

URGENT DRUG RECALL



June 30, 2015

<i>Product</i>	<i>NDC Number</i>	<i>Lot*</i>	<i>Expiration Date</i>
Ketorolac Tromethamine Inj., USP, 30 mg (30 mg/mL), 1 mL Fill, Single-dose	0409-3795-01	Reference Table 1	Reference Table 1
Ketorolac Tromethamine Inj., USP, 30 mg (30 mg/mL), 1 mL Fill, Single-dose, NOVAPLUS®	0409-3795-49		
Ketorolac Tromethamine Inj., USP, 60 mg (30 mg/mL), 2 mL Fill, Single-dose	0409-3796-01		
Ketorolac Tromethamine Inj., USP, 60 mg (30 mg/mL), 2 mL Fill, Single-dose, NOVAPLUS®	0409-3796-49		

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

Dear Valued Customer:

Hospira, Inc. is issuing this voluntary recall letter to alert health care providers of the potential for particulate in glass vials containing ketorolac. Multiple product lists and lots are potentially impacted by this issue; refer to Table 1 for product list/lot information. Through visual inspection of retained product, three lots displayed visible, floating particulate within glass flip-top vials. The particulate was identified as calcium-ketorolac crystals. The remaining lots are being recalled out of an abundance of caution.

If particulate is not observed prior to administration, injected particulate theoretically could result in localized inflammation, allergic reaction, granuloma formation or microembolic effects. However, there is no evidence indicating that intramuscular or intravenous injection of inert particles results in harm to patients when only a small amount over a limited period of time is administered, as is the case with ketorolac. The probability of harm is negligible. If the defective vial is not detected until the point of care, a resulting delay in pain management would be of limited duration and likely of low clinical significance while another vial is obtained.

The lots included in this recall were distributed by Hospira to direct accounts August 2013 through May 2015. To date, Hospira has not received reports of any adverse events associated with this issue for these lots.

Hospira is working with its supplier and 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 health care providers in your organization of this recall.

Return affected product to Stericycle using the label provided with this letter. If you have not received a return label or require additional assistance contact Stericycle at 1-888-943-5177 (M-F, 8am to 5pm ET). 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.

5347_01_01AS_V1.1

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



This recall is being carried out to the user level (both human and veterinary). Please notify all users in your facility. If you have further distributed the recalled product please notify any accounts or additional locations which may have received the recalled product from you and instruct them if they have redistributed the product to notify their accounts, locations or facilities to the user level. If additional copies of the letter and/or reply form are needed, please contact Stericycle at 1-888-943-5177 (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.

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
- **Regular Mail or Fax**: Download form 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 recall is being made 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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Lake Forest, IL 60045
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Table 1
Ketorolac Tromethamine Inj., USP – Potential for Calcium-Ketorolac Crystals
June 30, 2015



Product	NDC Number	Lot*	Expiration Date
Ketorolac Tromethamine Inj., USP, 30 mg (30 mg/mL), 1 mL Fill, Single-dose	0409-3795-01	31-077-DK	01JUL2015
		31-078-DK	01JUL2015
		31-338-DK	01JUL2015
		31-339-DK	01JUL2015
		31-340-DK	01JUL2015
		32-068-DK	01AUG2015
		32-069-DK	01AUG2015
		33-270-DK	01SEP2015
		34-084-DK	01OCT2015
		34-085-DK	01OCT2015
		34-161-DK	01OCT2015
		34-162-DK	01OCT2015
		34-298-DK	01OCT2015
		34-299-DK	01OCT2015
		34-300-DK	01OCT2015
		35-011-DK	01NOV2015
		35-081-DK	01NOV2015
		35-082-DK	01NOV2015
		35-116-DK	01NOV2015
		38-139-DK	01FEB2016
		38-140-DK	01FEB2016
		38-144-DK	01FEB2016
		39-256-DK	01MAR2016
		39-257-DK	01MAR2016
		42-210-DK	01JUN2016
		42-227-DK	01JUN2016
		43-017-DK	01JUL2016
		43-116-DK	01JUL2016
		43-117-DK	01JUL2016
		43-292-DK	01JUL2016
43-293-DK	01JUL2016		
45-034-DK	01SEP2016		
45-035-DK	01SEP2016		
45-118-DK	01SEP2016		
45-120-DK	01SEP2016		
46-310-DK	01OCT2016		
46-311-DK	01OCT2016		

Table 1 continued on next page

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Table 1 continued
Ketorolac Tromethamine Inj., USP – Potential for Calcium-Ketorolac Crystals
June 30, 2015



Product	NDC Number	Lot*	Expiration Date
Ketorolac Tromethamine Inj., USP, 30 mg (30 mg/mL), 1 mL Fill, Single-dose, NOVAPLUS®	0409-3795-49	32-106-DK	01AUG2015
		32-220-DK	01AUG2015
		32-221-DK	01AUG2015
		33-235-DK	01SEP2015
		33-236-DK	01SEP2015
		34-163-DK	01OCT2015
		34-164-DK	01OCT2015
		39-263-DK	01MAR2016
		39-264-DK	01MAR2016
Ketorolac Tromethamine Inj., USP, 60 mg (30 mg/mL), 2 mL Fill, Single-dose	0409-3796-01	31-075-DK	01JUL2015
		31-076-DK	01JUL2015
		32-345-DK	01AUG2015
		32-368-DK	01AUG2015
		33-152-DK	01SEP2015
		34-538-DK	01OCT2015
		37-227-DK	01JAN2016
		41-525-DK	01MAY2016
		42-255-DK	01JUN2016
		46-042-DK	01OCT2016
		46-045-DK	01OCT2016
		46-048-DK	01OCT2016
		46-304-DK	01OCT2016
		46-305-DK	01OCT2016
46-432-DK	01OCT2016		
46-433-DK	01OCT2016		
Ketorolac Tromethamine Inj., USP, 60 mg (30 mg/mL), 2 mL Fill, Single-dose, NOVAPLUS®	0409-3796-49	31-074-DK	01JUL2015

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

Urgent Drug Recall Reply Form – Response Required
Ketorolac Tromethamine Inj., USP – Potential for Calcium-Ketorolac Crystals
June 30, 2015



Check your inventory and complete the information below, even if you do not have the affected product. Please be sure to include all pages of the Urgent Drug Recall Reply Form when faxing or e-mailing. *Failure to complete all sections of this page may result in improper, delayed or denied credit.*

Fax the completed form to 1-888-965-5806 or e-mail the completed form to Hospira5347@stericycle.com.

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 1-888-943-5177 (M-F, 8am to 5pm ET).

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 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)

