_ NO\_\_\_
  - If yes, have you notified your customers?    YES\_\_\_ NO\_\_\_ (if no, explain below)

NDC	Lot*	Quantity to be returned	Wholesaler/Distributor Name <small>If you purchased from Wholesalers/Distributors include name, address, city, state, ZIP, quantity from each, and invoice number. If you purchased directly from Hospira leave this section blank.</small>	PO, debit memo or invoice
0409-8060-29	42-257-DK			
	49-426-DK			
	51-394-DK			
	53-228-DK			

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