Baxter

Important Product Information

February 13, 2018

Dear Director of Pharmacy:

Problem Description

Baxter Healthcare Corporation is issuing this notification to make customers aware of labeling discrepancies for two products: 1) Clindamycin in 0.9% Sodium Chloride Injection and 2) Clindamycin in 5% Dextrose Injection.

The Clindamycin in 0.9% Sodium Chloride Injection solution bag and carton labeling incorrectly state that each 50 mL solution bag contains 9 mg of Sodium Chloride when it should correctly state each 50 mL bag contains 450 mg of Sodium Chloride.

The Clindamycin in 5% Dextrose Injection prescribing information/package insert states that each mL of solution contains 2.5 g of Dextrose, Hydrous, USP, when it should correctly state each 50 mL of solution contains 2.5 g of Dextrose Hydrous, USP.

The solutions were formulated and confirmed to be filled with the correct concentrations of Sodium Chloride and Dextrose Hydrous. Customers may continue to safely use the affected products. The affected lots were first distributed on June 6, 2017 in the United States. The table below contains a description of the products distributed with the incorrect labeling.

Affected Product

Product Code	Product Description	Lot Number	Expiration Date	NDC
2G3455	Clindamycin in 0.9% Sodium Chloride Injection, 300mg	All	All non-expired product	0338-9545-50
2G3456	Clindamycin in 0.9% Sodium Chloride Injection, 600mg	All	All non-expired product	0338-9549-60
2G3457	Clindamycin in 0.9% Sodium Chloride Injection, 900mg	All	All non-expired product	0338-9553-90
2G3452	Clindamycin in 5% Dextrose Injection, 300mg	All	All non-expired product	0338-3410-50
2G3453	Clindamycin in 5% Dextrose Injection, 600mg	All	All non-expired product	0338-3612-50
2G3454	Clindamycin in 5% Dextrose Injection, 900mg	All	All non-expired product	0338-3814-50

Hazard Involved

Adverse health consequences are unlikely to occur as a result of the use of incorrectly labeled content of Sodium Chloride or Dextrose in the Clindamycin Injection. There have been no reports of adverse events associated with this issue.

Actions to be Taken by Customers

1. Customers may continue to safely use the affected product.
2. **If you purchased this product directly from Baxter, complete the enclosed Baxter customer reply form and return it to Baxter** by faxing it to 224-270-5457 or scanning and e-mailing it to fca@baxter.com, **even if you do not have any inventory**. Returning the Baxter customer reply form promptly will prevent you from receiving repeat notices.
3. If you purchased this product from a distributor, please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions.
4. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
5. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please distribute this notification to customers.

The United States Food and Drug Administration (FDA) has been notified of this action. Any adverse reactions or quality problems experienced with the use of these products may be reported using one of the following options:

- Calling Baxter Product Surveillance at 800-437-5176 between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.
- Emailing to Baxter at: corporate_product_complaints_round_lake@baxter.com.
- Reporting to the FDA MedWatch Adverse Event Reporting Program:
  - **Online:** By completing and submitting the report online at: www.fda.gov/medwatch/report
  - **Regular mail or Fax:** Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

C. Chamoun

Camil Chamoun
Vice President, Quality
Hospital Products
Baxter Healthcare Corporation

cc: Director of Materials Management

Enclosure: Baxter Customer Reply Form