Important Prescribing Information

October 20. 2017

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 Mexico. 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 Mexico and marketed in Mexico. 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 Mexico.

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 in Water for Injection BAXTER in VIAFLEX plastic container	50 mL	ABB1306U	116	0338-9520-11
	100 mL	ABB1307U	72	0338-9525-72
5% Dextrose in Water for Injection BAXTER in VIAFLEX plastic container	50 mL	ABB0086U	116	0338-9521-11
	100 mL	ABB0087U	72	0338-9527-72

It is important to note the following:

- The imported product's administration port system is fully compatible with IV set spike heads on Baxter IV sets marketed in the United States.
- **The barcode may not register accurately on the U.S. scanning systems.** Institutions should manually input the product into their systems to confirm that barcode systems do not provide incorrect information when the product is scanned. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.

There are some differences in the labeling between the U.S. marketed products and the products manufactured in Mexico. Please see the product comparison tables at the end of this letter for:

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

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 (click here)
- 5% Dextrose Injection, USP (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

Product Comparison Tables

Table 1. Key differences in 0.9% Sodium Chloride Injection

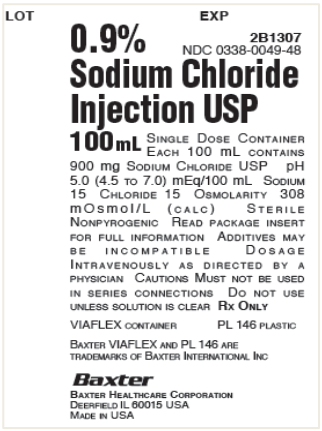
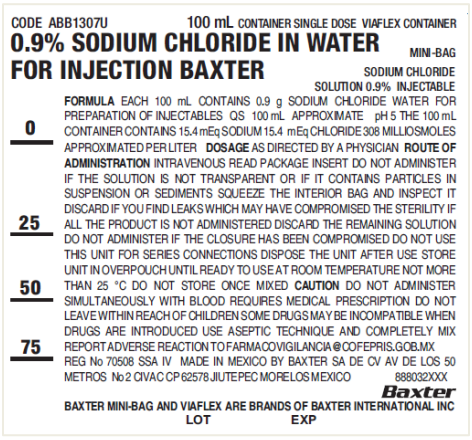
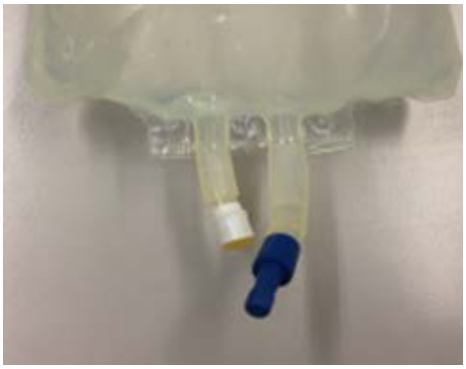
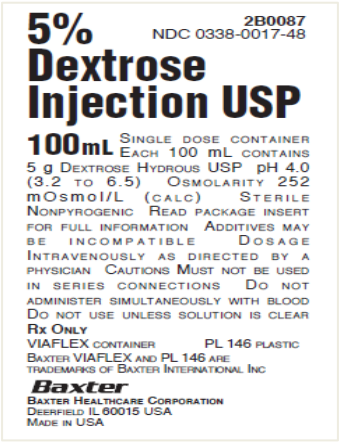
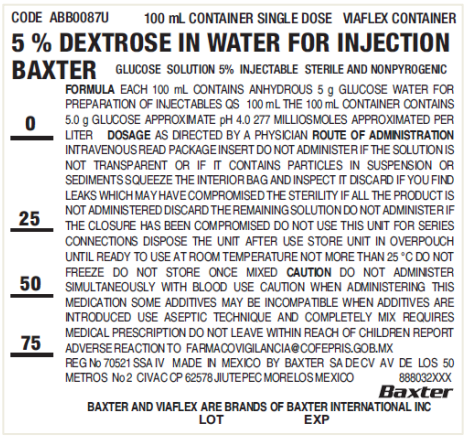
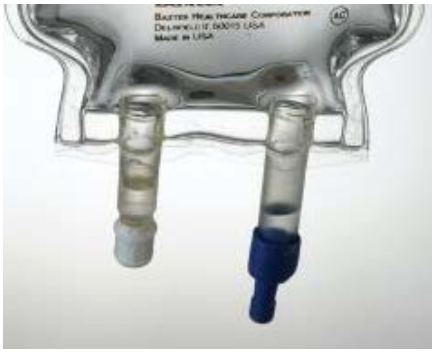
	US FDA approved product	Import product
		
Product name	**0.9% Sodium Chloride Injection, USP**	**0.9% Sodium Chloride in Water for Injection**
Indications	Sodium Chloride Injection, USP is indicated as a source of water and electrolytes. 0.9% Sodium Chloride Injection, USP is also indicated for use as a priming solution in hemodialysis procedures.	The 0.9% Sodium Chloride in Water for Injection Baxter solutions are indicated for cases of hypotonic dehydration with real hyponatremia. To recover or maintain the water-electrolyte balance. Hypochloraemic alkalosis. To solubilize and apply medication via intravenous infusion.
Active ingredients	Each 100 mL contains 900 mg Sodium Chloride USP	Each 100 mL contains Sodium Chloride 0.9 g
Additional information	pH is 5.0 (4.5 to 7.0) Osmolarity 308 mOsmol/L (calc) Sodium 15 mEq/100 mL Chloride 15 mEq/100 mL	pH 5.0 approximate Osmolality 308 mOsmol/ L (approx.) Sodium 15.4 mEq/100 mL Chloride 15.4 mEq/100 mL
Storage conditions	Stored at room temperature 25°C/77°F	Store at room temperature no more than 25°C. Do not freeze. Do not store once mixed
Container type	VIAFLEX Container (PVC)	VIAFLEX container
Administration port closures	Pull off port protector (blue color) 	Blue tip 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 in Water for Injection**
Indications	Dextrose Injection, USP is indicated as a source of water and calories.	The 5% Dextrose in Water for Injection solutions are indicated as a source of water and calories, in cases of plasma volume deficiency and serum electrolyte concentration, in cases of hypertonic dehydration (hypernatremia) to keep permeable vein.
Active ingredients*	Each 100 mL contains 5 g Dextrose Hydrous USP Each 50 mL contains 2.5 g Dextrose Hydrous USP	Each 100 mL contains Anhydrous Glucose 5 g Each 50 mL contains Anhydrous Glucose 2.5 g
Additional information	pH is 4.0 (3.2 to 6.5) Osmolarity 252 mOsmol/L (calc)	Approx. pH 4.0 Osmolality 277 mOsmol/L (approx.)
Storage conditions	Stored at room temperature 25°C/77°F	Store at room temperature no more than 25°C. Do not freeze. Do not store once mixed.
Container type	VIAFLEX Container (PVC)	VIAFLEX Container (PVC)
Administration port closures	Pull off port protector (blue color) 	Blue tip protector (blue color) 

* dextrose monohydrate (or glucose monohydrate) = anhydrous dextrose (or anhydrous glucose)