Important Prescribing Information

January 15, 2018

Subject: Temporary importation of intravenous drug products to address drug shortages

Dear Healthcare Professional,

In order to address shortages of critical drug products from the aftermath of Hurricane Maria, Baxter Healthcare Corporation (Baxter) is coordinating with the U.S. Food and Drug Administration (FDA) to increase the availability of products from Baxter's manufacturing facility in Brazil. The information contained in this letter pertains only to the products listed below. You may be provided with additional letters for other imported products you receive. Please read each letter in its entirety because each letter may contain different, product-specific information.

Baxter has initiated temporary importation of the products tabulated below. These products are manufactured by Baxter's manufacturing facility in Brazil and marketed in Brazil. At this time, no other entity except Baxter is authorized by the FDA to import or distribute these products in the United States. FDA has not approved the listed products manufactured by Baxter's manufacturing facility in Brazil.

Effective immediately, and during this temporary period, Baxter will offer the following:

Product name and description	Size	Product code	Pack Factor	NDC code
0.9% Sodium Chloride Injection (VIAFLEX Container)	100 mL	FZB1307	72	0338-9517-72
5% Dextrose Injection (VIAFLEX Container)	100 mL	FZB0087	72	0338-9523-72

It is important to note the following:

After opening the carton or box, the bags should be inspected visually to confirm there is no visible particulate matter or bag defects; such as, leaks. Container integrity is imperative to ensure sterility of products listed in Table 1. Parenteral drug products should be inspected visually for particulate matter and bag defects prior to administrations, whenever solution or container permits. This requirement is specifically stated in the package insert for the products which are subject to this notification.

You should perform a visual inspection of the bag prior to administration of the solution. DO NOT USE IF PARTICULATES ARE VISIBLE OR IF IV BAG CONTAINS A LEAK, USE A NEW BAG.

- The imported products' administration port system is fully compatible with Baxter IV sets marketed in the United States.
- These imported products do not have a bar code. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.

There are some key differences in the labeling between the U.S. FDA-approved products and the imported products. Please see the product comparison tables at the end of this letter for:

- Table 1. Key differences in 0.9% Sodium Chloride Injection
- Table 2. Key differences in 5% Dextrose Injection

Please refer to the FDA-approved package insert for the full prescribing information of each drug product as follows:

- 0.9% Sodium Chloride Injection, USP, in Viaflex plastic container (click here)
- 5% Dextrose Injection, USP, in Viaflex plastic container (click here)

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.

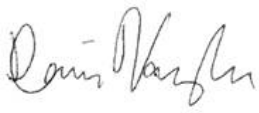
To place an order, please contact Baxter's Center for Service by calling 1-888-229-0001.

To report product quality issues, please contact Baxter Product Surveillance at 1-800-437-5176.

To report adverse events associated with these imported products, please call Baxter at 1-866-888-2472, or fax: 1-800-759-1801. Adverse events or quality problems experienced with the use of this product may also 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.

Sincerely,



Dennis Vaughn
Vice President, Marketing Operations
Baxter Healthcare Corporation

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Product Comparison Tables

Table 1. Key differences in 0.9% Sodium Chloride Injection

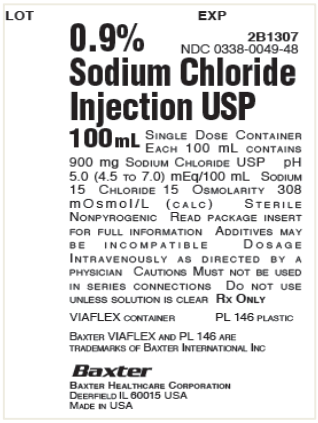
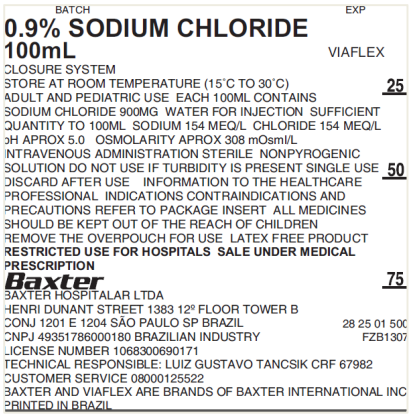
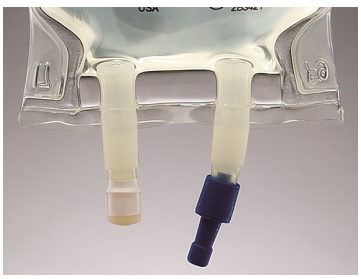
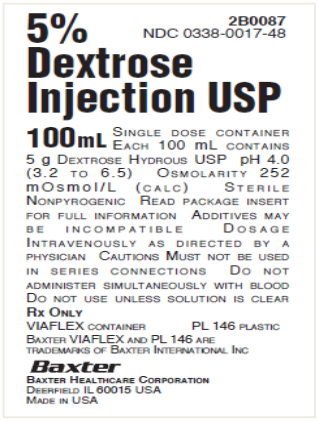
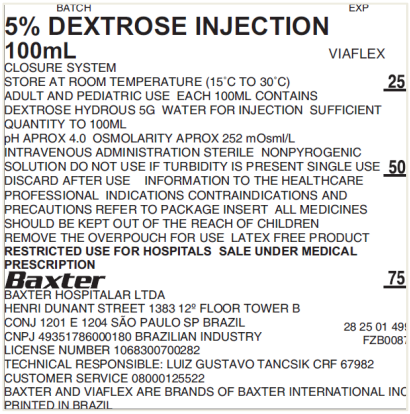
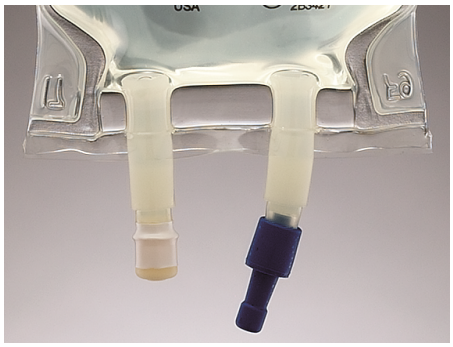
	US FDA approved product	Import product
		
Product name	**0.9% Sodium Chloride Injection, USP**	**0.9% Sodium Chloride Injection**
Indications	Sodium Chloride Injection, USP is indicated as a source of water and electrolytes. 0.9% Sodium Chloride Injection, USP is also indicated for use as a priming solution in hemodialysis procedures.	This solution is indicated for fluid and electrolyte replenishment. The solution is also used as a water and electrolyte repository in case of moderate metabolic alkalosis, sodium deficiency and as a drug diluent.
Active ingredients	Sodium 15 mEq/100 mL Chloride 15 mEq/100 mL Each 100 mL contains 900 mg Sodium chloride USP	Sodium 154 mEq/L (or 15.4 mEq/100 mL) Chloride 154 mEq/L (or 15.4 mEq/100 mL) Each 100 mL contains 900 mg Sodium chloride USP
Additional information	pH is 5.0 (4.5 to 7.0) Osmolarity 308 mOsmol/L (calc)	pH approx. 5.0 Osmolarity approx. 308 mOsm/L
Storage conditions	Stored at room temperature 25°C/77°F	Stored at room temperature (15°C to 30°C)
Container type	VIAFLEX Container (PVC)	VIAFLEX container (PVC)
Administration port closures	Pull off port protector (blue color) 	Pull off port protector (blue color) 

Table 2. Key differences in 5% Dextrose Injection

	US FDA approved product	Import product
		
Product name	**5% Dextrose Injection USP**	**5% Dextrose Injection**
Indications	Dextrose Injection, USP is indicated as a source of water and calories.	5% dextrose injection is indicated as source of water, calories and osmotic diuresis. 5% dextrose injection is indicated in cases of dehydration, caloric replacement, hypoglycemia and as a vehicle for dilution of compatible medicines. The 5% glucose solution is often the concentration used in fluid depletion and is usually administered through a peripheral vein.
Active ingredients	Each 100 mL contains 5 g Dextrose Hydrous USP	Each 100 mL contains Dextrose Hydrous 5g Water for Injection qs 100 mL
Additional information	pH is 4.0 (3.2 to 6.5) Osmolarity 252 mOsmol/L (calc)	pH approx. 4.0 Osmolarity approx 252 mOsm/L
Storage conditions	Stored at room temperature 25°C/77°F	Stored at room temperature (15°C to 30°C)
Container type	VIAFLEX Container (PVC)	VIAFLEX Container (PVC)
Administration port closures	Pull off port protector (blue color) 	Pull off port protector (blue color)