Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: December 24, 2014

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Hospira, Inc. [Drug]

AFFECTED PRODUCT: MitoXANTRONE (both human and veterinary)

SUMMARY: Unclassified Recall; The recall is due to confirmed subpotency and elevated impurity levels.

The lot numbers affected by the recall are:

Product	NDC Number	Lot	Expiration Date
MitoXANTRONE Injection, USP, (concentrate) 20 mg/10 mL, 2 mg/mL in 10 mL, 10 mL Vial, Multi Dose Vial	61703-343-18	Z054636AA	December 2014
		A014636AA	April 2015
		A024636AB	July 2015
MitoXANTRONE Injection, USP, (concentrate) 25 mg/12.5 mL, 2 mg/mL in 12.5 mL, 12.5 mL Vial, Multi Dose Vial	61703-343-65	A014643AA	April 2015
MitoXANTRONE Injection, USP, (concentrate) 30 mg/15 mL, 2 mg/mL in 15 mL, 15 mL Vial, Multi Dose Vial	61703-343-66	A014645AA	November 2015

These lots were distributed to hospitals and veterinary clinics worldwide from February 2013 through November 2014.

SUGGESTED ACTION: For consumer inquiry only. For additional assistance in the U.S., call Stericycle at 1-844-265-7407 between the hours of 8 a.m. to 5 p.m. 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 Announces Voluntary Worldwide Recall of 10 Lots of Mitoxantrone Due to Confirmed Subpotency and Out-Of-Specification Impurities

Contact:
Consumers:
1-800-615-0187

Media:
224-212-2357

FOR IMMEDIATE RELEASE – December 23, 2014 – LAKE FOREST, Ill. – Hospira, Inc. (NYSE: HSP), announced today it has initiated a voluntary recall of 10 lots, identified below, of MitoXANTRONE (both human and veterinary), due to confirmed subpotency and elevated impurity levels.

Risk factors associated with these types of out of specifications may include the potential for decreased potency which can lead to decreased effectiveness, additional dosing and the potential for cumulative impurity toxicity requiring medical intervention. To date, Hospira has not received reports of any adverse events associated with subpotency and impurities for these lots.

These lots were distributed to hospitals and veterinary clinics worldwide from February 2013 through November 2014. The lot numbers affected by the recall are:

United States

Product	NDC Number	Lot	Expiration Date
MitoXANTRONE Injection, USP, (concentrate) 20 mg/10 mL, 2 mg/mL in 10 mL, 10 mL Vial, Multi Dose Vial	61703-343-18	Z054636AA	December 2014
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MitoXANTRONE Injection, USP, (concentrate) 30 mg/15 mL, 2 mg/mL in 15 mL, 15 mL Vial, Multi Dose Vial	61703-343-66	A014645AA	November 2015

Australia and New Zealand

Product	Product Code	Batch Number	Expiration Date
DBL™ MitoXANTRONE Hydrochloride Injection (concentrate) 20mg/10mL Injection Vial	M4636A	A024636AA	July 2015

Canada

Product	List Number	DIN	Lot	Expiration Date
MitoXANTRONE for Injection 20mg /10mL USP	4636A001	02244614	A024636AC	July 2015

United Kingdom, Ireland, Cyprus, Saudi Arabia, Qatar, Oman and Bahrain

Product	List Number	Lot	ExpirationDate
MitoXANTRONE 2 mg/mL; Concentrate for Infusion	M4636AGB1	A014636AB	April 2015
		A024636AD	July 2015
		Z054636AB	Dec 2014

Hospira initiated an investigation to determine the root cause and corrective and preventive actions. The root cause was subsequently found and appropriate implementations of improvements have been initiated for batches manufactured from March 2014.

Anyone with an existing inventory of the recalled lot should stop use and distribution, and quarantine the product immediately. This recall is being carried out to the user level (both human and veterinary). 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 consumer 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 in the U.S., call Stericycle at 1-844-265-7407 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday. Customers outside the United States should work with their local Hospira offices to return the product per local recall notifications.

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, 8 a.m. to 5 p.m. 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 conducted with the knowledge of the U.S. Food and Drug Administration, and relevant regulatory agencies outside the United States, including the Therapeutic Goods Administration, Health Canada and Medicines and Healthcare Products Regulatory Agency.

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., and has approximately 19,000 employees. Learn more at www.hospira.com.

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