URGENT DRUG RECALL

January 22, 2015

Product: Ketorolac Tromethamine Inj., USP (Reference Table 1)

Subject: Potential for Particulate

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. Several product lists and lots are potentially impacted by this issue; refer to Table 1 for product list/lot information. Particulate has been confirmed through a customer report of visible, floating particulate identified in glass fliptop vials. The particulate was identified as calcium-ketorolac crystals. Risk factors associated with particulate include the potential for particles to be injected and/or a delay of therapy.

If particulates are not observed prior to administration, intramuscular (IM) or intravenous (IV) administration theoretically could result in localized inflammation, allergic reaction, granuloma formation or microembolic effects (IV only). However, there is no evidence indicating that IM or IV 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.

Delay of therapy may occur due to particulates blocking the infusion of solution or due to observation of particulates at the point of care. However, this delay is likely to be of negligible clinical significance as this medication is administered by a health care provider and remediation is readily available.

The lots were originally distributed by Hospira to direct accounts February 2013 to December 2014. 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.

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 1-888-345-4680 (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.

This recall is being carried out to the medical facility/retail level (both human and veterinary). Please notify users in your facility and any accounts or additional locations that received this recalled product from you and instruct them if they have redistributed this product to notify their accounts, locations or facilities to the medical facility/retail level. To receive a reply form and/or return labels for returning the product, contact Stericycle at 1-888-345-4680 (M-F, 8am to 5pm ET).

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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

Shane Ernst
Vice President, Quality
Rocky Mount, North Carolina

8962_01_02AS_V1.1

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Urgent Drug Recall Reply Form – Response Required
Ketorolac Tromethamine Inj., USP – Potential for Particulate
January 22, 2015

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 1-888-943-4897 or e-mail the completed form to Hospira8962@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 1-888-345-4680 (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 affected product is not being returned, please explain:

- Have you distributed the product further to the medical facility/retail level? YES___ NO___
  - If yes, have you notified your medical facility/retail customers? YES___ NO___ (if no, explain below)

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Ketorolac Tromethamine Inj., USP – Potential for Particulate
January 22, 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. *Failure to complete all sections of this page may result in improper, delayed or denied credit.*

_____ _____

Customer Name Customer Number

NDC and Lot Number	Quantity to be returned	Wholesaler/Distributor Name 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.	PO, debit memo or invoice
		1.	
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Table 1

Product	NDC Number	Lot*	Expiration Date
Ketorolac Tromethamine Inj., USP, 30 mg (30 mg/mL), 1 mL Fill, Single-dose	0409-3795-01	25-047-DK	1JAN2015
		25-048-DK	1JAN2015
		26-151-DK	1FEB2015
		28-059-DK	1APR2015
		28-071-DK	1APR2015
		28-072-DK	1APR2015
		28-479-DK	1APR2015
		28-480-DK	1APR2015
		29-556-DK	1MAY2015
		29-557-DK	1MAY2015
		35-232-DK	1NOV2015
		35-233-DK	1NOV2015
		35-234-DK	1NOV2015
		35-501-DK	1NOV2015
		36-341-DK	1DEC2015
		36-342-DK	1DEC2015
		36-343-DK	1DEC2015
		36-353-DK	1DEC2015
		36-429-DK	1DEC2015
		36-430-DK	1DEC2015
		37-141-DK	1JAN2016
		37-142-DK	1JAN2016
		37-144-DK	1JAN2016
		37-145-DK	1JAN2016
		37-353-DK	1JAN2016
		38-141-DK	1FEB2016
		38-143-DK	1FEB2016
		39-014-DK	1MAR2016
		39-104-DK	1MAR2016
		40-301-DK	1APR2016
		40-536-DK	1APR2016
		40-537-DK	1APR2016
		40-544-DK	1APR2016
		40-548-DK	1APR2016
		41-078-DK	1MAY2016
		42-207-DK	1JUN2016
		42-253-DK	1JUN2016

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Table 1 continued

Product	NDC Number	Lot*	Expiration Date
Ketorolac Tromethamine Inj., USP, 30 mg (30 mg/mL), 1 mL Fill, Single-dose	0409-3795-01	45-358-DK	1SEP2016
		45-359-DK	1SEP2016
		46-043-DK	1OCT2016
		46-044-DK	1OCT2016
		46-047-DK	1OCT2016
Ketorolac Tromethamine Inj., USP, 30 mg (30 mg/mL), 1 mL Fill, Single-dose, NOVAPLUS®	0409-3795-49	27-101-DK	1MAR2015
		35-229-DK	1NOV2015
		36-217-DK	1DEC2015
		36-218-DK	1DEC2015
		40-534-DK	1APR2016
Ketorolac Tromethamine Inj., USP, 60 mg (30 mg/mL), 2 mL Fill Single-dose	0409-3796-01	26-098-DK	1FEB2015
		29-239-DK	1MAY2015
		29-240-DK	1MAY2015
		34-540-DK	1OCT2015
		37-037-DK	1JAN2016
		37-038-DK	1JAN2016
		37-147-DK	1JAN2016
		37-148-DK	1JAN2016
		37-228-DK	1JAN2016
		37-282-DK	1JAN2016
		41-282-DK	1MAY2016
		41-284-DK	1MAY2016
		44-076-DK	1AUG2016
		45-240-DK	1SEP2016
		46-306-DK	1OCT2016
Ketorolac Tromethamine Inj., USP, 60 mg (30 mg/mL), 2 mL Fill, Single-dose, NOVAPLUS®	0409-3796-49	26-097-DK	1FEB2015

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

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