Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: March 13, 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: **Lactated Ringer's Irrigation, 3000mL**

SUMMARY: **Unclassified Recall; The recall is due to a confirmed customer report of several dark, fibrous particulates floating within the solution of the primary container. The particulate was confirmed as a common non-toxic, non-invasive mold, Aspergillus kanagawaensis.**

The product is packaged in 3000 mL flexible container bags and sold four bags per carton (NDC: 0409-7828-08, Lot 40-008-JT, Expiry 1APR2016).

The lot was distributed nationwide in the United States to wholesalers, distributors, surgery centers, and hospitals from June 2014 through September 2014.

SUGGESTED ACTION: **For consumer inquiry only. For additional assistance, call Stericycle at 1-877-907-7037 between the hours of 8 am to 5 pm ET, Monday through Friday.**

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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 Nationwide Recall of One Lot of Lactated Ringer's Irrigation Due to Mold Contamination

Contact:
Consumer:
1-800-615-0187

Media:
224-212-2357

FOR IMMEDIATE RELEASE — March 11, 2015 — LAKE FOREST, Ill. — Hospira, Inc. (NYSE: HSP), announced today it is initiating a voluntary recall of one lot of Lactated Ringer's Irrigation, 3000mL (NDC 0409-7828-08, Lot 40-008-JT; Expiry 1APR2016) to the user level (both human and veterinary) due to a confirmed customer report of several dark, fibrous particulates floating within the solution of the primary container. The

particulate was confirmed as a common non-toxic, non-invasive mold, Aspergillus kanagawaensis. To date, Hospira has not received reports of any adverse events associated with this issue for this lot.

A loss of sterility is a primary concern when there is a presence of mold in a sterile, nonpyrogenic solution. If contaminated solution is used on a patient it may cause bacteremia, sepsis, septic shock and endocarditis, and death may result. Signs and symptoms may include redness, pain, swelling at the site, fever, shortness of breath, tachycardia, nausea, and vomiting. Septicemia could lead to shock and multi-system organ failure, requiring critical medical intervention. The mold is considered allergenic and exposure to it may induce an allergic response or immune response to the particulate including anaphylaxis. Delayed therapy may occur if the particulate were to block the flow of the solution during irrigation. However, this delay is likely to be of short duration as the medication is administered by a healthcare provider and remediation is readily available.

Lactated Ringers Irrigation is a sterile, nonpyrogenic solution of electrolytes in water for injection, intended only for sterile irrigation, washing and rinsing purposes. The product is packaged in 3000 mL flexible container bags and sold four bags per carton (NDC: 0409-7828-08, Lot 40-008-JT, Expiry 1APR2016). The lot was distributed nationwide in the United States to wholesalers, distributors, surgery centers, and hospitals from June 2014 through September 2014. Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

Anyone with an existing inventory of the recalled lot should stop use and distribution, and quarantine the product immediately. Customers should notify all users in their facility. 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 user level (both human and veterinary). Hospira will be notifying 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 1-877-907-7037 between the hours of 8 am to 5 pm ET, Monday through Friday. Patients should contact their physician or health care provider if they have experienced any problems that may be related to using this drug product.

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. Learn more at www.hospira.com.

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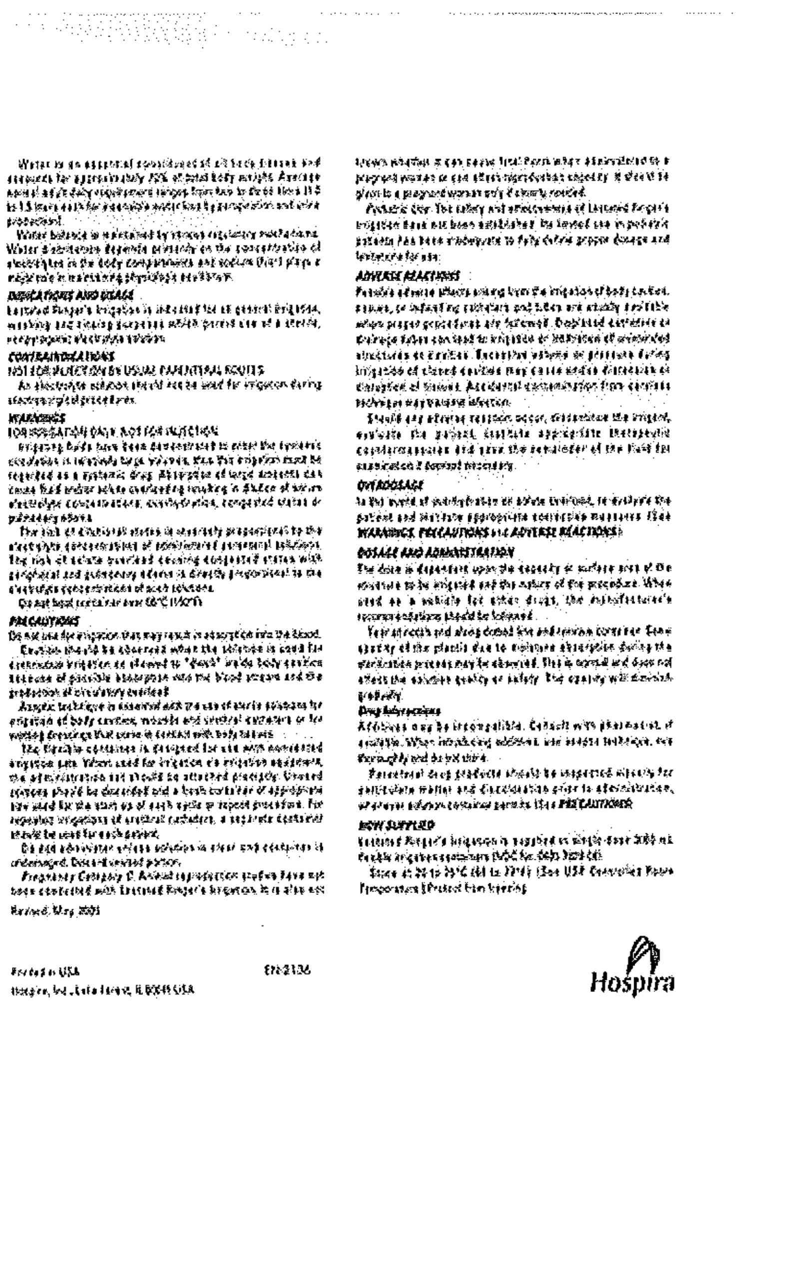
Hospira Issues a Voluntary Nationwide Recall of One Lot of Lactated Ringer's Irrigation Due to Mold Contamination
Photo



3000 mL

NDC 0409-7828-08

LACTATED RINGER'S IRRIGATION

2750
2500
2250
2000
1750
1500
1250
1000
750
500
250

EACH **100 mL** CONTAINS SODIUM CHLORIDE 600 mg; SODIUM LACTATE, ANHYD. 310 mg; POTASSIUM CHLORIDE 30 mg; CALCIUM CHLORIDE, DIHYDRATE 20 mg IN WATER FOR INJECTION. CONTAINS NaOH AND MAY CONTAIN HCl FOR pH ADJUSTMENT.

ELECTROLYTES PER 1000 mL (NOT INCLUDING pH ADJUSTMENT): SODIUM 130 mEq; POTASSIUM 4 mEq; CALCIUM 3 mEq; CHLORIDE 109 mEq; LACTATE 28 mEq.

274 mOsmol/LITER (CALC). pH 6.6 (6.0 TO 7.5) STERILE NONPYROGENIC.

ISOTONIC SOLUTION FOR IRRIGATION.

CONTRAINDICATIONS: NOT FOR INJECTION.

USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED.

WARNINGS: DO NOT HEAT CONTAINER OVER 66°C (150°F). SINGLE-DOSE CONTAINER. CONTAINS NO BACTERIOSTAT. DISCARD UNUSED PORTION. USE ASEPTIC TECHNIQUE.

USUAL DOSAGE: SEE INSERT.

Rx only

3 V CONTAINS DEHP

LATEX

IM-0198 (5/04)

PRINTED IN USA

HOSPIRA, INC., LAKE FOREST, IL 60045 USA

Hospira

1-NDC 0409-7828-08

L/N 7828-08 LC 04 IC 18

CASE PACK 1 X 4-3000 ML

LACTATED RINGERS IRR.

LOT NO. 40-008-JT-01

EXP. DATE 1APR2016

(01)10304097828082 (10)01

TO OPEN TEAR AT NOTCH

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