Important Prescribing Information

January 31, 2018

Subject: Temporary importation of intravenous (IV) fluid drug products

Dear Healthcare Professional,

The purpose of this letter is to inform you of additional large volume parenteral (LVP) IV fluid drug products that Baxter will be importing in the United States (U.S.) to ensure supply continuity of these products. 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. 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 are 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)	250 mL	FZB1322	50	0338-9517-50
	500 mL	FZB1323	30	0338-9517-30
	1,000 mL	FZB1324	16	0338-9517-16

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.

- **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 key differences in the labeling between the U.S. 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. Label images of 0.9% Sodium Chloride Injection

Please refer to the FDA-approved package insert for the full prescribing information of 0.9% Sodium Chloride 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,

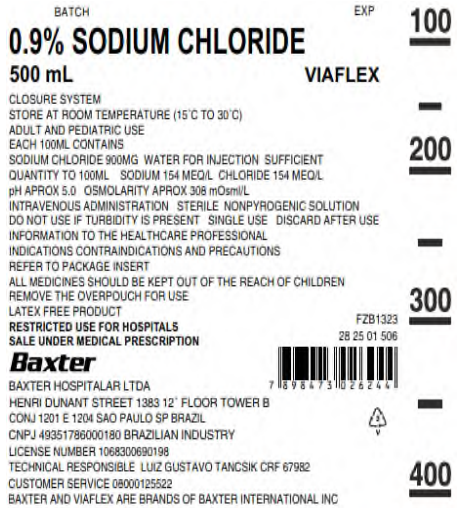
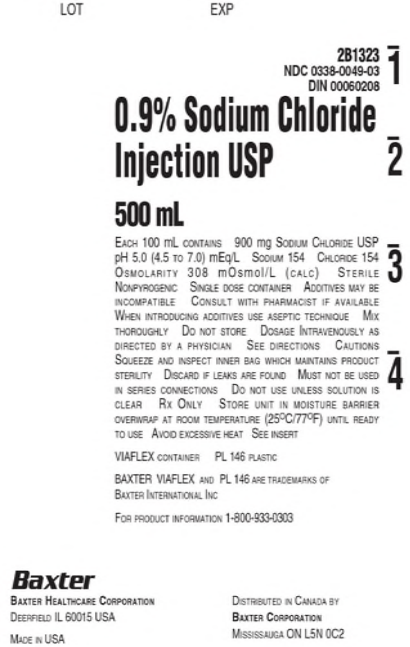
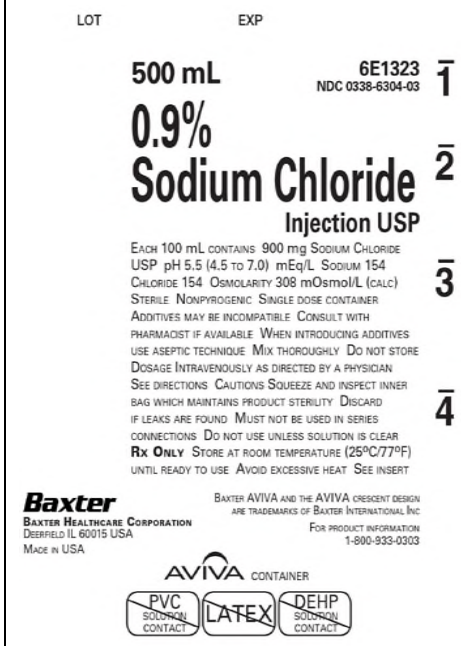
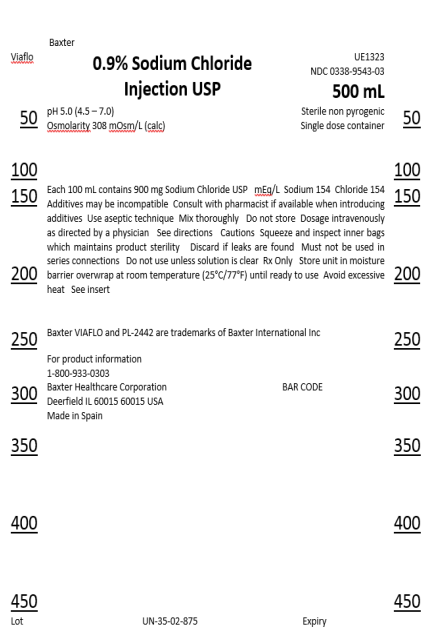
Dennis Vaughn
Vice President, Marketing Operations
Baxter Healthcare Corporation

Product Comparison Table

Table 1. Key differences in 0.9% Sodium Chloride Injection

	Import product	US FDA approved product		
Product name	**0.9% Sodium Chloride Injection**	**0.9% Sodium Chloride Injection, USP**		
Indications	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.	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.		
Active ingredients	Sodium 154 mEq/L Chloride 154 mEq/L Each 100 mL contains 900 mg Sodium chloride	Sodium 154 mEq/L Chloride 154 mEq/L Each 100 mL contains 900 mg Sodium chloride USP		
Additional information	pH approx. 5.0 (4.5 – 7.0) Osmolarity approx. 308 mOsm/L	pH is 5.0 (4.5 to 7.0) Osmolarity 308 mOsmol/L (calc)		
Storage conditions	Store at room temperature (15°C to 30°C)	Store at room temperature 25°C/77°F		
Container type	VIAFLEX (PVC)	VIAFLEX (PVC)	AVIVA (non-PVC)	VIAFLO (non-PVC)
Administration port closures	Pull off port protector (blue color) 	Pull off port protector (blue color) 	Pull off port protector (natural/gum color) 	Twist off port protector (white) 

Table 2. Label images of 0.9% Sodium Chloride Injection products*

Imported product	US FDA approved product		
0.9% Sodium Chloride Injection	0.9% Sodium Chloride Injection, USP		
VIAFLEX (PVC)	**VIAFLEX (PVC)**	**AVIVA (non-PVC)**	**VIAFLO (non-PVC)****
			

* Comparison of 500 mL container labels is provided as a representative sample. Labels are similar across product sizes.

** Viaflo product codes may carry a “D” suffix (e.g., UE1323D)