

## **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 <u>here</u>)

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

Dan Marken

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	
	D.9% NDC 0338-0049-48  Sodium Chloride Injection USP  100mL Single Dose Container Each 100 mL container Each 100 mL container 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 Nonytrogenic Read package insert For full information Additives may be incompatible Dosage Intravenously as directed by a physician Cauttons Must not be used in series connections Do not use unless solutions is clear Rx Only VIAFLEX container Baxter MaFlex and PL 146 prestic Baxter MaFlex and PL 146 are Tragemans of Baxter International Derpresent 60015 USA Made in USA	BATCH  0.9% SODIUM CHLORIDE  100mL  VIAFLEX  CLOSURE SYSTEM STORE AT ROOM TEMPERATURE (15°C TO 30°C)  ADULT AND PEDIATRIC USE EACH 100ML CONTAINS  SODIUM CHLORIDE 3000MG WATER FOR INJECTION SUFFICIENT COUNTY TO 100ML SODIUM 154 MEO/L CHLORIDE 154 MEO/L  HAPROX 5.0 OSMOLARITY APROX 308 MOSMILL  INTRAVENOUS ADMINISTRATION STERILE NONPYROGENIC  SOLUTION DO NOT USE IF TURBIDITY IS PRESENT SINGLE USE  DISCARD AFTER USE INFORMATION TO THE HEALTHCARE PROFESSIONAL INDICATIONS CONTRIAINDICATIONS AND PRECAUTIONS REFER TO PACKAGE INSERT ALL MEDICINES  SHOULD BE KEPT OUT OF THE REACH OF CHILDREN  REMOVE THE OVERPOUCH FOR USE LATEX FRIEE PRODUCT RESTRICTED USE FOR HOSPITIALS SALE UNDER MEDICAL PRESCRIPTION  BAXTER  AXTER HOSPITALAR LITDA HENRI DUNANT STREET 1383 12° FLOOR TOWER B  CONJ 1201 E 1204 SAO PAULO SP BRAZIL  CENSE SUMBER 1068300690171  TECHNICAL RESPONSIBLE: LUIZ GUSTAVO TANCSIK CRF 67982 CUSTOMER SERVICE 08000125522  BAXTER AND VIAFLEX ARE BRANDS OF BAXTER INTERNATIONAL INC PRINTED IN BRAZIL	
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	
	5% NDC 0338-0017-48  Dextrose Injection USP  100mL Single dose container Lack 100mL contains 5 g Dextrose Hydroug USP pH 4.0 (3.2 to 6.5) Osmolarity 252 mOsmol/L (ca.c) Stefile Nonpyrogenic Read packade insent for full information Additives may be incompatible Dosage Intravenously as directed by a physician Cautions Must not be used in senies connections Do not administer simultaneously with blood Do not use unless solution is clear Rx Only ViAFLEX container PL 146 are trademined of Baxter Hallexand PL 146 are trademined Deserved D	5% DEXTROSE INJECTION  100mL VIAFLEX CLOSURE SYSTEM STORE AT ROOM TEMPERATURE (15°C TO 30°C) ADULT AND PEDIATRIC USE EACH 100ML CONTAINS DEXTROSE HYDROUS 5G WATER FOR INJECTION SUFFICIENT QUANTITY TO 100ML ph APPROX 40 OSMOLARITY APROX 252 mOsmill INTRAVENOUS ADMINISTRATION STERILE NOMPYROGENIC SOLUTION DO NOT USE IF TURBIDITY IS PRESENT SINGLE USE 50 DISCARD AFTER USE INFORMATION TO THE HEALTHCARE PROFESSIONAL INDICATIONS CONTRIAINDICATIONS AND PRECAUTIONS REFER TO PACKAGE INSERT ALL MEDICINES SHOULD BE KEPT OUT OF THE REACH OF CHILDREN REMOVE THE OVERPOUCH FOR USE LATEX FREE PRODUCT RESTRICTED USE FOR HOSPITALS SALE UNDER MEDICAL PRESCRIPTION  PRESCRIPTION  AT 100 PROVIDED TO	
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)	