Important Drug Information

November 19, 2024

Subject: Release of Baxter's 0.9% Sodium Chloride Injection USP (1000 mL), Lot # Y455404, with potentially leaking units to prevent drug shortage.

Dear Healthcare Professional,

To address the current drug shortage, Baxter is coordinating with the U.S. Food and Drug Administration to release the lot below with potentially leaking units while under investigation. Leaking bags could be an indicator of non-sterility of the product and therefore should not be used.

The SKU, corresponding lot number, and product description below was under quality investigation at the time of Hurricane Helene and was stored in our warehouse.

SKU	Lot #	NDC	Product size	Expiration Date	Description
2B1324X	Y455404	0338-0049-04	1,000 ml	12/31/2025	0.9% SODIUM CHLORIDE INJECTION USP VIAFLEX

Description of the Issue

The defect type that was under investigation for this issue was a potentially leaking unit. The leak would most likely be presented as an obvious defect before handling, and/or would present itself as an obvious defect once pressure is applied. The total amount of leaking units within the lot is low, and the leaking unit would most likely be able to be identified before use.

During the internal review of lot Y455404, the leaks in the primary units were found to be occurring at a rate of 509 Defects Per Million (0.0509%). However, the total number of potential leaking units that are estimated to be in the lot after sorting processes is 3 Defects Per Million (0.0003%).

Recommended Action

Before using this product, we recommend that you apply pressure to and inspect the bag for leakage or signs of leakage. This could include evidence of past leakage, such as dry residue on the exterior of the bag. Additionally, check to see that solution is clear and free of foreign matter. Discard the solution if solution is not clear.

Reporting Complaints and Adverse Events

Healthcare providers should report quality complaints or adverse events associated with the use of Baxter products:

- **Complaints:** Contacting Baxter Product Surveillance at the Baxter product feedback portal at https://productfeedback.baxter.com, or emailing Baxter at corporate_product_complaints_round_lake@baxter.com, note the lot number(s) and that this product was part of a lot under investigation and affected by Hurricane Helene.

- **Adverse Events:** Contacting Baxter Patient Safety by calling 866-888-2472 between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday, or emailing USAT_Pharmacovigilance@Baxter.com

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:

- **Online:** Complete and submit the report online at: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.accessdata.fda.gov/scripts/medwatch/index.cfm or call 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 800-FDA-0178 (800-332-0178).

If you have any questions about the information contained in this letter or the use of the imported products, please contact Baxter's Medical Information Service at 1-800-933-0303, or Email: medinfo@baxter.com.

This letter is not intended as a complete description of the benefits and risks related to the use of Baxter's 0.9% Sodium Chloride Injection USP, 1000 ML. Please refer to the enclosed full prescribing information.

Sincerely,

Simone Diorio

Electronically signed by:
Simone Diorio
Reason: I approve this document
Date: Nov 19, 2024 12:04 EST

Simone Diorio

VP Quality, Medical Products & Therapies

Enclosure(s): Full Prescribing Information