UNITED ARAB EMIRATES
MINISTRY OF HEALTH

الإمارات العربية المتحدة
وزارة الصحـــــــة

التاريخ:21/10/2014
الرقم:2012/1212/

السادة الأفاضل/ مدراء المناطق الطبية المحترمين
السادة الأفاضل / مدراء المستشفيات الحكومية و الخاصة المحترمين
تحية طيبة وبعد،

م/ تقارير السلامة للوسائل الطبية
LifeCare™ line of flexible intravenous solutions
من إنتاج شركة HOSPIRA Inc.

حفاظا على المصلحة العامة وصحة المجتمع، نود أن نلفت انتباهكم بأن الهيئة العامة للغذاء والدواء الأمريكية والشركة المصنعة قد قامتا بسحب عدد من التشغيلات لمجموعة المنتجات المذكورة أعلاه، والمستخدمة كمحاليل للحقن عبر الوريد، وذلك بسبب إحتمالية تسرب محلول الحقن من العبوة الأصلية، مما قد يؤدي إلى التلوث، عدم عقامة المنتج، أو تأخير في العلاج. فيما يلي قائمة بالمنتجات والتشغيلات المعيبة:

Normosol®-R Multiple Electrolytes Injection Type 1, USP; 1000 mL container	**32-082-JT**
Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP; 1000 mL container	**34-017-JT, 35-100-JT**
5% Dextrose Injection, USP; 1000 mL container	**33-094-JT, 35-028-JT**
5% Dextrose and 0.45% Sodium Chloride Injection, USP; 1000 mL container	**33-095-JT, 36-030-JT**
Lactated Ringer's and 5% Dextrose Injection, USP; 1000 mL container	**34-134-JT, 34-166-JT**
5% Dextrose and 0.9% Sodium Chloride Injection, USP; 1000 mL container	**32-104-JT, 34-136-JT, 36-092-JT**
Lactated Ringer's Injection, USP; 1000 mL container	**32-099-JT, 32-103-JT, 34-070-JT, 34-086-JT, 34-165-JT, 35-085-JT, 35-115-JT, 35-121-JT, 36-057-JT**
Normosol®-R Multiple Electrolytes Injection Type 1, USP; 1000 mL container	**32-081-JT, 34-115-JT**
0.9% Sodium Chloride Injection, USP; 1000 mL container	**32-044-JT, 32-072-JT, 32-102-JT, 33-028-JT, 33-046-JT, 33-049-JT, 33-061-JT, 33-085-JT, 33-096-JT, 33-101-JT, 33-102-JT, 34-016-JT, 34-085-JT, 34-122-JT, 34-123-JT, 35-026-JT, 35-030-JT, 35-067-JT, 36-002-JT, 36-029-JT, 36-049-JT, 36-058-JT, 36-103-JT, 37-013-JT**
0.45% Sodium Chloride Injection	**33-027-JT, 33-045-JT, 33-097-JT, 35-068-JT, 36-112-JT, 37-012-JT**
Sterile Water for Injection	**36-084-JT**

ولمزيد من المعلومات عن التشغيلات المعيبة يرجى الاطلاع على الموقع:

http://www.fda.gov/Safety/Recalls/ucm418879.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

علما بأن هذه المنتجات غير مسجلة في إدارة الدواء بوزارة الصحة و لكن حرصا منا على سلامة المرضى ارتأت الإدارة إبلاغكم بذلك لاتخاذ الإجراءات اللازمة إن وجد لديكم.

وفي حال حدوث أي أعراض جانبية يرجى ملئ الإستمارة الخاصة بالآثار الجانبية للدواء ADR والمتوفرة على الموقع http://www.cpd-pharma.ae ، أو الإتصال على العناوين التالية:

هاتف: 6117391 - 02 أو 6117642 - 02 أو فاكس6313742- 02 أو البريد الالكتروني: pv @moh.gov.ae

و تفضلوا بقبول فائق الاحترام و التقدير.

د. أمين حسين الأميري
وكيل الوزارة المساعد لسياسة الصحة العامة والتراخيص

صدر بديوان عام الوزارة/ابوظبي بتاريخ: 2014/10

نسخة:

- معالي / وزير الصحة
- سعادة / وكيل وزارة الصحة .. المحترم ،،،
- سعادة / المدير العام لهيئة الصحة – أبو ظبي المحترم ،،،
- سعادة / المدير العام لهيئة الصحة – دبي .. المحترم ،،،
- سعادة / وكيل الوزارة المساعد لقطاع المستشفيات .. المحترم ،،،
- سعادة / وكيل الوزارة المساعد لقطاع المراكز والعيادات الصحية .. المحترم ،،،
- سعادة / مدير المكتب الطبي/وزارة شؤون الرئاسة المحترم ،،،
- سعادة / المدير التنفيذي لمدينة دبى الطبية .. المحترم ،،،
- سعادة / مدير إدارة سلاح الخدمات الطبية/القوات المسلحة .. المحترم ،،،
- سعادة / مديرة إدارة الدواء .. المحترمة ،،،

مدير ادارة الدواء

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

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 NATIONWIDE RECALL OF CERTAIN LOTS OF SEVERAL LIFECARE PRODUCTS DUE TO POTENTIAL FOR LEAKAGE

Contact:
Consumer:
1-800-615-0187
Media:
224-212-2357

FOR IMMEDIATE RELEASE - October 14, 2014 - Hospira, Inc. (NYSE: HSP), today announced the voluntary recall of certain lots of several products in its LifeCare™ line of flexible intravenous solutions due to the potential for leakage. The issue, which Hospira notified customers about in a Dear Health Care Provider letter issued earlier this year, was identified during re-inspection of a manufactured product lot in which a single puncture mark was identified going through the overwrap and primary container.

The puncture in the primary container may result in leakage that is difficult to detect. Leakage may result in an open system, which has the potential for contamination, compromised sterility, drug waste, spillage, inadequate or inconsistent solution/medication dosing, and/or delay in therapy, all of which may require medical intervention and should be reported to Hospira and/or the U.S. Food and Drug Administration (FDA). Hazardous topical exposure may occur if a hazardous drug is added to the flexible container. Hospira's product insert packaged with LifeCare flexible intravenous containers recommends providers do not administer unless solution is clear and the container is undamaged.

The root cause is attributed to a defect in a conveyance system, and corrective actions have since been implemented to prevent a reoccurrence. To date there have been no reports of adverse events associated with this issue for the impacted lots. The manufacturing issue that caused this incident has been addressed. Hospira recommends impacted customers check with their local Hospira representative or with Hospira Customer Care regarding replacement product.

The affected lots (see table below) were originally distributed by Hospira to direct accounts from September 2013 through October 2014.

Product	NDC Number	Lot	Expiration Date
Normosol®-R pH 7.4 Multiple Electrolytes Injection Type 1, USP; 1000 mL container	0409-7670-09	32-082-JT	1AUG2015
Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP; 1000 mL container	0409-7902-09	34-017-JT	1OCT2015
		35-100-JT	1NOV2015
5% Dextrose Injection, USP; 1000 mL container	0409-7922-09	33-094-JT	1SEP2015
		35-028-JT	1NOV2015
5% Dextrose and 0.45% Sodium Chloride Injection, USP; 1000 mL container	0409-7926-09	33-095-JT	1SEP2015
		36-030-JT	1DEC2015
Lactated Ringer's and 5% Dextrose Injection, USP; 1000 mL container	0409-7929-09	34-134-JT	1OCT2015
		34-166-JT	1OCT2015
5% Dextrose and 0.9% Sodium Chloride Injection, USP; 1000 mL container	0409-7941-09	32-104-JT	1AUG2015
		34-136-JT	1OCT2015
		36-092-JT	1DEC2015
Lactated Ringer's Injection, USP; 1000 mL container	0409-7953-09	32-099-JT	1AUG2015
		32-103-JT	1AUG2015
		34-070-JT	1OCT2015
		34-086-JT	1OCT2015
		34-165-JT	1OCT2015
		35-085-JT	1NOV2015
		35-115-JT	1NOV2015
		35-121-JT	1NOV2015
		36-057-JT	1DEC2015

Product	NDC Number	Lot	Expiration Date
		32-081-JT	1AUG2015
		34-115-JT	1OCT2015
0.9% Sodium Chloride Injection, USP; 1000 mL container	0409-7983-09	32-044-JT	1AUG2015
		32-072-JT	1AUG2015
		32-102-JT	1AUG2015
		33-028-JT	1SEP2015
		33-046-JT	1SEP2015
		33-049-JT	1SEP2015
		33-061-JT	1SEP2015
		33-085-JT	1SEP2015
		33-096-JT	1SEP2015
		33-101-JT	1SEP2015
		33-102-JT	1SEP2015
		34-016-JT	1OCT2015
		34-085-JT	1OCT2015
		34-122-JT	1OCT2015
		34-123-JT	1OCT2015
		35-026-JT	1NOV2015
		35-030-JT	1NOV2015
		35-067-JT	1NOV2015
		36-002-JT	1DEC2015
		36-029-JT	1DEC2015
		36-049-JT	1DEC2015
		36-058-JT	1DEC2015

Product	NDC Number	Lot	Expiration Date
		36-103-JT	1DEC2015
		37-013-JT	1JAN2016
0.45% Sodium Chloride Injection, USP; 1000 mL container	0409-7985-09	33-027-JT	1SEP2015
		33-045-JT	1SEP2015
		33-097-JT	1SEP2015
		35-068-JT	1NOV2015
		36-112-JT	1DEC2015
		37-012-JT	1JAN2016
Sterile Water for Injection, USP; 1000 mL container	0409-7990-09	36-084-JT	1DEC2015

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 (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 medical facility/retail level. In addition, customers should inform potential users of these products in their organizations of this notification. Hospira will be notifying its direct customers via a recall letter and will arrange for impacted product to be returned to Stericycle. For additional assistance, call Stericycle at 1-844-861-6221 between the hours of 8am to 5pm ET, Monday through Friday.

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-5pm CT) (**ProductComplaintsPP@hospira.com (mailto:ProductComplaintsPP@hospira.com)**)	To report adverse events or product complaints
Hospira Medical Communications	1-800-615-0187 or **medcom@hospira.com (mailto: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 (http://www.fda.gov/MedWatch/report.htm)**
- **Regular Mail or Fax**: Download form **www.fda.gov/MedWatch/getforms.htm (http://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., and has approximately 17,000 employees. Learn more at **www.hospira.com (http://www.hospira.com)**.
(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm).

###

RSS Feed for FDA Recalls Information (/AboutFDA/ContactFDA/StayInformed/RSSFeeds/Recalls/rss.xml) [what's this? (/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm)]