Important Safety Information on Baxter Intravenous Solution Bags – Potential Leak During Spiking of Administration Port

Baxter

October 6, 2023

Audience

Healthcare professionals including physicians, nurses, pharmacists, and other medical and support personnel including inventory management and home healthcare agencies involved in the administration and handling of the following Baxter products:

- 0.4% LIDOCAINE & 5% DEXTROSE INJECTION (250ML)
- 0.9% SODIUM CHLORIDE INJECTION, USP (100ML, and 250ML)
- LACTATED RINGER'S INJECTION, USP (250ML)
- METRONIDAZOLE INJECTION, USP (100ML)

Key messages

- **Certain lots of Baxter intravenous solution bags have the potential to leak during the process of spiking the administration port.**
- **Healthcare professionals are advised to:**
  - **NOT use the product if the defect is observed.**
  - **Follow guidance on the handling and verification of affected products (see the "Information for healthcare professionals" section) and**
  - **Ensure preparedness at points of use where affected products are identified.**
- **Avoid using affected lots when feasible, particularly in situations requiring immediate product use (e.g., operating room, critical care and emergency). If only products from affected lots are available, additional measures should be considered, including the immediate supply of replacement bags at point of use and additional safety measures based on professional practice.**

What is the issue?

Intravenous bags of Baxter's 0.4% Lidocaine & 5% Dextrose Injection 250 mL, 0.9% Sodium Chloride Injection, USP 100 mL and 250 mL, Lactated Ringer's Injection, USP 250 mL, and Metronidazole Injection, USP 100mL from certain lots have the potential to leak during the process of spiking the administration port.

The affected lots identified in Appendix A are not being recalled at this time in order to prevent a shortage of these medically necessary products.

Products affected

Product Name	Package Size	Product Code	Market Authorization Holder	DIN	Lot Numbers/ Expiration Dates of products not recalled
0.4% Lidocaine & 5% Dextrose Injection	250mL	JB0972	Baxter Corporation	00828602	See Appendix A
0.9% Sodium Chloride Injection, USP	100 mL 250 mL	JB1302 JB1322	Baxter Corporation	00060208	See Appendix A
Lactated Ringer's Injection, USP	250 mL	JB2322	Baxter Corporation	00061085	See Appendix A
Metronidazole Injection, USP	100 mL	JB3415	Baxter Corporation	00870420	See Appendix A

Background information

There have been reports of leaks and/or disconnections observed during spiking on the administration port at the connection of the lower tubing section and the main port tube (see Appendix B as an example).

Baxter identified the cause of the leakage of these intravenous bags as a combination of factors related to the manufacturing process. Baxter has implemented appropriate measures to address the leaks and prevent reoccurrence. Products from the affected lots were distributed by Baxter Corporation in Canada beginning April 28, 2023.

The safety risks that could occur because of a leaking solution bag include:

- Delay or interruption in therapy resulting in the administration of an inaccurate dose.
- Healthcare professionals or patients being exposed to the drug product, including hazardous medications (e.g., cytotoxic chemotherapeutic drugs) when these medications have been added to the bags.
- Patients receiving an infusion of contaminated solution due to microbial contamination of the solution at the point of use.
- Healthcare professionals or patients being exposed to harm due to the solution leaking onto electrical equipment.

Baxter is taking a phased-in recall approach to prevent a product shortage. In consultation with Health Canada, the affected lots identified in Appendix A are not being recalled at this time to ensure the continued availability of these medically

necessary products. Further market actions may be taken in the future once sufficient non affected supply is available.

Baxter has previously initiated similar recalls of products affected by this issue, in consultation with Health Canada. For additional details, consult the Recalls and Safety Alerts Database on the Healthy Canadians Web Site.

Information for consumers (home patients)
Do NOT use the bags from affected lots if you see any damage or fluid leakage.

If you see any fluid leakage from the bags before or during treatment, stop using the product as there may be a potential risk of harm and consult your healthcare professional.

Gloves should be worn when handling the bag to avoid exposure to any cytotoxic drugs (such as some cancer drugs) that may have been added to the fluid in the bags.

Consult with your healthcare professional if you have used product from an affected lot, or are unsure and have questions or concerns about your health.

Information for healthcare professionals

- Visually inspect the container. If the administration port is damaged, detached, or not present, discard container, as solution sterility may be compromised.
- Check for administration port leaks after spiking the bag, by applying gentle pressure near the administration port. If leaks are found, discard solution as sterility may be compromised.
- Due to the possibility that a port leak may not be immediately observed, wait 1-2 minutes before adding medications.
- During the preparation of cytotoxic medications, follow pharmacy practice standards, and consider:
    - Spiking the bag first with either the administration set or the CSTD (closed system transfer device) bag spike
    - Inspect the bag prior to adding the medication
    - Admix the medication after spiking the bag
    - After adding the medication, leave the bag hanging under the hood for 1-2 extra minutes before sending to the units to ensure there is no leaking
    - Regularly monitor for leakage from the bag during treatment and discontinue use if leakage is observed.
    - Ensure spill kits are readily available on the unit when administering cytotoxic medications and staff are prepared, trained, and are aware of how to manage and handle hazardous materials

        - Gloves should be worn when handling the bags to avoid exposure to any hazardous medications that may have been added to the bags
    - Avoid using affected lots of Baxter IV solutions when feasible, particularly in situations requiring immediate product use (e.g., operating room, critical care and emergency). If only products from affected lots are available, additional measures should be considered, including the immediate supply of replacement bags at point of use and additional safety measures based on professional practice.

Action taken by Health Canada
Health Canada is communicating this important safety information to healthcare professionals and Canadians via the Recalls and Safety Alerts Database on the Healthy Canadians Web Site. This communication will be further distributed through the MedEffect™ e-Notice email notification system.

Health Canada has requested Baxter Corporation, the market authorization holder for 0.4% Lidocaine & 5% Dextrose Injection, 250 mL, 0.9% Sodium Chloride Injection, USP 100 mL and 250 mL, Lactated Ringer's Injection, USP 250 mL, and Metronidazole Injection, USP 100mL to ensure that they inform all affected healthcare professionals, patients and personnel administering or handling these products.

Health Canada is monitoring the company's implementation of any additional corrective and preventative actions. If additional safety information is identified, Health Canada will take appropriate action and inform Canadians as needed.

Report health or safety concerns
Health Canada's ability to monitor the safety of marketed health products depends on healthcare professionals and consumers reporting adverse reactions and medical device incidents. Any serious or unexpected adverse reactions in patients receiving 0.4% Lidocaine & 5% Dextrose Injection, 250 mL, 0.9% Sodium Chloride Injection, USP 100 mL and 250 mL, Lactated Ringer's Injection, USP 250 mL, and Metronidazole Injection, USP 100mL should be reported to Baxter Corporation or to Health Canada.

Baxter Corporation
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To correct your mailing address or fax number, contact Baxter Corporation at fca_canada@baxter.com

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax.

For other health product inquiries related to this communication, contact Health Canada at:

Health Product Compliance Directorate, Regulatory Operations and Enforcement Branch
E-mail: hpce-cpsal@hc-sc.gc.ca
Telephone: 1-800-267-9675

Sincerely,

Brandon Gingrich
Senior Manager, Quality
Baxter Corporation – Canada

Appendix A: Affected Lots NOT Subject to Recall

Product Code	Product Description	Lot Number	Expiration Date	DIN
JB0972 (JB0972)	0.4% LIDOCAINE & 5% DEXTROSE INJECTION (250ML)	W3E11C1	AUG 2024	00828602
JB2322 (JB2322P)	LACTATED RINGER'S INJECTION, USP (250 ML)	W3F22C1	SEP 2024	00061085
JB3415	METRONIDAZOLE INJECTION, 500 mg / 100 mL, USP (100ML)	W3E30C1	NOV 2024	00870420
JB1302 (JB1302P)	0.9% SODIUM CHLORIDE INJECTION, USP (100 ML)	W3D25C0	APR 2024	00060208
		W3D26C0	APR 2024	
		W3D29C2	APR 2024	
		W3E03C0	MAY 2024	
		W3E04C0	MAY 2024	
		W3E09C0	MAY 2024	
		W3E18C0	MAY 2024	

		W3E30C0	MAY 2024	
		W3F06C0	JUN 2024	
		W3F13C0	JUN 2024	
		W3F21C0	JUN 2024	
		W3F28C0	JUN 2024	
		W3F29C0	JUN 2024	
		W3G11C0	JUL 2024	
		W3G12C0	JUL 2024	
		W3G13C0	JUL 2024	
		W3G17C3	JUL 2024	
		W3G18C0	JUL 2024	
JB1322 (JB1322P)	0.9% SODIUM CHLORIDE INJECTION, USP (250 ML)	W3D24B0	JUL 2024	00060208
		W3D27C0	JUL 2024	
		W3E01B0	AUG 2024	
		W3E02B0	AUG 2024	
		W3E05C1	AUG 2024	
		W3E10B0	AUG 2024	
		W3E13C1	AUG 2024	
		W3E15B1	AUG 2024	
		W3E16B0	AUG 2024	
		W3E25C2	AUG 2024	
		W3F01C0	SEP 2024	
		W3F01C0S	SEP 2024	
		W3F02C1	SEP 2024	
		W3F05B0	SEP 2024	
		W3F12B0	SEP 2024	
		W3F14C0	SEP 2024	
		W3F16B0	SEP 2024	
		W3F19B0	SEP 2024	
		W3F20B0	SEP 2024	
		W3F21B0KX	SEP 2024	
		W3F21B0X	SEP 2024	
		W3F22C0	SEP 2024	
		W3F30C0	SEP 2024	
		W3G10B0	OCT 2024	
		W3G11B0	OCT 2024	
		W3G12B0K	OCT 2024	

		W3G12B0X	OCT 2024	
		W3G14C0	OCT 2024	
		W3G15C0	OCT 2024	
		W3G17B0	OCT 2024	
		W3G17B0S	OCT 2024	
		W3G18B0	OCT 2024	
		W3G18B0S	OCT 2024	

Appendix B

The following photo is an example of where the leaks can occur for the implicated lots: