

SODIUM CHLORIDE- sodium chloride injection
Baxter Healthcare Corporation

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

0.9% Sodium Chloride Injection
(VIAFLEX Container)

Health Care Provider Letter

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

Baxter and Viaflex are trademarks of Baxter International Inc.

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)**
<p>BATCH EXP <u>100</u></p> <p>0.9% SODIUM CHLORIDE 500 mL VIAFLEX</p> <p>CLOSURE SYSTEM STORE AT ROOM TEMPERATURE (15°C TO 30°C) ADULT AND PEDIATRIC USE EACH 100mL CONTAINS <u>200</u></p> <p>SODIUM CHLORIDE 900mg WATER FOR INJECTION SUFFICIENT QUANTITY TO 100mL SODIUM 154 MEQ/L CHLORIDE 154 MEQ/L pH APPROX 5.0 OSMOLARITY APPROX 308 mOsm/L</p> <p>INTRAVENOUS ADMINISTRATION: STERILE, NONPYROGENIC SOLUTION DO NOT USE IF TURBIDITY IS PRESENT. SINGLE USE. DISCARD AFTER USE INFORMATION TO THE HEALTHCARE PROFESSIONAL INDICATIONS, CONTRAINDICATIONS AND PRECAUTIONS REFER TO PACKAGE INSERT</p> <p>ALL MEDICINES SHOULD BE KEPT OUT OF THE REACH OF CHILDREN REMOVE THE OVERSPOON FOR USE</p> <p>LATEX FREE PRODUCT</p> <p>RESTRICTED USE FOR HOSPITALS SALE UNDER MEDICAL PRESCRIPTION</p> <p>Baxter BAXTER HOSPITALAR LTDA HENRI DUNANT STREET 1383 12° FLOOR TOWER B CONJ 1311 E 1106 SÃO PAULO SP BR/042L CNPJ 49351786/000180 BRAZILIAN INDUSTRY LICENSE NUMBER 10683069/018 TECHNICAL RESPONSIBLE: LUIZ GUSTAVO TANCSKI CRF 67362 CUSTOMER SERVICE 0800210522 BAXTER AND VIAFLEX ARE BRANDS OF BAXTER INTERNATIONAL INC</p> <p>F291323 28 25 01 506</p> <p><u>300</u></p> <p><u>400</u></p>	<p>LOT EXP</p> <p>NDC 0338-0049-03 281323 281323</p> <p>0.9% Sodium Chloride Injection USP 500 mL</p> <p>Each 100 mL contains 900 mg Sodium Chloride USP pH 5.0 (4.5 to 7.0) mEq/L Sodium 154 Chloride 154 Osmolality 308 mOsmol/L (calc.) Sterile Nonpyrogenic Squeeze dose container Additives may be incompatible Consult with pharmacist if available When introducing additives use aseptic technique Mix thoroughly Do not store Dilute intravenously as directed by a physician See directions Cautions Squeeze and inspect inner bag which maintains product sterility Discard if leaks are found Must not be used in series connections Do not use unless solution is clear Rx Only Store unit in moisture barrier container at room temperature (20°C/77°F) until ready to use Avoid excessive heat See insert</p> <p>VIAFLEX container PL 146 plastic BAXTER VIAFLEX and PL 146 are trademarks of Baxter International Inc</p> <p>For product information 1-800-893-0303</p> <p>Baxter Baxter Healthcare Corporation Drexel Hill, 69015 USA Made in USA</p> <p>Distributed in Canada by Baxter Corporation Mississauga ON L5N 9C2</p>	<p>LOT EXP</p> <p>500 mL 6E1323 NDC 0338-0304-03</p> <p>0.9% Sodium Chloride Injection USP</p> <p>Each 100 mL contains 900 mg Sodium Chloride USP pH 5.5 (4.5 to 7.0) mEq/L Sodium 154 Chloride 154 Osmolality 308 mOsmol/L (calc.) Sterile Nonpyrogenic Squeeze dose container Additives may be incompatible Consult with pharmacist if available When introducing additives use aseptic technique Mix thoroughly Do not store Dilute intravenously as directed by a physician See directions Cautions Squeeze and inspect inner bag which maintains product sterility Discard if leaks are found Must not be used in series connections Do not use unless solution is clear Rx Only Store at room temperature (25°C/77°F) until ready to use Avoid excessive heat See insert</p> <p>Baxter BAXTER HEALTHCARE CORPORATION Drexel Hill, 69015 USA Made in USA</p> <p>Baxter AVIVA and the AVIVA design design are trademarks of Baxter International Inc</p> <p>For product information 1-800-893-0303</p> <p>AVIVA CONTAINER</p> <p>PVC SOFTENING CONTACT LATEX DEHP SOFTENING CONTACT</p>	<p>Baxter 0.9% Sodium Chloride Injection USP U13233 NDC 0338-0049-03 500 mL</p> <p>50 pH 5.0 (4.5 - 7.0) Osmolality 308 mOsmol/L (calc.) Baxter non pyrogenic Single dose container <u>50</u></p> <p>100 Each 100 mL contains 900 mg Sodium Chloride USP (90mg/L Sodium 154 Chloride 154 Additives may be incompatible Consult with pharmacist if available when introducing additives Use aseptic technique Mix thoroughly Do not store Dilute intravenously as directed by a physician See directions Cautions Squeeze and inspect inner bag which maintains product sterility Discard if leaks are found Must not be used in series connections Do not use unless solution is clear Rx Only Store unit in moisture barrier container at room temperature (20°C/77°F) until ready to use Avoid excessive heat See insert <u>100</u></p> <p>150 <u>150</u></p> <p>200 <u>200</u></p> <p>250 Baxter VIAFLO and PL 2442 are trademarks of Baxter International Inc <u>250</u></p> <p>For product information 1-800-893-0303 Baxter Healthcare Corporation Drexel Hill, 69015 69023 USA Made in Spain <u>300</u></p> <p>350 <u>350</u></p> <p>400 <u>400</u></p> <p>450 <u>450</u></p> <p>Lot UN-03-02-875 Injpy</p>

* 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)

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

BATCH EXP **100**
0.9% SODIUM CHLORIDE
500 mL VIAFLEX

CLOSURE SYSTEM —
STORE AT ROOM TEMPERATURE (15°C TO 30°C)
ADULT AND PEDIATRIC USE
EACH 100ML CONTAINS **200**
SODIUM CHLORIDE 900MG WATER FOR INJECTION SUFFICIENT
QUANTITY TO 100ML SODIUM 154 MEQ/L CHLORIDE 154 MEQ/L
pH APROX 5.0 OSMOLARITY APROX 308 mOsm/L
INTRAVENOUS ADMINISTRATION STERILE NONPYROGENIC SOLUTION
DO NOT USE IF TURBIDITY IS PRESENT SINGLE USE DISCARD AFTER USE
INFORMATION TO THE HEALTHCARE PROFESSIONAL —
INDICATIONS CONTRAINDICATIONS AND PRECAUTIONS
REFER TO PACKAGE INSERT
ALL MEDICINES SHOULD BE KEPT OUT OF THE REACH OF CHILDREN
REMOVE THE OVERPOUCH FOR USE **300**
LATEX FREE PRODUCT
RESTRICTED USE FOR HOSPITALS
SALE UNDER MEDICAL PRESCRIPTION

Baxter FZB1323 28 25 01 506
BAXTER HOSPITALAR LTDA 7 8 9 8 4 7 3 0 2 6 2 4 4
HENRI DUNANT STREET 1383 12° FLOOR TOWER B
CONJ 1201 E 1204 SAO PAULO SP BRAZIL
CNPJ 49351786000180 BRAZILIAN INDUSTRY
LICENSE NUMBER 1068300690198
TECHNICAL RESPONSIBLE LUIZ GUSTAVO TANCSIK CRF 67982
CUSTOMER SERVICE 08000125522
BAXTER AND VIAFLEX ARE BRANDS OF BAXTER INTERNATIONAL INC **400**

LAYOUT NÃO ESTÁ NO TAMANHO ORIGINAL

BATCH
EXP
0.9% SODIUM CHLORIDE
500 mL
VIAFLEX
CLOSURE SYSTEM
STORE AT ROOM TEMPERATURE (15°C TO 30°C)
ADULT AND PEDIATRIC USE
EACH 100ML CONTAINS
SODIUM CHLORIDE 900MG WATER FOR INJECTION SUFFICIENT
QUANTITY TO 100ML SODIUM 154 MEQ/L CHLORIDE 154 MEQ/L
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BAXTER Logo
BAXTER HOSPITALAR LTDA
HENRI DUNANT STREET 1383 12° FLOOR TOWER B

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100
200
300
400
 FZB1323
 28 25 01 506

SODIUM CHLORIDE

sodium chloride injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0338-9517
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	900 mg in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-9517-50	50 in 1 CARTON	01/31/2018	
1		250 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:0338-9517-30	30 in 1 CARTON	01/31/2018	
2		500 mL in 1 BAG; Type 0: Not a Combination Product		
3	NDC:0338-9517-16	16 in 1 CARTON	01/31/2018	
3		1000 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		01/31/2018	

Labeler - Baxter Healthcare Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Hospitalar Ltda.		900203175	ANALYSIS(0338-9517) , MANUFACTURE(0338-9517) , LABEL(0338-9517) , PACK(0338-9517) , STERILIZE(0338-9517)

Revised: 1/2018

Baxter Healthcare Corporation