**GLUCOSE AND SODIUM CHLORIDE- dextrose anhydrous and sodium chloride 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.*

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## 5% GLUCOSE/0.9% SODIUM CHLORIDE INJECTION

## HEALTH CARE PROFESSIONAL LETTER

Baxter

**Important Prescribing Information**

January 24, 2025

**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/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 Electronically signed by: Lee Ann Schuette Reason: I approve this document Date: Jan 24, 2025 13:29 CST

Lee Ann Schuette
Vice President, Global and US Marketing IV solutions, Clinical Nutrition, Pharmacy Tools
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**

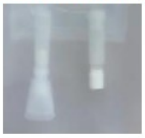
| | FDA-approved product | Imported product from Shanghai, China |
|---|---|---|
| **Product name** | **0.9% Sodium Chloride Injection USP** | **0.9% Sodium Chloride Injection** |
| **Label volume** | **100 mL; 150 mL; 250 mL; 500 mL; 1000 mL** | **250 mL; 500 mL; 1000 mL** |
| **Language of the Labels** | English | English |
| **Indications** | Sodium Chloride Injection, USP is indicated as a source of water and electrolytes.<br>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)<br>Osmolarity 308 mOsm/L (calc) | pH is 5.0 (4.5 to 7.0)<br>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**

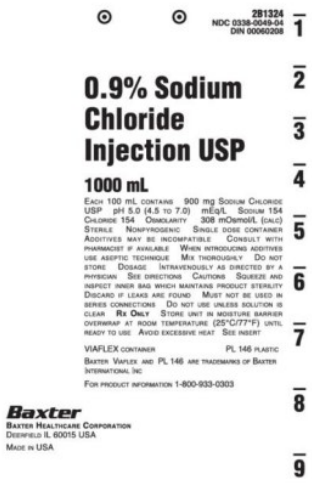
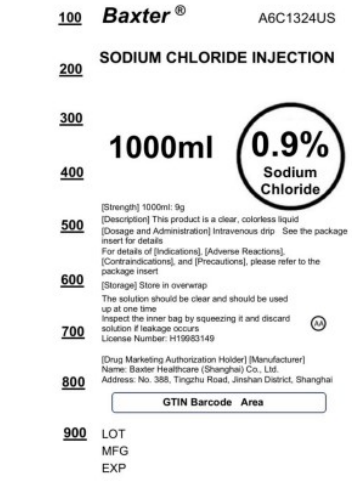
| FDA-approved product | Imported product from Shanghai, China |
|---|---|
| 0.9% Sodium Chloride Injection USP | 0.9% Sodium Chloride Injection |
| Label Color: Black. Barcode not shown.<br>**1000 mL shown as representative label.** | Label Color: Black.<br>**1000 mL shown as representative label. Imported 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)<br>Osmolarity 252 mOsmol/L (calc) | 4.0 (3.2 to 6.5)<br>**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<br>  | Contains medication port and administration port; **Twist off port protector (white color), left side**<br>  |



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

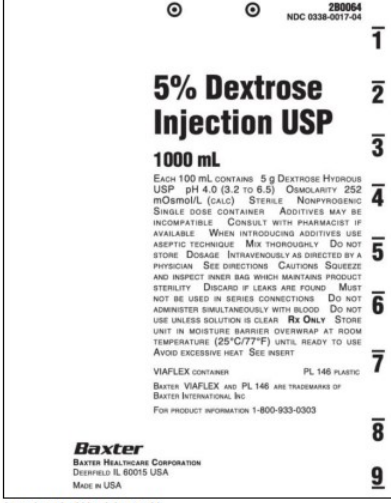
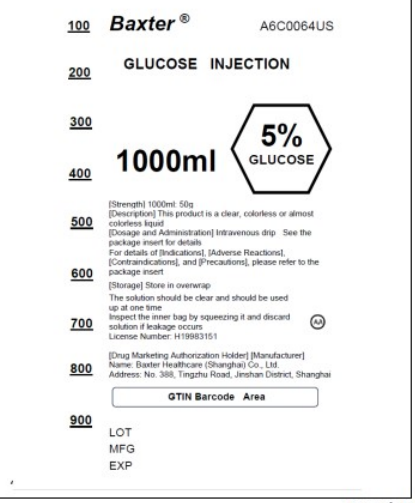
| FDA-approved product | Imported product from Shanghai, China |
|---|---|
| 5% Dextrose Injection USP | 5% Glucose Injection |
| Label Color: Black. Barcode not shown.<br>**1000 mL shown as representative label.** | Label Color: Black.<br>**1000 mL shown as representative label. Imported product contains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

**Table 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)<br>Osmolarity 505 mOsmol/L (calc ) | pH 4.0 (3.2 to 6.5)<br>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**

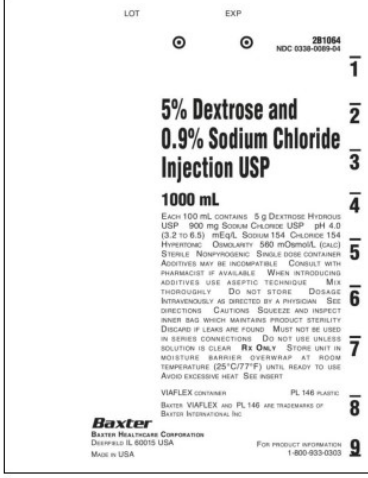
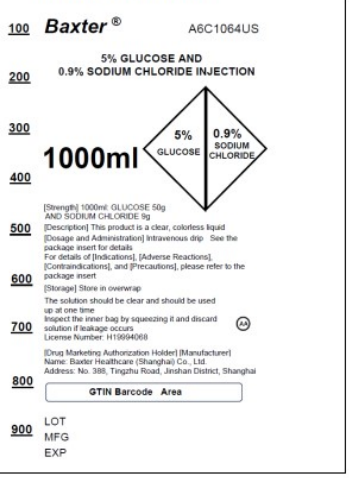
| US-FDA approved product | Imported product from Shanghai, China |
|---|---|
| 10% Dextrose Injection USP | 10% Glucose Injection |
| Label Color: Black. Barcode not shown. | Label Color: Black.<br>**Imported product contains the NDC number, which is not yet shown below. Barcode location is shown and will contain a linear barcode with human readable information.** |
| LOT EXP<br>280162<br>NDC 0338-0023-02<br>**10% Dextrose Injection USP**<br>50<br>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<br>100<br>150<br>200<br>VIAFLEX container PL 146 plastic<br>BAXTER VIAFLEX and PL 146 are trademarks of Baxter International Inc<br>Baxter<br>Baxter Healthcare Corporation Deerfield IL 60015 USA<br>For product information 1-800-933-0303<br>Made in USA | Baxter ® A6C0162US<br>GLUCOSE INJECTION<br>50<br>250ml<br>10% GLUCOSE<br>100<br>[Strength] 250ml: 25g<br>[Description] This product is a clear, colorless or almost colorless liquid<br>[Dosage and Administration] Intravenous drip See the package insert for details<br>For details of [Indications], [Adverse Reactions], [Contraindications], and [Precautions], please refer to the package insert<br>150<br>[Storage] Store in overwrap<br>The solution should be clear and should be used up at one time<br>Inspect the inner bag by squeezing it and discard solution if leakage occurs<br>200<br>License Number: H19994063<br>[Drug Marketing Authorization Holder] [Manufacturer]<br>Name: Baxter Healthcare (Shanghai) Co., Ltd.<br>Address: No. 388, Tingzhu Road, Jinshan District, Shanghai<br>GTIN Barcode Area<br>LOT<br>MFG<br>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. | Glucose 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)<br>Osmolarity 560 mOsmol/L (calc) | pH 4.0 (3.2 to 6.5)<br>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.<br>**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

Approval Date: October 26, 2006
Revision Date: April 15, 2008, February 1, 2009, October 1, 2010, February 2, 2012, March 12, 2012, March 22, 2012, July 10, 2012, December 1, 2013, June 27, 2014, December 1, 2015, August 2, 2016, January 25, 2019, June 16, 2020, June 22, 2020, December 1, 2020

# Glucose and Sodium Chloride Injection Package Insert

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

**[Drug Name]**
Generic Name: Glucose and Sodium Chloride Injection
English Name: Glucose and Sodium Chloride Injection
Chinese Pinyin: Putaotang Lühuana Zhusheye

**[Ingredients]**
The product is a compound preparation containing glucose and sodium chloride.

**[Description]**
The product is a clear, colorless liquid.

**[Indications]**
To replenish heat energy and fluids. The product is indicated for underfeeding or loss of large amounts of fluids caused by various reasons.

**[Strength]**
1000ml: glucose 50g and sodium chloride 9g
1000ml: glucose 25g and sodium chloride 4.5g

**[Dosage and Administration]**
The dosage depends on the age, weight, clinical and biological (acid-base balance) conditions of the patient, as well as concomitant therapy, it should be determined by the physician.
The dosage and administration of both glucose and sodium chloride should be considered:
(i) Dosage and administration of glucose:

1. Supply of heat energy. When patients eat less or cannot eat for some reasons, 10% to 25% glucose injection can generally be given intravenously. This 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 into different concentrations of 25% to 50%. Insulin can be added if necessary, with 1 unit of regular insulin added for every 5 to 10 g of glucose. As the product is generally used as a hypertonic solution, which is highly irritating to the veins and requires the infusion of fat emulsion, large veins located deeper in the body are generally selected, such as the subclavian vein and internal jugular vein etc.
3. Hypoglycemia. Patients with severe hypoglycemia can be administered 20–40 ml of 50% glucose injection by intravenous injection first.
4. Starvation ketosis. Patients with severe starvation ketosis should be administered 5%–25% glucose injection by intravenous drip. Administration of 100 g 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% glucose 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, the total potassium content in the body remains unchanged. If potassium elimination measures are not taken, hyperkalemia may still occur again.
7. Tissue dehydration. 20–50 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, so 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$_2$O. That is, for every 1% increase in glucose concentration in the dialysis solution, the osmotic pressure increases by 55 mOsm/kgH$_2$O.

(ii) Dosage and administration of sodium chloride:

1. Hypertonic dehydration. During hypertonic dehydration, the osmotic concentration of brain cells and cerebrospinal fluid increases. If treatment causes a rapid drop in sodium concentration and osmotic concentration of plasma and extracellular fluid, it can lead to cerebral edema. Therefore, it is generally believed that during the first 48 hours of treatment, the plasma sodium concentration should not decrease by more than 0.5 mmol/L per hour.
   If the patient is in shock, sodium chloride injection should be given first, with colloids added as appropriate. Once shock is corrected, and plasma sodium >155 mmol/L, with plasma osmotic concentration >350 mOsm/L, a 0.6% hypotonic sodium chloride injection can be administered. Once plasma osmotic concentration <330 mOsm/L, switch to 0.9% sodium chloride injection. Total fluid replacement is calculated using the following formula for reference:

| | | |
|---|---|---|
| Required fluid volume (L) = | [Plasma sodium concentration (mmol/L) - 142] / Plasma sodium concentration (mmol/L) | × 0.6 × Body weight (kg) |

   It is generally recommended to supplement half the needed volume on the first day, with the remainder supplemented over the next 2–3 days, which can be adjusted as appropriate based on heart, lung, and kidney functions.
2. Isotonic dehydration. Isotonic solutions should generally be provided, such as 0.9% sodium chloride injection or compound sodium chloride injection. However, these solutions have chloride concentrations significantly higher than plasma; using them alone in large amounts may cause hyperchloremia. Therefore, it is recommended to mix 0.9% sodium chloride injection with 1.25% sodium bicarbonate or 1.86% (1/6M) sodium lactate in a 7:3 ratio for supplementation. The latter has a chloride concentration of 107 mmol/L and can correct metabolic acidosis. The amount to be supplied can be calculated based on weight or hematocrit as a reference. ① By weight: Fluid volume (L) = (Weight loss (kg) × 142) / 154; ② By hematocrit: Fluid volume (L) = (Actual hematocrit - Normal hematocrit) × Weight (kg) × 0.2 / Normal hematocrit. Normal hematocrit is 48% for males and 42% for females.
3. Hypotonic dehydration: In severe hypotonic dehydration, solutes inside brain cells decrease to maintain cell volume. If treatment causes a rapid rise in the sodium concentration and osmotic concentration in plasma and extracellular fluid, it may lead to brain cell damage. It is generally believed that when plasma sodium is below 120 mmol/L, the treatment increases plasma sodium at a rate of 0.5 mmol/L per hour, and must not exceed 1.5 mmol/L per hour.
   When plasma sodium is below 120 mmol/L or when central nervous system symptoms occur, slow IV administration of 3%–5% sodium chloride injection can be given. It is usually required to raise the plasma sodium concentration to above 120 mmol/L within 6 hours. Sodium supplementation (mmol/L) = [142 - Actual plasma sodium concentration (mmol/L)] × Body weight (kg) × 0.2. Once plasma sodium rises to above120–125 mmol/L, isotonic solutions can be used instead or isotonic solutions with hypertonic glucose injection or 10% sodium chloride injection can be administered as appropriate.
4. Hypochloremic alkalosis: Administer 500–1000 ml of 0.9% sodium chloride injection or compound sodium chloride injection (Ringer's solution), and subsequently adjust the dose based on the degree of alkalosis.

(iii) Other dosages and administrations

1. The theoretical values of the molar concentration of the osmotic pressure of the product with different concentrations are as follows: 280 mOsmol/L for 0.45% sodium chloride and 2.5% glucose, 560 mOsmol/L for 0.9% sodium chloride and 5% glucose.
2. Solutions with a high osmotic pressure and molar concentration may cause venous irritation and phlebitis. Therefore, it is recommended to administer solutions with a high osmotic pressure and molar concentration through a large central vein to allow rapid dilution of the solution.
3. The specific concentration, dosage, volume, and rate and duration of administration of sodium chloride and glucose depend on the patient's age, weight, and clinical condition as well as concomitant therapy, and should be determined by a clinician. For patients with electrolyte or glucose abnormalities and pediatric patients, consult a physician experienced in intravenous fluid therapy.
4. Rapid correction of hyponatremia and hypernatremia is potentially dangerous (risk of serious neurologic complications). The dosage and rate and duration of administration should be determined by a physician experienced in intravenous fluid therapy.
5. When starting to administer glucose-containing products, consideration should be given to gradually increasing the drip rate.
6. Electrolyte supplementation may be indicated based on the patient's clinical needs.
7. When administering any injection, it is recommended to use an in-line filter if conditions permit.

**[Adverse Reactions]**

(1) Excessive or rapid infusion can cause water and sodium retention, leading to edema, increased blood pressure, rapid heart rate, chest tightness, difficulty breathing, and even acute left heart failure.
(2) Improper administration of hypertonic sodium chloride can cause hypernatremia.
(3) Excessive or rapid administration of hypotonic sodium chloride may result in hemolysis or cerebral edema.
(4) Phlebitis, which occurs during the administration of hypertonic glucose injection by drip. Administration by drip through a large vein can reduce the incidence of phlebitis.
(5) Extravasation of high-concentration solution during injection can cause local swelling and pain.
(6) 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.
(7) Hyperglycemic non-ketotic coma, which is more common in patients with diabetes, patients with stress, patients receiving high doses of glucocorticoids, and patients with uremia peritoneal dialysis who are given intraperitoneal hypertonic glucose solution or total intravenous nutrition therapy.
(8) Electrolyte imbalance. Long-term supplementation of glucose alone can easily lead to hypokalemia, hyponatremia, and hypophosphatemia.
(9) Anaphylaxis, hypersensitivity, chills, and fever.
(10) Hyponatremia (not applicable to IV solutions containing 0.9% sodium chloride and 5% glucose and IV solutions containing 0.9% sodium chloride and 10% glucose).
(11) Metabolic and nutritional disorders: Hypernatremia (applies to solutions containing 0.9% sodium chloride and solutions containing 5%–10% glucose) and hyperglycemia.
(12) Skin and subcutaneous tissue diseases: Rash and pruritus.
(13) Systemic diseases and medication site conditions: Injection site reactions, including injection site pain, injection site blisters, chills, and fever.
(14) Other adverse reactions (class reactions) (applies to solutions containing 0.9% sodium chloride and solutions containing 5%–10% glucose).
Other adverse reactions reported with similar products include: symptomatic hyponatremia; hyponatremic encephalopathy; and hyperchloremic acidosis.

**[Contraindications]**

Contraindicated in the following patients:
(1) Those who are allergic to any ingredient in the product.
(2) Patients with brain, kidney, or heart dysfunction.
(3) Patients with low plasma protein.
(4) Patients with uncontrolled diabetes or ketoacidosis.
(5) Patients with hypertonic dehydration.
(6) Patients with a hyperglycemic non-ketotic hyperosmolar state.
(7) Clinically significant hyperglycemia.

**[Precautions]**

1. Warnings

I. Hypersensitivity reactions
Hypersensitivity/infusion reactions, including anaphylaxis, have been reported with the product. Stop the infusion immediately if signs or symptoms of hypersensitivity/infusion reactions develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated. Solutions containing glucose should be used with caution in patients with known allergy to corn or corn products.

II. Use in patients at risk for sodium retention, fluid overload, and edema
The product should be used with particular caution, in patients with or at risk for: (1) hypernatremia (only applies to IV solutions containing 0.9% sodium chloride and 5% glucose); (2) hyperchloremia (only applies to IV solutions containing 0.9% sodium chloride and 5% glucose); (3) metabolic acidosis (only applies to IV solutions containing 0.9% sodium chloride and 5% glucose); (4) hypervolemia; (5) conditions that may cause sodium retention, fluid overload, and edema (central and peripheral); and (6) medications that may increase the risk of sodium and fluid retention （such as corticosteroids）.
Solutions containing sodium ions should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and clinical manifestations of sodium retention and edema. In patients with diminished renal function, administration of solutions containing sodium ions may result in sodium retention.
Infusion of isotonic (0.9%) sodium chloride solution during or immediately after surgery may result in excessive sodium retention. The patient's circulatory status can serve as a guide.

III. Hypokalemia
Infusion of the product may result in hypokalemia. Particular caution should be exercised when using the product in patients with hypokalemia or at risk for hypokalemia, who may require close clinical monitoring. For example: ① patients with metabolic alkalosis; ② patients with thyrotoxic periodic paralysis. Administration of intravenous glucose has been associated in aggravating hypokalemia; ③ patients with gastrointestinal losses (e.g., diarrhea, vomiting); ④ patients on a prolonged low potassium diet; ⑤ patients with primary hyperaldosteronism; and ⑥ patients treated with medications that increase the risk of hypokalemia (e.g. diuretics, β-2 agonists, or insulin).
Administration of excessive amounts of potassium-free glucose solution may result in severe hypokalemia. Serum potassium levels should be maintained, and potassium supplemented as needed. Solutions containing glucose and 0.20%, 0.30%, or 0.33% sodium chloride should not be infused simultaneously with blood through the same infusion set as this may cause coagulation.

IV. Hyponatremia
Infusion of solutions with a sodium concentration <0.9% may result in hyponatremia. Close clinical monitoring may be warranted. Hyponatremia can cause headache, nausea, seizures, lethargy, coma, cerebral edema, and death. Acute symptomatic hyponatremic encephalopathy is considered a medical emergency. The risk for hyponatremia is increased in: ① pediatric patients ; ② the elderly; ③ women, postoperatively; ④ in persons with psychogenic polydipsia; and ⑤ in patients treated with medications that increase the risk of hyponatremia (such as certain antiepileptic and psychotropic medications).The risk for developing hyponatremic encephalopathy is increased in: ① pediatric patients (≤16 years of age); ② women (in particular pre-menopausal women); ③ patients with hypoxemia; and ④ in patients with underlying central nervous system disease.

V. Risk of hyperosmolality, serum electrolytes, and water imbalance
Depending on the volume and rate of infusion of solutions containing 0.9% sodium chloride and 5% glucose and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of the product can cause: (1) hyperosmolality, osmotic diuresis, and

dehydration; (2) electrolyte disturbances, such as hyponatremia, hypokalemia, hypophosphatemia, and hypomagnesemia; (3) acid-base imbalance; (4) overhydration/hypervolemia and, for example, congested states, including central (e.g. pulmonary congestion) and peripheral edema; and (5) an increase in serum glucose concentration is associated with an increase in serum osmolality. Osmotic diuresis associated with hyperglycemia can result in or contribute to the development of dehydration and in electrolyte losses.
The intravenous administration of the product can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentration. The risk of solute overload causing congested states, with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.

VI. Risk of hypoosmolality and hyperosmolality, serum electrolytes, and water imbalance
Depending on the volume and rate of infusion of solutions containing 0.45% sodium chloride and 2.5% glucose, and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of the product can cause: (1) hypoosmolality; (2) hyperosmolality, osmotic diuresis, and dehydration; (3) electrolyte disturbances, such as hyponatremia, hypokalemia, hypophosphatemia, and hypomagnesemia; (4) overhydration/hypervolemia and, for example, congested states, including central (e.g. pulmonary congestion) and peripheral edema; (5) clinical evaluation and periodic laboratory determinations may be necessary to monitor changes in 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.
The intravenous administration of the product can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentration. The risk of solute overload causing congested states, with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.

VII. Use in patients at risk for sodium imbalance
In the body, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolization. Monitoring of serum sodium is particularly important for hypotonic fluids. Depending on the tonicity of the solution, the volume and rate of infusion, and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of glucose can cause electrolyte disturbances, most notably hypoosmotic or hyperosmotic hyponatremia. Large volume infusion must be used under specific monitoring 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. Solutions containing 0.9% sodium chloride and 5% glucose should be used with particular caution in patients with or at increased risk for hyponatremia, for example, in pediatric patients, elderly patients, women, postoperative patients, or in persons with psychogenic polydipsia. 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. Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in 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.

VIII. Hyperglycemia
Rapid administration of glucose solutions may produce substantial hyperglycemia and a hyperosmolar syndrome. In order to avoid hyperglycemia, the infusion rate should not exceed the patient's ability to utilize glucose. 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. Intravenous glucose should be administered with caution in patients with: (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 lactic acidosis due to impaired oxidative metabolization of pyruvate); (4) water and electrolyte disturbances that could be aggravated by increased glucose and/or free water load.
Other groups of patients in whom the product should be used with caution include: (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 severe traumatic brain injury; (3) newborns.
Prolonged intravenous administration of glucose and associated hyperglycemia may result in decreased rates of glucose-stimulated insulin secretion.

IX. Refeeding syndrome
Refeeding severely undernourished patients may result in the refeeding syndrome that is characterized by the shift of potassium, phosphorus, and magnesium intracellularly as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. Careful monitoring and slowly increasing nutrient intakes while avoiding overfeeding can prevent these complications.

X. Use in patients with or at risk of severe renal impairment
The product should be administered with particular caution to patients with or at risk of (severe) renal impairment. In such patients, administration of the product may result in sodium retention and/or fluid overload.

2. General

(1) Use with caution in the following situations: ① edematous diseases, such as nephrotic syndrome, liver cirrhosis, ascites, congestive heart failure, acute left heart failure, cerebral edema, and idiopathic edema etc.; ② acute renal failure during oliguric phase, chronic renal failure with reduced urine output and poor response to diuretics; ③ hypertension; ④ hypokalemia; ⑤ the volume and rate of fluid replacement in the elderly and pediatric patients should be strictly controlled.
(2) Follow-up tests: ① serum sodium, potassium, and chloride concentrations; ② blood acid-base balance indicators; ③ renal function; ④ blood pressure and cardiopulmonary function.
(3) Excessive intrapartum maternal intravenous glucose infusion may result in fetal insulin production and hypoglycemia in the neonate.
(4) Use with caution in the following circumstances: ① patients with periodic paralysis or hypokalemia; ② patients who are prone to stress- or glucocorticoid-induced hyperglycemia; ③ for patients with edema, severe heart or kidney failure, cirrhosis, or ascites who are prone to water retention, the infusion volume should be controlled; for patients with heart failure, the infusion rate should be particularly controlled.
(5) 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 or discoloration, and should be used once.
(6) It is not recommended to add a medication; if necessary, please squeeze the bag after adding a medication to check carefully for leakage.
(7) Add a medication using aseptic technique as directed by the physician, and mix thoroughly.
(8) The product is a large-volume injection. In view of the large temperature difference between northern and southern China, avoid overheating or freezing.
(9) The product should not be administered at the same time as blood transfusion. The product should not be administered simultaneously with blood through the same administration set because of the possibility of pseudo agglutination or hemolysis.
(10) 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 embolisms.
(11) When using an air inlet infusion set for infusion, make sure the air inlet is closed.
(12) 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]**
Not clear yet.
Intrapartum maternal intravenous glucose infusion may result in fetal hyperglycemia and metabolic acidosis as well as rebound neonatal hypoglycemia due to fetal insulin production.

Carefully consider the potential risks and benefits for each specific patient before administering the product.

**[Pediatrics Use]**
The volume and rate of fluid replacement should be strictly controlled. The infusion rate and volume depend on the age, weight, metabolic, clinical conditions and concomitant therapy of the patient, the product should be used under the guidance of a physician experienced in pediatric intravenous fluid therapy. Plasma electrolyte concentrations should be closely monitored.
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 intraventricular hemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotizing enterocolitis, increased oxygen requirements, prolonged length of hospital stay, and death.
Pediatric patients (including neonates and older pediatric patients) are at increased risk of developing hyponatremia as well as for developing hyponatremic encephalopathy. The infusion of hypotonic fluids together with the non-osmotic secretion of antidiuretic hormone (ADH) may result in hyponatremia (not applicable to IV solutions containing 0.9% sodium chloride and 5% glucose). 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 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. The volume and rate of fluid replacement should be strictly controlled.

**[Drug Interactions]**
Both the glycemic effects of the product and its effects on water and electrolyte balance should be taken into account when using the product in patients treated with other substances that affect glycemic control, or fluid and/or electrolyte balance.
Caution is advised in patients treated with lithium. Renal sodium and lithium clearance may be increased during administration of the product and can result in decreased lithium levels.
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), and cyclophosphamide.
- Vasopressin analogs 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]**
Excessive administration of glucose and sodium chloride injection may lead to hypernatremia and hypokalemia, as well as bicarbonate loss.
Excess administration of the product can cause: (1) hyperglycemia, adverse effects on water and electrolyte balance, and corresponding complications. For example, severe hyperglycemia and severe dilutional hyponatremia, and their complications, can be fatal; (2) hyponatremia (which can lead to CNS manifestations, including seizures, coma, cerebral edema, and death); (3) hypernatremia, especially in patients with severe renal impairment (applies to IV solutions containing 0.9% sodium chloride and 5% glucose and IV solutions containing 0.9% sodium chloride and 10% glucose); (4) fluid overload (which can lead to central and/or peripheral edema).
When assessing an overdose, any additives in the solution must also be considered.
Clinically significant overdose of the product may, therefore, constitute a medical emergency.
Interventions include discontinuation of the product, dose reduction, administration of insulin, and other measures as indicated for the specific clinical constellation.

**[Pharmacology and Toxicology]**
Glucose is one of the main sources of heat for the human body. Sodium and chloride are important electrolytes in the body, which mainly exist in the extracellular fluid and play a very important role in maintaining the normal volume and osmotic pressure of blood and extracellular fluid in the human body.

**[Pharmacokinetics]**
After glucose enters a normal human body, it is utilized 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. Instructions for 1000 ml/bag: 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. Instructions for 1000 ml/bag: 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 and Sodium Chloride Injection | 1000ml: 50g glucose and 9g sodium chloride | H19994068 |
| Glucose and Sodium Chloride Injection | 1000ml: 25g glucose and 4.5g sodium chloride | H20013223 |

**[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**


**5% Glucose/0.9% Sodium Chloride Injection**

**1000ml X 12** LOT S0000000 EXP YYYY-MM
A6C1064US 1C/N LIC H19994068

**5% Glucose/0.9% Sodium Chloride Injection**

**1000ml X 12** LOT S0000000 EXP YYYY-MM
MFG YYYY-MM-DD 1C/N 0000

*Baxter Logo* Trademark

A6C1064US

GLUCOSE AND
SODIUM CHLORIDE INJECTION

100

200

300

400

500

600

700

800

900

**1000ml**
**5% GLUCOSE**

**0.9% SODIUM CHLORIDE**

[Strength] 1000ml: glucose 50g
and sodium chloride 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

[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: H19994068

AA

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

*BarCode*
(01) 00303389799016

LOT
MFG
EXP

5% Glucose/0.9% Sodium Chloride Injection

1000ml X 12

LOT S0000000 EXP YYYY-MM
A6C1064US 1C/N LIC H19994068

5% Glucose/0.9% Sodium Chloride Injection

1000ml X 12

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

## GLUCOSE AND SODIUM CHLORIDE

dextrose anhydrous and sodium chloride injection, solution

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0338-9799 |
| **Route of Administration** | INTRAVENOUS | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **DEXTROSE MONOHYDRATE** (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK) | DEXTROSE MONOHYDRATE | 5.5 g in 100 mL |
| **SODIUM CHLORIDE** (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698) | SODIUM CHLORIDE | 0.9 g in 100 mL |

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

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:0338-9799-12 | 12 in 1 CARTON | 10/11/2024 | |
| **1** | NDC:0338-9799-01 | 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 | | 10/11/2024 | |

## Labeler - Baxter Healthcare Corporation (005083209)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Baxter Healthcare (Shanghai) Co. Ltd. | | 527191860 | MANUFACTURE(0338-9799) , ANALYSIS(0338-9799) , LABEL(0338-9799) , PACK(0338-9799) , STERILIZE(0338-9799) |

Revised: 1/2025 Baxter Healthcare Corporation