Pfizer Logo

# Hospira, Inc., Issues A Voluntary Nationwide Recall for one lot of BACTERIOSTATIC WATER for Injection, USP, due to a Potential Lack of Sterility Assurance

Friday, September 06, 2019 - 05:47pm

Hospira, Inc., a Pfizer company, is voluntarily recalling BACTERIOSTATIC WATER for Injection, USP, 30 mL, multi-dose vial, lot W20308, to the Hospital/Retail level. Hospira initiated this recall due to lack of confirmation of sterilization for some vials from this lot.

In the event that impacted product is administered to a patient, there is an increased risk that severe adverse events such as invasive bacterial infection, including bacterial meningitis, septicemia, and limited adverse events such as fever, chills, malaise, and cutaneous abscess may occur. To date, Hospira has not received reports of any such adverse events associated with this issue for this lot.

BACTERIOSTATIC WATER for Injection, USP, 30 mL, multi-dose vial is a sterile, nonpyrogenic preparation of water for injection containing 0.9% (9 mg/mL) of benzyl alcohol added as a bacteriostatic preservative. It is indicated only for diluting or dissolving drugs for intravenous, intramuscular or subcutaneous injection, according to instructions of the manufacturer of the drug to be administered.

BACTERIOSTATIC WATER for Injection, USP, 30 mL, multi-dose vial is packaged as described below. Product was distributed in the U.S. and Puerto Rico to Hospitals/Retailers from March 2018, to April 2018.

| NDC | Lot Number | Expiration Date | Presentation | Configuration/Count |
|---|---|---|---|---|
| Vial: 0409-3977-01 Carton: 0409-3977-03 | W20308 | 01 DEC 2019 | 30 mL, Multiple dose | 4 x 25 x 30mL vials |

Hospira, Inc., places the utmost emphasis on patient safety and product quality at every step in the manufacturing and supply chain process. Hospira is notifying its direct customers via a recall letter to arrange for return of any recalled product.

Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine immediately. Inform Healthcare Professionals in your organization of this recall. For additional assistance, call Stericycle at 1-800-805-3093 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday.

For clinical inquiries please contact Pfizer using the below information.

| Contact | Contact Information | Areas of Support |
|---|---|---|

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|---|---|---|
| Pfizer Medical Information | 1-800-438-1985, option 3 (9am to 5pm ET Monday through Friday) | For Medical questions regarding this product |
| Pfizer Drug Safety | 1-800-438-1985, option 1 (24 hours a day 7 days per week) | To report adverse events or product complaints |

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 executed with the knowledge of the U.S. Food and Drug Administration.

Example of Vial label




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