GLUCOSE- dextrose anhydrous injection, solution
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.

10% GLUCOSE INJECTION

HEALTH CARE PROFESSIONAL LETTER

Baxter

Important Prescribing Information

November 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.

- **CORRECTION: The 250 mL product is NOT compatible for admixing with Baxter's Vial Mate adapter because the Vial-Mate adapter can introduce particles into the admixture.**

- 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,

Electronically signed by: Maria Soriano
Reason: I approve this document
Date: Nov 21, 2024 14:31 EST

Cecilia Soriano
President, Infusion Therapies & Technologies
Baxter Healthcare Corporation

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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 https://nctr-crs.fda.gov/fdalabel/ui/spl-summaries/criteria/723233)
• 5% Glucose Injection (click https://nctr-crs.fda.gov/fdalabel/ui/spl-summaries/criteria/723235)
• 10% Glucose Injection (click https://nctr-crs.fda.gov/fdalabel/ui/spl-summaries/criteria/723237)
• 5% Glucose/0.9% Sodium Chloride Injection (click https://nctr-crs.fda.gov/fdalabel/ui/spl-summaries/criteria/723238)

Please refer to the FDA-approved prescribing information for each drug product listed below:
• 0.9% Sodium Chloride Injection USP (click https://www.dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=f55bd888-5e01-474d-871b-24654c070178&type=pdf&name=f55bd888-5e01-474d-871b-24654c070178)
• 5% Dextrose Injection USP (click https://www.dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=3bb406a9-f5cb-403a-b1bb-5c4facbea3d5&type=pdf&name=3bb406a9-f5cb-403a-b1bb-5c4facbea3d5)
• 10% Dextrose Injection USP (click

https://www.dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=3bb406a9-f5cb-403a-b1bb-5c4facbea3d5&type=pdf&name=3bb406a9-f5cb-403a-b1bb-5c4facbea3d5)
• 5% Dextrose/0.9% Sodium Chloride Injection USP (click https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/016678s007,016683s103,016687s104,016689s107,016697s098lbl.pdf)

Product Comparison Tables

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

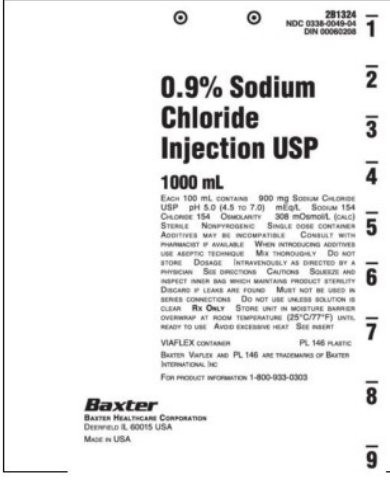
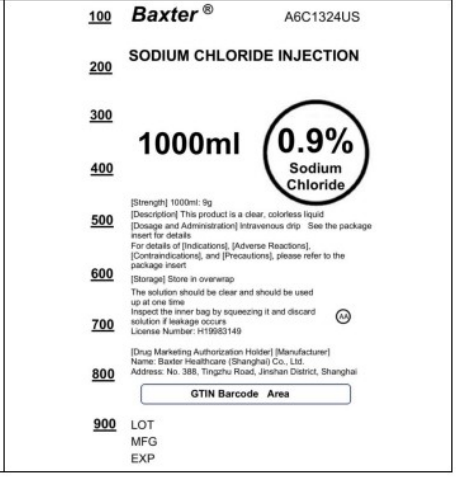
FDA-approved product	Imported product from Shanghai, China
0.9% Sodium Chloride Injection USP	0.9% Sodium Chloride Injection
Label Color: Black. Barcode not shown. **1000 mL shown as representative label.**	Label Color: Black. **1000 mL shown as representative label. Imported product contains the NDC number, which is not yet shown below. Barcode location is shown and will contain a linear barcode with human readable information.**
	

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 Hydrous 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
Label Color: Black. Barcode not shown. **1000 mL shown as representative label.**	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.**
2B0064 NDC 0338-0017-04 **5% Dextrose Injection USP** **1000 mL** EACH 100 mL CONTAINS 5 g DEXTROSE HYDROUS USP pH 4.0 (3.2 TO 6.5) OSMOLARITY 252 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 VIAFLEX CONTAINER PL 146 PLASTIC BAXTER VIAFLEX AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC FOR PRODUCT INFORMATION 1-800-933-0303 **Baxter** BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA 1 2 3 4 5 6 7 8 9	100 200 300 400 500 600 700 800 900 **Baxter** ® A6C0064US **GLUCOSE INJECTION** **1000ml** **5% GLUCOSE** [Strength] 1000ml: 50g [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 [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 License Number: H19983151 [Drug Marketing Authorization Holder] [Manufacturer] Name: Baxter Healthcare (Shanghai) Co., Ltd. Address: No. 388, Tingzhu Road, Jinshan District, Shanghai GTIN Barcode Area LOT MFG EXP

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** 

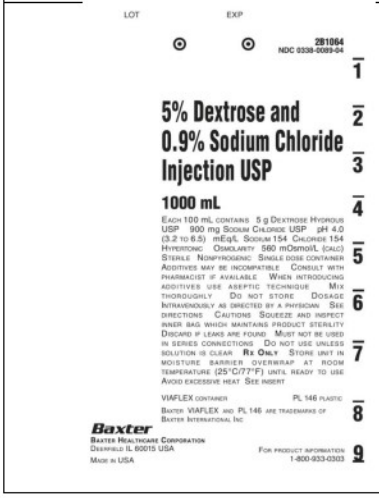
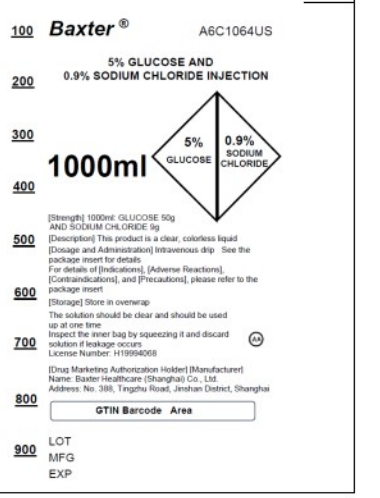
Table 6 **Label images of FDA-approved 10% Dextrose Injection USP and imported 10% Glucose Injection**

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.**
LOT EXP 2B0162 NDC 0338-0023-02 **10% Dextrose Injection USP** 50 **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 100 150 200 VIAFLEX container PL 146 plastic BAXTER VIAFLEX and PL 146 are trademarks of Baxter International Inc Baxter Baxter Healthcare Corporation Deerfield IL 60015 USA For product information 1-800-933-0303 Made in USA	Baxter ® A6C0162US GLUCOSE INJECTION 50 250ml 10% GLUCOSE 100 [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 150 [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 200 License Number: H19994063 [Drug Marketing Authorization Holder] [Manufacturer] Name: Baxter Healthcare (Shanghai) Co., Ltd. Address: No. 388, Tingzhu Road, Jinshan District, Shanghai GTIN Barcode Area LOT MFG EXP

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 mOsmol/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
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.**
	

PACKAGE INSERT

Baxter SPC-302US

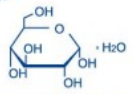
Approval Date: October 26, 2006
Revision Date: April 15, 2008, January 23, 2009, October 01, 2010, December 23, 2011, February 10, 2012, March 12, 2012, April 19, 2012, October 18, 2014, October 25, 2015, December 01, 2015, January 15, 2019, January 16, 2019, April 23, 2019, July 07, 2020, December 01, 2020

Glucose Injection Package Insert

Please read the package insert carefully and use under the direction of the physician

[Drug Name]
Generic Name: Glucose Injection
English Name: Glucose Injection
Chinese Pinyin: Putaotang Zhusheye

[Ingredients]
Chemical name: Glucose.
Structural formula:



Molecular formula: $C_6H_{12}O_6 \cdot H_2O$
Molecular weight: 198.17
Excipients: If necessary, adjust the pH value with an appropriate amount of dilute hydrochloric acid.

[Description]
This product is a colorless or almost colorless clear liquid.

[Indications]
(1) As a source of energy and fluids; indicated for underfeeding or loss of large amounts of fluids caused by various reasons (such as vomiting and diarrhea), total intravenous nutrition, and starvation ketosis.
(2) Hypoglycemia;
(3) Hyperkalemia;
(4) Hypertonic solution indicated as a tissue dehydrating agent;
(5) For preparation of peritoneal dialysis solution;
(6) Drug diluent;
(7) Intravenous glucose tolerance test;
(8) For preparation of GIK (polarized liquid).

[Strength]
(1) 100ml:5g (2) 250ml:12.5g (3) 500ml:25g
(4) 100ml:10g (5) 250ml:25g (6) 500ml:50g
(7) 250ml:50g (8) 500ml:100g (9) 50ml:2.5g
(10) 50ml:5g

[Dosage and Administration]
The infusion rate and volume should be calculated based on the patient's age, weight, clinical and metabolic conditions, and concomitant therapy. 20% glucose injection can be administered directly through a central venous catheter without dilution.
(1) Supply of heat energy. When patients eat less or cannot eat for certain reasons, 25% glucose injection can generally be given intravenously, which can also replace fluids. The dosage of glucose should be calculated based on the required amount of heat energy.
(2) Total intravenous nutrition therapy. Glucose is the most important energy supply substance for this therapy. In non-protein heat energy, the ratio of energy supplied by glucose to that supplied by fat is 2:1. The specific dosage is determined according to the clinical calorie requirement. Depending on the amount of fluid replacement required, glucose can be prepared in different concentrations between 25% and 50%. Insulin can be added if necessary, with 1 unit of regular insulin added for every 5 to 10 g of glucose. As the normal application of hypertonic glucose solution is highly irritating to the veins and requires the infusion of fat emulsion, large veins are generally used for infusion.
(3) Hypoglycemia. Patients with severe hypoglycemia can be administered 20-40 ml of 50% glucose injection by intravenous push first.
(4) Starvation ketosis. Patients with severe starvation ketosis should be administered 5-25% glucose injection by intravenous drip. Administration of 100 g of glucose daily can generally control the condition.
(5) Water loss. For isotonic water loss, 5% glucose injection should be administered by intravenous drip.
(6) Hyperkalemia. 10-25% injection should be administered. Adding 1 unit of regular insulin for every 2-4 g of glucose can reduce serum potassium concentration. However, this therapy only allows extracellular potassium ions to enter the cells, and the total potassium content in the body remains unchanged. If potassium elimination measures are not taken, hyperkalemia may still occur again.
(7) Tissue dehydration. 20 to 50 ml of hypertonic solution (generally 50% glucose injection) should be administered by rapid intravenous injection. However, the effect is short-lived. Clinically, attention should be paid to preventing hyperglycemia, and this therapy is rarely used at present. When used to adjust the osmotic pressure of peritoneal dialysis solution, 20 ml of 50% glucose injection, (i.e., 10 g of glucose), can increase the osmotic pressure of 1 L of peritoneal dialysis solution by 55 mOsm/kgH_2O.
(8) For 10% and 20% glucose injections, if administered via a peripheral vein, the osmotic pressure of the final mixed infusion solution must be considered.
(9) For 10% and 20% glucose injections, when using glucose-containing preparations, consider starting at a low infusion rate and then gradually increasing it. For 20% glucose injection, to reduce the risk of hypoglycemia after discontinuation, consider gradually slowing down the infusion rate before stopping the infusion.
(10) Electrolytes can be replenished according to the patient's clinical needs.
(11) For 20% glucose injection, vitamins, trace elements, and other ingredients (including amino acids and lipids) can be added to the parenteral nutrition regimen according to the patient's condition to meet individual nutritional needs and prevent the deficiency of such substances and the occurrence of complications.
(12) For 20% glucose injection, if it is to be co-administered with preparations containing amino acids (nitrogen), dilute the glucose injection to an appropriate thermal nitrogen ratio before injection to make the osmotic pressure of the diluted solution meet the requirements for the route of administration.
(13) It is recommended that an infusion line with a filter should be used whenever possible during the administration of all parenteral solutions.

[Adverse Reactions]
(1) Venous irritation and phlebitis, which occur during the administration of hypertonic glucose injection by drip. Administration by drip through a large vein can reduce the incidence of phlebitis.
(2) Extravasation of high-concentration glucose injection can cause local swelling and pain.
(3) Reactive hypoglycemia, which is prone to occur in the event of coadministration of an overdose of insulin, a pre-existing hypoglycemia tendency, or sudden withdrawal from total intravenous nutrition therapy.
(4) Hyperglycemic non-ketotic coma, which is more common in patients with diabetes, patients with stress, patients receiving large amounts of glucocorticoids, and patients with uremia peritoneal dialysis who are given intraperitoneal hypertonic glucose solution or total intravenous nutrition therapy.
(5) Electrolyte imbalance. Long-term supplementation of glucose alone can easily lead to hypokalemia, hyponatremia, and hypophosphatemia.
(6) Hyperkalemia, which occasionally occurs in patients with type 1 diabetes when they are administered glucose at a high concentration.
(7) Hypersensitivity/infusion reactions (including anaphylactic/anaphylactoid reactions), mild reactions such as pruritus, severe reactions such as bronchospasm, cyanosis, angioedema, and hypotension; fever, chills.
(8) Hyperglycemia.
(9) Rash.
(10) Infusion site reactions, including infusion site phlebitis and infusion site erythema.
(11) Other adverse reactions reported with similar products include: ① Symptomatic hyponatremia; ② Hyponatremic encephalopathy; and ③ Possible infusion site thrombophlebitis (related to hypertonic solution) when glucose injection with a concentration of 10% or higher is infused; adverse reactions that may be caused or induced by glucose when administered for parenteral nutrition include: liver failure, cirrhosis, liver fibrosis, cholestasis, hepatocellular steatosis, elevated levels of blood bilirubin, elevated levels of liver enzymes, cholecystitis, cholelithiasis, and pulmonary vascular precipitates.

[Contraindications]
Contraindicated in the following patients:
(1) Those who are allergic to any ingredient in the product;
(2) Patients with clinically significant hyperglycemia;
(3) Patients with hyperglycemic non-ketotic hyperosmolar state;
(4) Those with uncontrolled diabetic ketoacidosis.

[Precautions]
1. Warnings
Hypersensitivity reactions
(1) The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.
(2) Glucose-containing solutions should be administered to patients allergic to corn or corn products with caution.
Dilution and other effects on serum electrolytes
(1) Depending on the infusion volume and rate and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of glucose can cause: ① hyperosmolality, osmotic diuresis, and dehydration; ② hypoosmolality; ③ electrolyte disturbances, such as hypoosmotic or hyperosmotic hyponatremia, hypokalemia, hypophosphatemia, hypomagnesemia, overhydration/hypervolemia, and congested states, including pulmonary congestion and edema; the use of fluids without electrolytes and the use of glucose can trigger these reactions; ④ increased blood sugar levels increase serum osmotic pressure. Osmotic diuresis caused by hyperglycemia can lead to or induce dehydration and electrolyte loss; ⑤ hyperglycemia can also cause water to transfer across cells, resulting in a decrease in extracellular sodium concentration, thereby causing hyponatremia; ⑥ because the body can metabolize the glucose in the glucose injection, infusion of glucose injection will increase the body's free water load, which may lead to hypoosmotic hyponatremia.
(2) Monitoring of serum sodium is particularly important. High volume infusion must be administered under specific monitoring conditions in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including Syndrome of Inappropriate Antidiuretic Hormone Secretion, SIADH), due to the risk of hospital-acquired hyponatremia. Acute hyponatremia can lead to acute hyponatremic encephalopathy (brain edema) characterized by headache, nausea, seizures, lethargy, vomiting, and coma. Patients with brain edema are at particular risk of severe, irreversible, and life-threatening brain injury and death. The risk for developing hypoosmotic hyponatremia is increased, for example, ① in pediatric patients, ② in elderly patients, ③ in women, ④ postoperatively, and ⑤ in persons with psychogenic polydipsia. The risk for developing encephalopathy as a complication of hypoosmotic hyponatremia is increased, for example, ① in pediatric patients (≤16 years of age), ② in women (in particular, post-menopause women), ③ in patients with hypoxemia, and ④ in patients with underlying central nervous system disease.
(3) Clinical evaluation and periodic laboratory determination are necessary to monitor fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation. Particular caution is advised in patients at increased risk of and from water and electrolyte disturbances that could be aggravated by increased free water load, hyperglycemia, or insulin administration. Preventive and corrective measures must be instituted as clinically indicated.
Hyperglycemia
(1) As with the intravenous administration of nutrients (e.g., 13.3-70% glucose, amino acids, and lipids) in general, metabolic complications may occur if the nutrient intake is not adapted to the patient's requirements, or the metabolic capacity of any given dietary component is not accurately assessed. Adverse metabolic effects may arise from administration of inadequate or excessive nutrients or from inappropriate composition of an admixture for a particular patient's needs.
(2) Rapid administration of glucose solution may produce severe hyperglycemia and hyperosmolar syndrome.
(3) In order to avoid hyperglycemia, the infusion rate should not exceed the patient's ability to utilize glucose.
(4) To reduce the risk of hyperglycemia-associated complications, the infusion rate must be adjusted and/or insulin administered if blood glucose levels exceed levels considered acceptable for the individual patient.

Ⓗ

(5) Intravenous glucose should be administered with caution in patients with, for example: ① impaired glucose tolerance (such as in diabetes mellitus, renal impairment, or in the presence of sepsis, trauma, or shock), ② severe malnutrition (risk of precipitating a refeeding syndrome), ③ thiamine deficiency, e.g., in patients with chronic alcoholism (risk of severe lactic acidosis due to impaired oxidative metabolization of pyruvate), and ④ water and electrolyte disturbances that could be aggravated by increased glucose and/or free water load.

(6) Intravenous glucose should also be administered with caution in: ① patients with ischemic stroke (hyperglycemia has been implicated in increasing cerebral ischemic brain damage and impairing recovery after acute ischemic strokes), ② patients with severe traumatic brain injury (in particular during the first 24 hours following the trauma) (early hyperglycemia has been associated with poor outcomes in patients with traumatic brain injury), ③ newborns.

(7) Prolonged intravenous administration of glucose and associated hyperglycemia may result in decreased rates of glucose-stimulated insulin secretion.

Refeeding syndrome

Refeeding severely undernourished patients may result in refeeding syndrome which is characterized by the rapid shift of potassium, phosphorus, and magnesium from the blood to cells as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. Careful monitoring and slowly increasing nutrient intake while avoiding overfeeding can prevent these complications.

Liver disorders

For 20% glucose injection, hepatobiliary disorders including cholestasis, fatty liver, fibrosis and cirrhosis, possibly leading to hepatic failure, as well as cholecystitis and cholelithiasis are known to develop in some patients on parenteral nutrition. The etiology of these disorders is thought to be multifactorial and may differ between patients. Patients presenting with abnormal laboratory parameters or other signs of hepatobiliary disorders should be assessed early by a clinician knowledgeable in liver diseases in order to identify possible causative and contributory factors, and possible therapeutic and prophylactic interventions.

Catheter infection and sepsis

For 20% glucose injection

(1) Infection and sepsis may occur as a result of the use of intravenous catheters to administer parenteral formulations, poor maintenance of catheters, or contaminated solutions.

(2) Immunosuppression and other factors such as hyperglycemia, malnutrition and/or their underlying disease state may predispose patients to infectious complications.

(3) Careful symptomatic and laboratory monitoring for fever/chills, leukocytosis, technical complications with the access device, and hyperglycemia can help detect infections early.

(4) The occurrence of septic complications can be decreased with heightened emphasis on aseptic technique in catheter placement, maintenance, as well as aseptic technique in nutritional formula preparation.

Precipitates

For 20% glucose injection, pulmonary vascular precipitates have been reported in patients receiving parenteral nutrition. In some cases, fatal outcomes have occurred. Excessive addition of calcium and phosphate increases the risk of the formation of calcium phosphate precipitates. Precipitates have been reported even in the absence of phosphate salt in the solution. Precipitation distal to the in - line filter and suspected precipitate formation in the blood stream have also been reported. In addition to inspection of the solution, the infusion set and catheter should also periodically be checked for precipitates. If signs of pulmonary distress occur, the infusion should be stopped and medical evaluation initiated.

2. General

(1) Intrapartum maternal excess intravenous glucose infusion may result in fetal insulin production and hypoglycemia in neonates.

(2) Use with caution in the following circumstances: ① Patients who have undergone subtotal gastrectomy are prone to dumping syndrome and hypoglycemia during oral glucose tolerance tests and should be switched to intravenous glucose tests; ② Patients with periodic paralysis or hypokalemia; ③ Patients who are prone to hyperglycemia under stress or when administered glucocorticoids; ④ Patients with edema, severe heart or kidney failure, or hepatic ascites are prone to water retention, the infusion volume should be controlled; for patients with heart failure, the infusion rate should be particularly controlled.

(3) Check the packaging carefully before use to make sure that it is intact; squeeze and check the inner bag, and discard it if there is any leakage; the solution inside should be clear, without visible particles, This product is for one-time use.

(4) Add a medication using aseptic technique as directed by the physician, mix thoroughly, and squeeze to check for leakage.

(5) Glucose injection should not be administered at the same time as blood transfusion.

(6) Glucose injection is a high-volume injection. In view of the large temperature difference between northern and southern China, avoid overheating or freezing.

(7) Do not connect this product in series for infusion. Before use, it is necessary to closely check whether there is air in the infusion line. Before pressurized infusion, the air in the bag should be expelled to avoid the formation of air embolism. When using an air-inlet infusion set for infusion, make sure the air inlet is closed.

(8) Additives may be incompatible. Additives known to be incompatible should not be used. Before adding a medication, verify that it is soluble and/or stable in water and that the pH range of the product is appropriate. The instructions for use of the medication to be added and other relevant literature must be consulted. After addition, check for a possible color change and/or the appearance of precipitates, insoluble complexes, or crystals. Do not store solutions containing additives. For single use only. Discard any unused portion.

[Pregnancy and Lactation]

Intrapartum maternal intravenous glucose infusion may result in fetal insulin production, with an associated risk of fetal hyperglycemia and metabolic acidosis as well as rebound hypoglycemia in the neonate. Healthcare practitioners should carefully consider the potential risks and benefits for each specific patient before administering glucose injection.

[Pediatrics Use]

(1) The drug should be administered under the guidance of a physician experienced in pediatric intravenous fluid therapy. Excessive or rapid fluid replacement may result in palpitations, arrhythmia, and even acute left heart failure.

(2) Newborns (especially those born premature and with low birth weight), are at increased risk of developing hypoglycemia or hyperglycemia. Close monitoring during treatment with intravenous glucose solutions is needed to ensure adequate glycemic control, in order to avoid potential long term adverse effects. Hypoglycemia in the newborn can cause prolonged seizures, coma, and cerebral injury. Hyperglycemia has been associated with cerebral injury (including intraventricular hemorrhage), late onset bacterial and fungal infection, retinopathy of prematurity, necrotizing enterocolitis, increased oxygen requirements, prolonged length of hospital stay, and death.

(3) Pediatric patients including neonates and older children) are at increased risk of developing hypoosmotic hyponatremia as well as for developing hyponatremic encephalopathy. Acute hyponatremia can lead to acute hyponatremic encephalopathy (brain edema) characterized by headache, nausea, seizures, lethargy, vomiting, and coma. Patients with brain edema are at particular risk of severe, irreversible, and life-threatening brain injury and death. Plasma electrolyte concentrations should be closely monitored in the pediatric population. Rapid correction of hypoosmotic hyponatremia is potentially dangerous (risk of serious neurologic complications). Dosage, rate, and duration of administration should be determined by a physician experienced in pediatric intravenous fluid therapy.

[Geriatrics Use]

When selecting the type of infusion solution, and the volume /rate of infusion for a geriatric patient, consider that geriatric patients are generally more likely to have cardiac, renal, hepatic, and other diseases or concomitant drug therapy. Excessive or rapid fluid replacement may result in palpitations, arrhythmia, and even acute left heart failure.

[Drug Interactions]

No studies have been conducted.

Both the glycemic effects of glucose injection and its effects on water and electrolyte balance should be taken into account when using glucose injection in patients treated with other substances that affect glycemic control, or fluid and electrolyte balance.

Caution is advised when administering the product to patients treated with drugs leading to an increased vasopressin effect. The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and may increase the risk of hyponatremia following treatment with intravenous fluids.

- Drugs stimulating vasopressin release such as chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors (SSRIs), 3,4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, and opioids.
- Drugs potentiating vasopressin action such as chlorpropamide, non-steroidal anti-inflammatories (NSAIDS), cyclophosphamide.
- Vasopressin analogues such as desmopressin, oxytocin, vasopressin, and terlipressin.

Caution is advised when administering the product to patients treated with drugs that may increase the risk of hyponatremia, such as diuretics and antiepileptics (e.g., oxcarbazepine).

[Overdosage]

Excess administration of the product can cause hyperglycemia, adverse effects on water and electrolyte balance, and corresponding complications. For example, severe hyperglycemia, severe dilutional hyponatremia, and their complications, can be fatal. Interventions include discontinuation of administration, dose reduction, administration of insulin and other measures as indicated for the specific clinical constellation. Clinically significant overdose of glucose injection may, therefore, constitute a medical emergency.

[Pharmacology and Toxicology]

Glucose is one of the main sources of heat for the human body. Every 1 gram of glucose can produce 4 kcal (16.7 kJ) of heat energy, so it is used to supplement heat and treat hypoglycemia. When glucose is intravenously administered with insulin, glycogen synthesis requires potassium ions, resulting in potassium ions entering the cells and lowering blood potassium concentration, hence it is used to treat hyperkalemia. Hypertonic glucose injection can be rapidly administered intravenously for tissue dehydration and can be used as a tissue dehydrating agent. Additionally, glucose is the main substance that maintains and regulates the osmotic pressure of peritoneal dialysis solutions.

[Pharmacokinetics]

Intravenously administered glucose enters the bloodstream directly. Glucose is completely oxidized in the body to produce CO_2 and water, which are excreted through the lungs and kidneys, along with energy production, and can also be converted into glycogen and fat for storage. Generally, a normal human body utilizes glucose at a rate of 6 mg/kg per minute.

[Storage] Store in overwrap.

[Packaging]

A three-layer Co-extrusion Bags Used for Infusion with a special injection port and a special infusion port or a special injection port and a special flexible infusion port in double-layer, double-valve sterile packaging.

(1) A three-layer Co-extrusion Bags Used for Infusion with a special injection port and a special infusion port. For 50ml/bag, 100ml/bag, 250ml/bag, and 500ml/bag. Instructions: 1. This product is packaged sterile in inner and outer bags. When using, tear it vertically along the tear notch of the outer bag; 2. Both the injection port and the infusion port are equipped with a designed polyisoprene rubber stopper, and special valves for special purposes.

(2) A three-layer Co-extrusion Bags Used for Infusion with a special injection port and a special flexible infusion port. For 100ml/bag, 250ml/bag, and 500ml/bag. Instructions: 1. This product is packaged sterile in inner and outer bags. When using, tear it vertically along the tear notch of the outer bag; 2. The injection port is equipped with a designed polyisoprene rubber stopper, and special valves for special purposes.

[Shelf Life] 24 months

[Executive Standard] Pharmacopoeia of the People's Republic of China, Volume II, 2020 Edition

[License Number]

Product	Strength	License Number
Glucose Injection	100ml:5g	H19994070
Glucose Injection	250ml:12.5g	H19994071
Glucose Injection	500ml:25g	H19983150
Glucose Injection	100ml:10g	H19993736
Glucose Injection	250ml:25g	H19994063
Glucose Injection	500ml:50g	H19994062
Glucose Injection	250ml:50g	H20013219
Glucose Injection	500ml:100g	H20013218
Glucose Injection	50ml:2.5g	H19993747
Glucose Injection	50ml:5g	H19993748

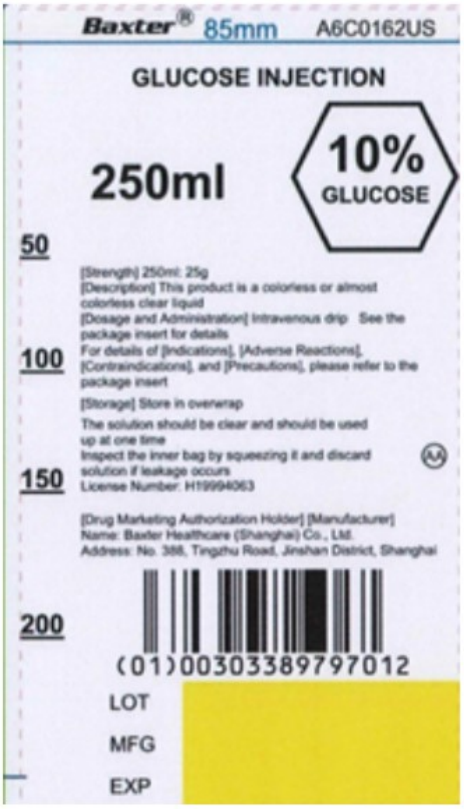
[Drug Marketing Authorization Holder]

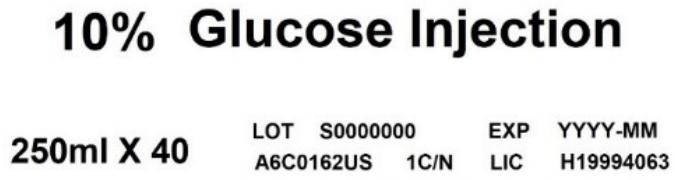
Name: Baxter Healthcare (Shanghai) Co., Ltd.
Registered Address: No. 388 Tingzhu Rd, Jinshan District, Shanghai

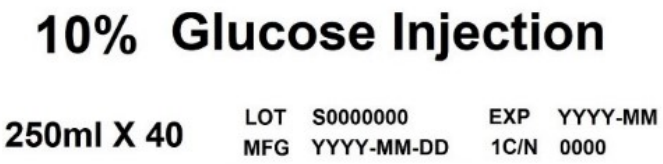
[Manufacturer]

Name: Baxter Healthcare (Shanghai) Co., Ltd.
Address: No. 388 Tingzhu Rd, Jinshan District, Shanghai
Postal Code: 201506
Tel: 86-21-57030000
Fax: 86-21-57270674

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL







Baxter Logo Trademark

A6C0162US

GLUCOSE INJECTION

50

100

150

200

250ml
10% GLUCOSE

[Strength] 250ml: 25g
[Description] This product is a colorless or almost colorless clear 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

[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
License Number: H19994063

AA

[Drug Marketing Authorization Holder] [Manufacturer]
Name: Baxter Healthcare (Shanghai) Co., Ltd.
Address: No. 388, Tingzhu Road, Jinshan District, Shanghai

BarCode
(01) 00303389797012

LOT
MFG
EXP

10% Glucose Injection

250ml X 40

LOT S0000000 EXP YYYY-MM
A6C0162US 1C/N LIC H19994063

10% Glucose Injection

250ml X 40

LOT S0000000 EXP YYYY-MM
MFG YYYY-MM-DD 1C/N 0000

GLUCOSE
dextrose anhydrous injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-9797
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	110 g in 1000 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0338-9797-40	40 in 1 CARTON	10/11/2024	
1	NDC:0338-9797-01	250 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		10/11/2024	

Labeler - Baxter Healthcare Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare (Shanghai) Co. Ltd.		527191860	MANUFACTURE(0338-9797) , ANALYSIS(0338-9797) , LABEL(0338-9797) , PACK(0338-9797) , STERILIZE(0338-9797)

Revised: 11/2024

Baxter Healthcare Corporation