Baxter

Important Prescribing Information

October 9, 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 Australia. The information contained in this letter pertains only to the products listed below. You may be provided with additional letters depending on the products you receive. Please read each letter in its entirety because the letters may contain different information.

Baxter has initiated temporary importation of the products tabulated below. These products are manufactured by Baxter's manufacturing facility in Australia and primarily marketed in Australia. 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 Australia.

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

Product name and description	Size	Product code	NDC code
Sodium Chloride 0.9% Intravenous Infusion in VIAFLEX Container	100 mL	AHB1307	0338-9563-48
	50 mL	AHB1306A	0338-9567-60
Glucose 5% Intravenous Infusion* in VIAFLEX Container	100 mL	AHB0087	0338-9569-48
	50 mL	AHB0086A	0338-9573-60

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

There are some key differences in the labeling between the U.S. marketed 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
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- Table 2. Key differences in 5% Dextrose Injection

It is also important to note the following:

- **While the injection or medication ports are similar** across the FDA-approved products and the imported products, the administration port protector on the imported products must be twisted off rather than pulled off.

- The imported products' administration port system is fully compatible with IV set spike heads that meet the International Organization of Standardization (ISO) standards and with Baxter IV sets marketed in the United States.

- **Prior to use, it is important to check for leaks** by squeezing the inner bag firmly. If leaks are found, discard solution as sterility may be impaired. Additionally, check to see that solution is clear and free of foreign matter. Discard the solution if solution is not clear.

- **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.

The U.S. approved products are only available by prescription.

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

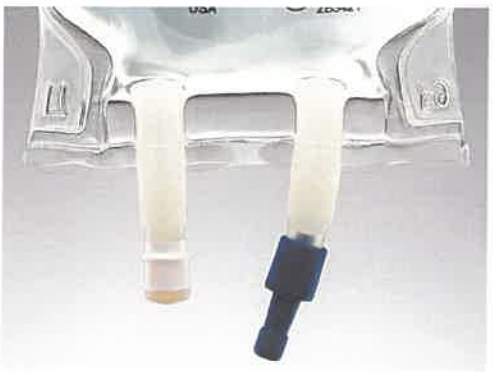
- Regular mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Sincerely,

Scott P. Luce
General Manager, US Hospital Products
Baxter Healthcare Corporation

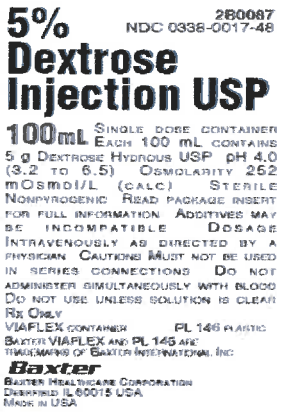
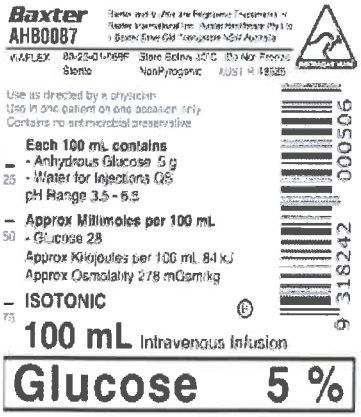
Product Comparison Tables

Table 1. Key differences in 0.9% Sodium Chloride Injection

	US FDA approved product	Import product
	LOT EXP 2B1307 **0.9% Sodium Chloride Injection USP** NDC 0338-0049-48 **100 mL** SINGLE DOSE CONTAINER EACH 100 mL CONTAINS 900 mg SODIUM CHLORIDE USP pH 5.0 (4.5 TO 7.0) mEq/100 mL SODIUM 15 CHLORIDE 15 OSMOLARITY 308 mOsmol/L (CALC) STERILE NONPYROGENIC READ PACKAGE INSERT FOR FULL INFORMATION ADDITIVES MAY BE INCOMPATIBLE DOSAGE INTRAVENOUSLY AS DIRECTED BY A PHYSICIAN CAUTIONS MUST NOT BE USED IN SERIES CONNECTIONS DO NOT USE UNLESS SOLUTION IS CLEAR Rx ONLY VIAFLEX CONTAINER PL 146 PLASTIC BAXTER VIAFLEX AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC Baxter BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA	Baxter AHB1307 VIAFLEX 88-26-01-100E Store Below 30°C Do Not Freeze Sterile NonPyrogenic AUST R 4A515 Use as directed by a physician Use in one patient on one occasion only Contains no antimicrobial preservative Each 100 mL contains - Sodium Chloride 900 mg - Water for Injections QS pH Range 4.0 - 7.0 Approx Millimoles per 100 mL - Sodium 15 - Chloride 15 Approx Osmolality 300 mOsm/kg ISOTONIC 100 mL Intravenous Infusion EAN 13 Barcode to be placed here 46 mm x 15mm 9318242000759 Sodium Chloride 0.9%
Product name	**0.9% Sodium Chloride Injection, USP**	**Sodium Chloride 0.9% Intravenous Infusion**
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.	Sodium Chloride (0.9%) Intravenous Infusion is indicated for extracellular fluid replacement and in the management of metabolic alkalosis in the presence of fluid loss, and for restoring or maintaining the concentration of sodium and chloride ions.
Active ingredients*	Sodium 15 mEq/100 mL Chloride 15 mEq/100 mL	Approx Millimoles per 100 mL: Sodium 15 Chloride 15
Additional information	pH is 5.0 (4.5 to 7.0) Osmolarity 308 mOsmol/L (calc)	pH Range 4.0-7.0 Approx Osmolality 300 mOsm/kg
Storage conditions	Stored at room temperature 25°C/77°F	Store below 30°C
Container type	VIAFLEX Container (PVC)	VIAFLEX container (PVC)
Administration port closures	Pull off port protector (blue color) 	Twist off port protector (blue color) 

* For monovalent ions, such as sodium and chloride, the numeric value of the millimole and milliequivalent are identical.

Table 2. Key differences in 5% Dextrose Injection

	US FDA approved product	Import product
		
Product name	**5% Dextrose Injection USP**	**Glucose 5% Intravenous Infusion**
Indications	Dextrose Injection, USP is indicated as a source of water and calories.	Isotonic (Glucose 5%) intravenous infusions are mainly indicated: • Whenever non-electrolyte fluid replacement is required. • As a vehicle for drug delivery, provided that the added components are compatible with glucose.
Active ingredients*	Each 100 mL contains 5 g Dextrose Hydrous USP Each 50 mL c contains 2.5 g Dextrose Hydrous USP	Each 100 mL contains Anhydrous Glucose 5g Each 50 mL contains Anhydrous Glucose 2.5g Water for Injections
Additional information	pH is 4.0 (3.2 to 6.5) Osmolarity 252 mOsmol/L (calc)	pH Range 4.0-7.0 Approx Osmolality 300 mOsm/kg
Storage conditions	Stored at room temperature 25°C/77°F	Store Below 30°C
Container type	VIAFLEX Container (PVC)	VIAFLEX Container (PVC)
Administration port closures	Pull off port protector (blue color) 	Twist off port protector (blue color) 

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