

Important Prescribing Information

October 21, 2024

Subject: Temporary importation of 0.9% Sodium Chloride Injection, 5% and 10% Glucose Injection, and 5% Glucose/0.9% Sodium Chloride Injection from Shanghai, China, labeled in English to address drug shortages

Dear Healthcare Professional,

To prevent a drug shortage of large volume parenteral fluid drug products, Baxter Healthcare Corporation (Baxter) is coordinating with the U.S. Food and Drug Administration (FDA) to temporarily import 0.9% Sodium Chloride Injection (250 mL and 1,000 mL), 5% Glucose Injection (250 mL and 1,000 mL), 10% Glucose Injection (250 mL), and 5% Glucose/0.9% Sodium Chloride Injection (1,000 mL) from Baxter's manufacturing facility in Shanghai, China. FDA has not approved these products manufactured by Baxter's Shanghai facility.

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.

At this time, no other entity except Baxter is authorized by the FDA to import or distribute these products in the United States.

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

Product name and description	Size	Product code	Bags per carton	NDC code of a single bag
0.9% Sodium Chloride Injection	250 mL	A6C1322US	40	0338-9791-01
	500 mL	A6C1323US	24	0338-9808-01
	1,000 mL	A6C1324US	12	0338-9793-01
5% Glucose Injection	250 mL	A6C0062US	40	0338-9795-01
	1,000 mL	A6C0064US	12	0338-9801-01
10% Glucose Injection	250 mL	A6C0162US	40	0338-9797-01
5% Glucose/0.9% Sodium Chloride Injection	1,000 mL	A6C1064US	12	0338-9799-01

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 the table above. Parenteral drug products should be inspected visually for particulate matter and bag defects prior to administration, whenever solution or container permits.

USE A NEW BAG IF PARTICULATES ARE VISIBLE OR IF THE IV BAG CONTAINS A LEAK.

- The imported products' administration port system is fully compatible with Baxter sets marketed in the United States.
- The products listed in the table above contain black barcodes (versus the white barcode on the approved product) and the barcode has been placed in a different position. The barcode on the imported product is encoded with the National Drug Code (NDC) that is specific to the imported product. However, the barcodes may not register accurately in the U.S. scanning systems. Institutions should manually input the product into their systems to ensure that barcode systems do not provide incorrect information when the product is scanned. Alternative procedures should be followed to ensure that the correct drug product is being used in all systems and processes and administered to individual patients
- The 250 mL product is compatible for admixing with Baxter's Vial-mate product.
- The imported product uses a carton box that is taped closed. To avoid damage to the solution container, take care not to use sharp instruments to open the carton.
- Dextrose, USP is a hydrated form of glucose. The imported glucose product is an anhydrous form of glucose. **Therefore on an energy content per mL basis,**
 - **5% Glucose/0.9% Sodium Chloride Injection (0.20 kcal/mL) is NOT equivalent to 5% Dextrose and 0.9% Sodium Chloride Injection USP (0.17 kcal/mL),**
 - **5% Glucose Injection (0.20 kcal/mL) is NOT equivalent to 5% Dextrose Injection USP (0.17 kcal/mL),**
 - **10% Glucose Injection (0.40 kcal/mL) is NOT equivalent to 10% Dextrose Injection USP (0.34 kcal/mL).**
- **The imported glucose containing products are NOT directly interchangeable with dextrose containing injections USP.** Protocols, order entry, and compounding systems will need to be adjusted.
- 0.9% Sodium Chloride Injection USP, 5% Dextrose Injection USP, 10% Dextrose Injection USP, and 5% Dextrose/0.9% Sodium Chloride Injection USP are available only by prescription in the U.S. However, the imported products do not have the statement "Rx only" on the labeling.

Additional key differences in the labeling between the FDA-approved products and the imported products are stated in the product comparison tables at the end of this letter as follows:

- Table 1 Key differences between FDA-approved and imported 0.9% Sodium Chloride Injection USP
- Table 2 Label images of FDA-approved and imported 0.9% Sodium Chloride Injection USP
- Table 3 Key differences between FDA-approved 5% Dextrose Injection USP and imported 5% Glucose Injection
- Table 4 Label images of FDA-approved 5% Dextrose Injection USP and imported 5% Glucose Injection
- Table 5 Key differences between FDA-approved 5% Dextrose Injection USP and imported 5% Glucose Injection
- Table 6 Label images of FDA-approved 10% Dextrose Injection USP and imported 10% Glucose Injection
- Table 7 Key differences between FDA-approved 5% Dextrose/0.9% Sodium Chloride Injection USP and imported 5% Glucose/0.9% Sodium Chloride Injection
- Table 8 Label images of FDA-approved 5% Dextrose/0.9% Sodium Chloride Injection USP and imported 5% Glucose/0.9% Sodium Chloride Injection

Reporting Adverse Events or Product Quality Issues

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 these imported products 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.

To report **product quality issues** associated with these imported products, please contact Baxter Product Surveillance through Baxter - Product Feedback Portal (<https://productfeedback.baxter.com/>).

Please also refer to the local prescribing information of the imported product, translated into English, available for:

- 0.9% Sodium Chloride Injection (click [here](#))
- 5% Glucose Injection (click [here](#))
- 10% Glucose Injection (click [here](#))
- 5% Glucose/0.9% Sodium Chloride Injection (click [here](#))


Please refer to the FDA-approved prescribing information for each drug product listed below:

- 0.9% Sodium Chloride Injection USP (click [here](#))
- 5% Dextrose Injection USP (click [here](#))
- 10% Dextrose Injection USP (click [here](#))
- 5% Dextrose/0.9% Sodium Chloride 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 at 1-888-229-0001.

Sincerely,


[Lee Ann Schuette \(Oct 21, 2024 10:10 CDT\)](#)

Lee Ann Schuette
VP Global and US Marketing IV solutions, Clinical Nutrition, Pharmacy Tools
Baxter Healthcare Corporation

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Product Comparison Table

Table 1 Key differences between FDA-approved and imported 0.9% Sodium Chloride Injection USP



	FDA-approved product	Imported product from Shanghai, China
Product name	0.9% Sodium Chloride Injection USP	0.9% Sodium Chloride Injection
Label volume	100 mL; 150 mL; 250 mL; 500 mL; 1000 mL	250 mL; 500 mL; 1000 mL
Language of the Labels	English	English
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 Injection is indicated as a source of water and electrolytes.
Active ingredients	Each 100 mL contains 900 mg Sodium Chloride, USP	Each 100 mL contains 900 mg Sodium Chloride
Additional information	pH is 5.0 (4.5 to 7.0) Osmolarity 308 mOsm/L (calc)	pH is 5.0 (4.5 to 7.0) Osmolarity 308 mOsm/L (calc)
Storage conditions	Store at room temperature 25°C/77°F.	Store at room temperature 15°C/59°F. to 30°C/86°F.
Container type	VIAFLEX (PVC)	IVINA (non-PVC)
Medication and Administration port closures	Contains medication port and administration port; Pull off port protector (blue color), right side 	Contains medication port and administration port; Twist off port protector (white color), left side 

Table 2 Label images of FDA-approved and imported 0.9% Sodium Chloride Injection USP

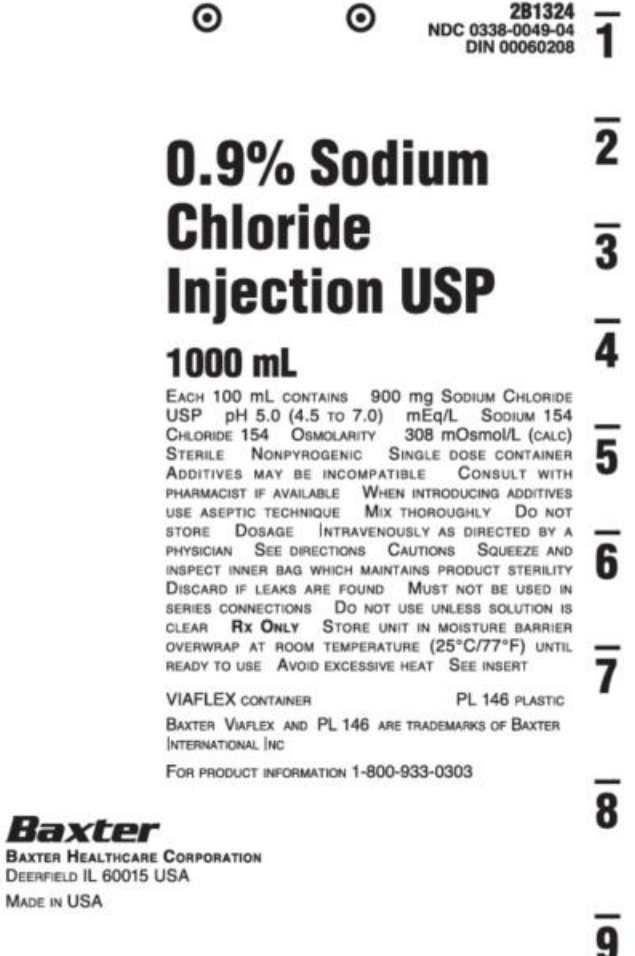
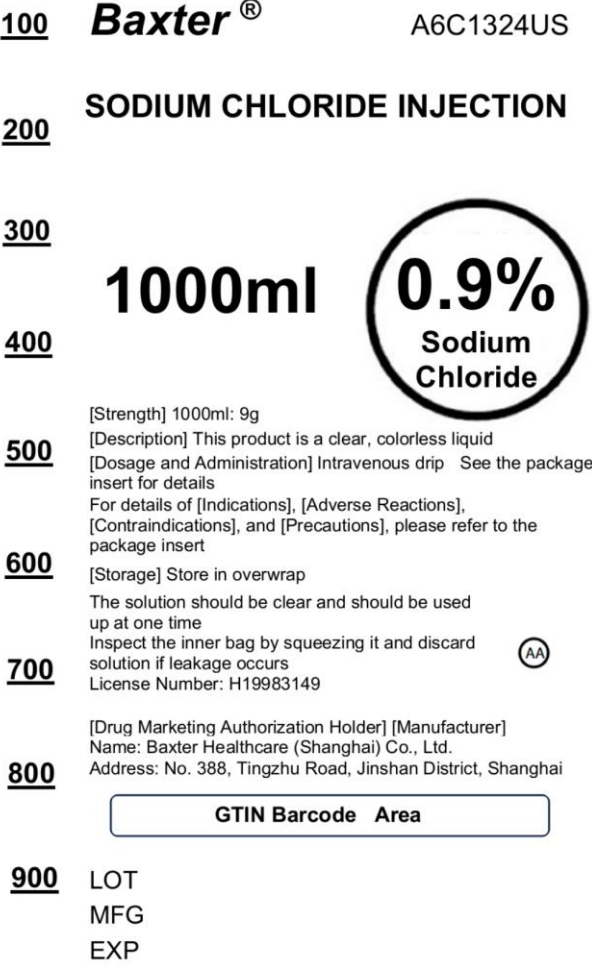
FDA-approved product	Imported product from Shanghai, China
0.9% Sodium Chloride Injection USP	0.9% Sodium Chloride Injection
<p>Label Color: Black. Barcode not shown. 1000 mL shown as representative label.</p>	<p>Label Color: Black. 1000 mL shown as representative label. Imported product contains the NDC number, which is not yet shown below. Barcode location is shown and will contain a linear barcode with human readable information.</p>
 <p>2B1324 NDC 0338-0049-04 DIN 00060208</p> <p>0.9% Sodium Chloride Injection USP 1000 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 OSMOLARITY 308 mOsmol/L (CALC) STERILE NONPYROGENIC SINGLE DOSE CONTAINER ADDITIVES MAY BE INCOMPATIBLE CONSULT WITH PHARMACIST IF AVAILABLE WHEN INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE MIX THOROUGHLY DO NOT STORE DOSAGE 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 OVERWRAP AT ROOM TEMPERATURE (25°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 FOR PRODUCT INFORMATION 1-800-933-0303</p> <p>Baxter BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA</p>	 <p><u>100</u> Baxter[®] A6C1324US</p> <p><u>200</u> SODIUM CHLORIDE INJECTION</p> <p><u>300</u> 1000ml 0.9% Sodium Chloride</p> <p><u>400</u></p> <p><u>500</u> [Strength] 1000ml: 9g [Description] This product is a clear, colorless liquid [Dosage and Administration] Intravenous drip See the package insert for details For details of [Indications], [Adverse Reactions], [Contraindications], and [Precautions], please refer to the package insert</p> <p><u>600</u> [Storage] Store in overwrap The solution should be clear and should be used up at one time Inspect the inner bag by squeezing it and discard solution if leakage occurs (AA) License Number: H19983149</p> <p><u>700</u></p> <p><u>800</u> [Drug Marketing Authorization Holder] [Manufacturer] Name: Baxter Healthcare (Shanghai) Co., Ltd. Address: No. 388, Tingzhu Road, Jinshan District, Shanghai</p> <p>GTIN Barcode Area</p> <p><u>900</u> LOT MFG EXP</p>

Table 3 Key differences between FDA-approved 5% Dextrose Injection USP and imported 5% Glucose Injection



	FDA-approved product	Imported product from Shanghai, China
Product name	5% Dextrose Injection USP	5% Glucose Injection
Label volume	250 mL, 1000 mL	250 mL, 1000 mL
Language of the Labels	English	English
Indications	Dextrose Injection, USP is indicated as a source of water and calories.	Glucose Injection is indicated as a source of water and calories.
Active ingredients	Each 100 mL contains 5 g Dextrose Hydrus USP	Each 100 mL contains 5 g Anhydrous Glucose
Additional information	pH 4.0 (3.2 to 6.5) Osmolarity 252 mOsmol/L (calc)	4.0 (3.2 to 6.5) Osmolarity 278 mOsmol/L (calc)
Caloric content	170 kcal/L	200 kcal/L
Storage conditions	Store at room temperature 25°C/77°F.	Store at room temperature 15°C/59°F. to 30°C/86°F.
Container type	VIAFLEX (PVC)	IVINA (non-PVC)
Medication and Administration port closures	Contains medication port and administration port; Pull off port protector (blue color), right side 	Contains medication port and administration port; Twist off port protector (white color), left side 

Table 4 Label images of FDA-approved 5% Dextrose Injection USP and imported 5% Glucose Injection

FDA-approved product	Imported product from Shanghai, China
5% Dextrose Injection USP	5% Glucose Injection
<p>Label Color: Black. Barcode not shown. 1000 mL shown as representative label.</p>	<p>Label Color: Black. 1000 mL shown as representative label. Imported product contains the NDC number, which is not yet shown below. Barcode location is shown and will contain a linear barcode with human readable information.</p>

Table 5 Key differences between FDA-approved 10% Dextrose Injection USP and imported 10% Glucose Injection



	FDA-approved product	Imported product from Shanghai, China
Product name	10% Dextrose Injection USP	10% Glucose Injection
Label volume	250 mL	250 mL
Language of the Labels	English	English
Indications	Dextrose Injection, USP is indicated as a source of water and calories.	Glucose Injection is indicated as a source of water and calories.
Active ingredients	Each 100 mL contains 10 g Dextrose Hydrous USP	Each 100 mL contains 10 g Anhydrous Glucose
Additional information	pH 4.0 (3.2 to 6.5) Osmolarity 505 mOsmol/L (calc)	pH 4.0 (3.2 to 6.5) Osmolarity 555 mOsmol/L (calc)
Caloric content	340 kcal/L	400 kcal/L
Storage conditions	Store at room temperature 25°C/77°F.	Store at room temperature 15°C/59°F. to 30°C/86°F.
Container type	VIAFLEX (PVC)	IVINA (non-PVC)
Medication and Administration port closures	Contains medication port and administration port; Pull off port protector (blue color), right side 	Contains medication port and administration port; Twist off port Protector (white color), left side 

Table 6 Label images of FDA-approved 10% Dextrose Injection USP and imported 10% Glucose Injection

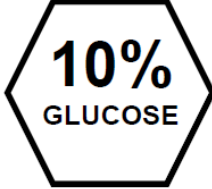
US-FDA approved product	Imported product from Shanghai, China
10% Dextrose Injection USP	10% Glucose Injection
Label Color: Black. Barcode not shown.	Label Color: Black. Imported product contains the NDC number, which is not yet shown below. Barcode location is shown and will contain a linear barcode with human readable information.
<p style="text-align: center;">LOT EXP</p> <p style="text-align: right;">280162 NDC 0338-0023-02</p> <h1 style="text-align: center;">10% Dextrose Injection USP</h1> <div style="display: flex; justify-content: space-between;"> <div style="width: 80%;"> <p>250 mL EACH 100 mL CONTAINS 10 g DEXTROSE HYDROUS USP pH 4.0 (3.2 TO 6.5) HYPERTONIC OSMOLARITY 505 mOsmol/L (CALC) STERILE NONPYROGENIC SINGLE DOSE CONTAINER ADDITIVES MAY BE INCOMPATIBLE CONSULT WITH PHARMACIST IF AVAILABLE WHEN INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE MIX THOROUGHLY DO NOT STORE DOSAGE 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 ADMINISTER SIMULTANEOUSLY WITH BLOOD DO NOT USE UNLESS SOLUTION IS CLEAR Rx ONLY STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°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>Baxter BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA</p> <p style="text-align: right;">FOR PRODUCT INFORMATION 1-800-933-0303</p> </div> <div style="width: 15%; text-align: center;"> <p><u>50</u></p> <p><u>100</u></p> <p><u>150</u></p> <p><u>200</u></p> </div> </div>	<p style="text-align: center;">Baxter® A6C0162US</p> <h2 style="text-align: center;">GLUCOSE INJECTION</h2> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <p><u>50</u></p> <p>250ml</p> <p><u>100</u></p> <p><u>150</u></p> <p><u>200</u></p> </div> <div style="text-align: center;">  </div> </div> <p>[Strength] 250ml: 25g [Description] This product is a clear, colorless or almost colorless liquid [Dosage and Administration] Intravenous drip See the package insert for details For details of [Indications], [Adverse Reactions], [Contraindications], and [Precautions], please refer to the package insert</p> <p>[Storage] Store in overwrap The solution should be clear and should be used up at one time Inspect the inner bag by squeezing it and discard solution if leakage occurs (AA) License Number: H19994063</p> <p>[Drug Marketing Authorization Holder] [Manufacturer] Name: Baxter Healthcare (Shanghai) Co., Ltd. Address: No. 388, Tingzhu Road, Jinshan District, Shanghai</p> <div style="border: 1px solid black; padding: 5px; text-align: center; margin: 10px auto; width: 150px;"> <p>GTIN Barcode Area</p> </div> <p style="text-align: center;">LOT MFG EXP</p>

Table 7 Key differences between FDA-approved 5% Dextrose/0.9% Sodium Chloride Injection USP and imported 5% Glucose/0.9% Sodium Chloride Injection



	FDA-approved product	Imported product from Shanghai, China
Product name	5% Dextrose and 0.9% Sodium Chloride Injection USP	5% Glucose and 0.9% Sodium Chloride Injection
Label volume	1000 mL	1000 mL
Language of the Labels	English	English
Indications	Dextrose and Sodium Chloride Injection, USP is indicated as a source of fluid and electrolyte replenishment and caloric supply.	Dextrose and Sodium Chloride Injection is indicated as a source of fluid and electrolyte replenishment and caloric supply.
Active ingredients	Each 100 mL contains 5 g Dextrose Hydrous USP and 900 mg Sodium Chloride USP	Each 100 mL contains 5 g Anhydrous Glucose and 900 mg Sodium Chloride
Additional information	pH 4.0 (3.2 to 6.5) Osmolarity 560 mOsm/L (calc)	pH 4.0 (3.2 to 6.5) Osmolarity 585 mOsm/L (calc)
Caloric content	170 kcal/L	200 kcal/L
Storage conditions	Store at room temperature 25°C/77°F.	Store at room temperature 15°C/59°F. to 30°C/86°F.
Container type	VIAFLEX (PVC)	IVINA (non-PVC)
Administration port closures	Contains medication port and administration port; Pull off port protector (blue color), right side 	Contains medication port and administration port; Twist off port protector (white color), left side 

Table 8 Label images of FDA-approved 5% Dextrose/0.9% Sodium Chloride Injection USP and imported 5% Glucose/0.9% Sodium Chloride Injection

FDA-approved product	Imported product from Shanghai, China
5% Dextrose and 0.9% Sodium Chloride Injection USP	5% Glucose and 0.9% Sodium Chloride Injection
<p>Label Color: Black. Barcode not shown.</p>	<p>Label Color: Black. Imported product contains the NDC number, which is not yet shown below. Barcode location is shown and will contain a linear barcode with human readable information.</p>
<p>LOT EXP</p> <p>⊙ ⊙ 281064 NDC 0338-0089-04</p> <p>1</p> <p>5% Dextrose and 0.9% Sodium Chloride Injection USP</p> <p>2</p> <p>1000 mL</p> <p>3</p> <p>EACH 100 mL CONTAINS 5 g DEXTROSE HYDROUS USP 900 mg SODIUM CHLORIDE USP pH 4.0 (3.2 TO 6.5) mEq/L SODIUM 154 CHLORIDE 154 HYPERTONIC OSMOLARITY 560 mOsmol/L (CALC) STERILE NONPYROGENIC SINGLE DOSE CONTAINER ADDITIVES MAY BE INCOMPATIBLE CONSULT WITH PHARMACIST IF AVAILABLE WHEN INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE MIX THOROUGHLY DO NOT STORE DOSAGE 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 OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT</p> <p>4</p> <p>VIAFLEX CONTAINER PL 146 PLASTIC</p> <p>BAXTER VIAFLEX AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> <p>5</p> <p>Baxter</p> <p>BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA</p> <p>MADE IN USA</p> <p>6</p> <p>FOR PRODUCT INFORMATION 1-800-933-0303</p> <p>7</p> <p>8</p> <p>9</p>	<p>100 Baxter® A6C1064US</p> <p>200 5% GLUCOSE AND 0.9% SODIUM CHLORIDE INJECTION</p> <p>300 1000ml</p> <p>400 5% GLUCOSE 0.9% SODIUM CHLORIDE</p> <p>500 [Strength] 1000ml: GLUCOSE 50g AND SODIUM CHLORIDE 9g</p> <p>600 [Description] This product is a clear, colorless liquid</p> <p>700 [Dosage and Administration] Intravenous drip See the package insert for details</p> <p>800 For details of [Indications], [Adverse Reactions], [Contraindications], and [Precautions], please refer to the package insert</p> <p>900 [Storage] Store in overwrap</p> <p>LOT The solution should be clear and should be used up at one time</p> <p>MFG Inspect the inner bag by squeezing it and discard solution if leakage occurs</p> <p>EXP License Number: H19994068</p> <p> [Drug Marketing Authorization Holder] [Manufacturer] Name: Baxter Healthcare (Shanghai) Co., Ltd. Address: No. 388, Tingzhu Road, Jinshan District, Shanghai</p> <p> GTIN Barcode Area</p>