Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: February 12, 2015

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Hospira, Inc. - RECALL [Drug]

AFFECTED PRODUCT: **Ketorolac tromethamine injection, USP**

SUMMARY: **Unclassified Recall; The recall is due to the presence of particulate.**

The recalled products are listed below:

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

Product	NDC Number	Lot*	Expiration Date
Ketorolac Tromethamine Inj., USP, 30 mg (30 mg/mL), 1 mL Fill, Single-dose	0409-3795-01	37-145-DK	1JAN2016
		37-353-DK	1JAN2016
		38-141-DK	1FEB2016
		38-143-DK	1FEB2016
		39-014-DK	1MAR2016

Product	NDC Number	Lot*	Expiration Date
		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
		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

The lots were distributed from February 2013 to December 2014 in the United States.

SUGGESTED ACTION: **For consumer inquiry only. For additional assistance, call Stericycle at 1-888-345-4680 between the hours of 8am to 5pm ET, Monday through Friday.**

****

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Hospira Issues a Voluntary Global Recall of Multiple Lots of Ketorolac Tromethamine Injection Due to Potential Particulate in Glass Vials

Contact:
Consumer:
1-888-345-4680

Media:
224-212-2357

FOR IMMEDIATE RELEASE — February 10, 2015 — LAKE FOREST, Ill. — Hospira, Inc., (NYSE: HSP) has announced a voluntary recall of ketorolac tromethamine injection, USP in the United States and Singapore due to potential particulate. The presence of 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. Multiple lots are impacted by this recall; refer to the addendum for product list and lot information.

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 distributed from February 2013 to December 2014 in the United States and from January 2014 to July 2014 in Singapore. Hospira has not received reports of any adverse events associated with this issue for these lots to date. Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

Anyone with an existing inventory of the recalled lots should stop use and distribution, and quarantine the product immediately. This recall is being carried out to the medical facility/retail level. Customers who have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product and instruct them if they have redistributed the product to notify their accounts, locations or facilities to the medical facility/retail level. Hospira has notified its direct customers via a recall letter and is arranging for impacted product to be returned to Stericycle in the United States. For additional assistance, call Stericycle at 1-888-345-4680 between the hours of 8am to 5pm ET, Monday through Friday. Customers outside the United States should work with their local Hospira offices to return the product per the local recall notification.

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 (8am-5pm CT, M-F) (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 conducted with the knowledge of the U.S. Food and Drug Administration.

About Hospira
Hospira, Inc. is the world's leading provider of injectable drugs and infusion technologies, and a global leader in biosimilars. Through its broad, integrated portfolio, Hospira is uniquely positioned to Advance Wellness™ by improving patient and caregiver safety while reducing healthcare costs. The company is headquartered in Lake Forest, Ill. Learn more at www.hospira.com.

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

Product	NDC Number	Lot*	Expiration Date
Ketorolac Tromethamine Inj., USP, 30 mg (30 mg/mL), 1 mL Fill, Single-dose	0409-3795-01	37-145-DK	1JAN2016
		37-353-DK	1JAN2016
		38-141-DK	1FEB2016
		38-143-DK	1FEB2016
		39-014-	1MAR2016

Product	NDC Number	Lot*	Expiration Date
		DK	
		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
		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

Product	NDC Number	Lot*	Expiration Date
Ketorolac Tromethamine Inj., USP, 60 mg (30 mg/mL), 2 mL Fill, Single-dose, NOVAPLUS®	0409-3796-49	44-076-DK	1AUG2016
		45-240-DK	1SEP2016
		46-306-DK	1OCT2016
		26-097-DK	1FEB2015

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

###