SODIUM CHLORIDE- 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.

0.9% Sodium Chloride Injection

HEALTH CARE PROFESSIONAL LETTER

Baxter

Important Prescribing Information

November 21, 2024

Subject: Temporary importation of 0.9% Sodium Chloride Injection from Shanghai, China, labeled in Chinese, 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; 500 mL and 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 imported 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	A6C1322	40	0338-9804-01
	500 mL	A6C1323	24	0338-9810-01
	1,000 mL	A6C1324	12	0338-9806-01

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 have primary container labels written in Chinese. The primary container labels contain the active pharmaceutical ingredient, concentration, volume, and product code in English.

- The imported products' administration port system is fully compatible with Baxter sets marketed in the United States.

- **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 products use 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.

- **The imported products do not contain barcodes on the unit label.** 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 and concentration are being used in all systems and processes and administered to individual patients.

- 0.9% Sodium Chloride Injection is available only by prescription in the United States. However, the imported products do not have the statement "Rx only" on the labeling.

Additional key differences in the labeling between the FDA-approved product and the imported products are stated in the product comparison table 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

Please refer to the FDA approved package insert for the full prescribing information of the drug product as follows:

- 0.9% Sodium Chloride Injection, USP (click here)

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 (1-800-332-0178).

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

If you have any questions about the information contained in this letter or the use of the imported products, please contact Baxter's Medical Information Service at 1-800-933-0303.

To place an order, please contact Baxter's Center for Service by calling 1-888-229-0001.

Please refer to the FDA approved package insert for the full prescribing information of the drug product as follows:
• 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)

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 (1-800-332-0178).

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

Sincerely,

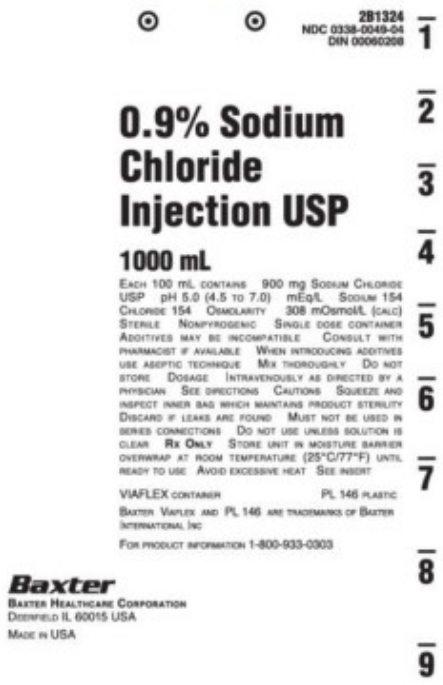
Cecilia Soriano
President, Infusion Therapies & Technologies
Baxter Healthcare Corporation

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	**Chinese**
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.**
	

	0.9% Sodium Chloride Injection
	English translation **1000 mL shown as representative label.**
	 100 *Baxter* ® 200 SODIUM CHLORIDE INJECTION 300 1000ml 0.9% Sodium Chloride 400 [Strength] 1000ml: 9g 500 [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 600 [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 700 License Number: H19983149 [Drug Marketing Authorization Holder] [Manufacturer] Name: Baxter Healthcare (Shanghai) Co., Ltd. 800 Address: No. 388, Tingzhu Road, Jinshan District, Shanghai GTIN Barcode Area 900 LOT MFG EXP

PACKAGE INSERT

Approval Date: November 03, 2006
Revision Date: April 15, 2008, January 23, 2009, October 01, 2010, June 17, 2011, December 23, 2011, February 13, 2012, March 12, 2012, April 19, 2012, June 27, 2014, October 25, 2015, December 01, 2015, February 02, 2019, July 09, 2020, December 01, 2020

Sodium Chloride Injection Package Insert

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

[Drug Name]
Generic Name: Sodium Chloride Injection
English Name: Sodium Chloride Injection
Chinese Pinyin: Lühuana Zhusheye

[Ingredients] Chemical name: Sodium chloride
Molecular formula: NaCl
Molecular weight: 58.44

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

[Indications]
Dehydration caused by various reasons, including hypotonic, isotonic, and hypertonic dehydration; hypertonic non-ketotic diabetic coma, isotonic or hypotonic sodium chloride can be used to correct dehydration and hyperosmolar state; hypochloremic metabolic alkalosis; topical application of normal saline to rinse eyes, wash wounds, etc.; also used in obstetrics to induce labor using a water bag.

[Strength]
(1) 50ml:0.45g (2) 100ml:0.9g
(3) 250ml:2.25g (4) 500ml:4.5g

[Dosage and Administration]
Dosage, rate, and duration of administration are to be individualized and depend upon the indication for use, the patient's age, weight, clinical condition, and concomitant treatment, and on the patient's clinical and laboratory response to treatment.

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:
   plasma sodium is below 120 mmol/L, the rate of increase in plasma sodium should be no more than 0.5 mmol/L per hour, not exceeding 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 120-125 mmol/L, isotonic solutions or isotonic solutions with hypertonic dextrose 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.
5. Topical application: Use physiological sodium chloride solution to wash wounds or rinse eyes.

[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; it can also lead to clinically significant electrolyte disturbances and acid - base imbalance.
(2) Excessive or rapid administration of hypotonic sodium chloride may result in hemolysis, cerebral edema, etc.
(3) Immune system disorders: Hypersensitivity/infusion reactions, including hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus
(4) General disorders and administration site conditions: Infusion site reactions, such as infusion site erythema, injection site streaking, burning sensation, and infusion site urticaria.
(5) Other adverse reactions reported with similar products include: ①hypernatremia; ②hyperchloremic metabolic acidosis; ③symptomatic hyponatremia; and ④hyponatremic encephalopathy.

[Contraindications]
1. Contraindicated in those who are allergic to any ingredient in the product;
2. Contraindicated in patients with pregnancy-induced hypertension.

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. ①By 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 for males is 48%, and for females is 42%.
3. Hypotonic dehydration: In severe hypotonic dehydration, osmotic substances 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

[Precautions]

(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; ② Severe renal damage; acute renal failure during oliguric phase, chronic renal failure with reduced urine output and poor response to diuretics; ③ Hypertension; ④ Hypokalemia; ⑤ Hypernatremia; ⑥ Hyperchloremia;⑦ Metabolic acidosis; ⑧ Hypervolemia; ⑨ Conditions that may cause sodium retention, fluid overload, and edema (central or peripheral); ⑩ Patients receiving medications that may increase sodium and fluid retention (e.g., corticosteroids).

(2) Risk of hyponatremia: Monitoring of serum sodium is important for all fluids. The osmolarity of this product is 260-320 mOsmol/kg. High 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. 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.

(3) Check the concentration of sodium, potassium, and chloride ions in the serum; the acid-base concentration balance index, renal function, blood pressure, and cardiopulmonary function in the blood as clinically necessary.

(4) 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.

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

(6) When other electrolytes or drugs are added to this solution, the dose and infusion rate will also be dictated by the additives dose regime.

(7) Stop the infusion immediately if signs or symptoms of hypersensitivity /infusion reactions develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

(8) Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte balance, and acid-base balance for patients requiring long-term injection therapy or whenever the condition of the patient or the rate of administration warrants such evaluation.

(9) Do not connect flexible plastic containers 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.

(10) 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.

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

[Pregnancy and Lactation]
There are no adequate data from the use of sodium chloride injection in pregnant or lactating women. Sodium chloride injection is contraindicated in patients with pregnancy-induced hypertension. The potential risks and benefits for each specific patient should be carefully considered before using sodium chloride injection in pregnant or lactating women.

[Pediatrics Use]
The volume and rate of fluid replacement should be strictly controlled. Plasma electrolyte concentrations should be closely monitored in the pediatric population.

It can also cause bicarbonate loss. When assessing an overdose, any additives in the solution must also be considered.

[Pharmacology and Toxicology]
Sodium chloride is an electrolyte supplement. Sodium and chlorine 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. The normal serum sodium concentration is 135-145 mmol/L, accounting for 92% of plasma cations and 90% of the total osmotic pressure. Therefore, the amount of plasma sodium plays a decisive role in the osmotic pressure. The normal serum chloride concentration is 98-106 mmol/L. The sodium and chloride ions in the human body are mainly regulated by the hypothalamus, posterior pituitary gland, and kidneys to maintain the stability of fluid volume and osmotic pressure.

[Pharmacokinetics]
After intravenous injection, sodium chloride directly enters the blood circulation and is widely distributed in the body, but mainly exists in extracellular fluid. Both sodium and chloride ions can be filtered by the glomerulus and partially reabsorbed by the renal tubules. It is excreted by the kidneys in urine, and only a small amount is excreted through sweat.

[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 100 ml/bag, 250 ml/bag, and 500 ml/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.

[Geriatrics Use]
The volume and rate of fluid replacement should be strictly controlled. 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.

[Drug Interactions]
When sodium chloride injection is used as a drug solvent or diluent, attention should be paid to the incompatibility between drugs. Caution is advised during coadministration of sodium chloride injection with lithium preparations, as it may 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 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]
Excessive administration of sodium chloride injection may lead to hypernatremia (which can lead to CNS manifestations, including seizures, coma, cerebral edema, and death), sodium overload (which can lead to central and/or peripheral edema), and hypokalemia.

[Shelf Life] 24 months
[Executive Standard] Pharmacopoeia of the People's Republic of China, Volume II, 2020 Edition

[License Number]

Product	Strength	License Number
Sodium Chloride Injection	50ml:0.45g	H19993745
Sodium Chloride Injection	100ml:0.9g	H19994067
Sodium Chloride Injection	250ml:2.25g	H19994066
Sodium Chloride Injection	500ml:4.5g	H19983148

[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

Approval Date: November 03, 2006
Revision Date: April 15, 2008, January 23, 2009, October 01, 2010, June 17, 2011, March 12, 2012, April 19, 2012, June 27, 2014, October 25, 2015, December 01, 2015, February 02, 2019, July 09, 2020, December 01, 2020

Sodium Chloride Injection Package Insert

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

[Drug Name]
Generic Name: Sodium Chloride Injection
English Name: Sodium Chloride Injection
Chinese Pinyin: Lühuana Zhusheye

[Ingredients] Chemical name: Sodium chloride
Molecular formula: NaCl
Molecular weight: 58.44

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

[Indications]
Dehydration caused by various reasons, including hypotonic, isotonic, and hypertonic dehydration; hypertonic non-ketotic diabetic coma, isotonic or hypotonic sodium chloride can be used to correct dehydration and hyperosmolar state; hypochloremic metabolic alkalosis; topical application of normal saline to rinse eyes, wash wounds, etc.; also used in obstetrics to induce labor using a water bag.

[Strength]
1000ml:9g

[Dosage and Administration]
Dosage, rate, and duration of administration are to be individualized and depend upon the indication for use, the patient's age, weight, clinical condition, and concomitant treatment, and on the patient's clinical and laboratory response to treatment.

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:
   plasma sodium should be no more than 0.5 mmol/L per hour, not exceeding 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 120-125 mmol/L, isotonic solutions or isotonic solutions with hypertonic dextrose 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.
5. Topical application: Use physiological sodium chloride solution to wash wounds or rinse eyes.

[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; it can also lead to clinically significant electrolyte disturbances and acid - base imbalance.
(2) Excessive or rapid administration of hypotonic sodium chloride may result in hemolysis, cerebral edema, etc.
(3) Immune system disorders: Hypersensitivity/infusion reactions, including hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus.
(4) General disorders and administration site conditions: Infusion site reactions, such as infusion site erythema, injection site streaking, burning sensation, and infusion site urticaria.
(5) Other adverse reactions reported with similar products include:① hypernatremia; ② hyperchloremic metabolic acidosis; ③ symptomatic hyponatremia; and ④ hyponatremic encephalopathy.

[Contraindications]
1. Contraindicated in those who are allergic to any ingredient in the product;
2. Contraindicated in patients with pregnancy-induced hypertension.

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 for males is 48%, and for females is 42%.
3. Hypotonic dehydration: In severe hypotonic dehydration, osmotic substances 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 rate of increase in

[Precautions]

(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; ② Severe renal damage; acute renal failure during oliguric phase, chronic renal failure with reduced urine output and poor response to diuretics; ③ Hypertension; ④ Hypokalemia; ⑤ Hypernatremia; ⑥ Hyperchloremia; ⑦ Metabolic acidosis; ⑧ Hypervolemia; ⑨ Conditions that may cause sodium retention, fluid overload, and edema (central or peripheral); ⑩ Patients receiving medications that may increase sodium and fluid retention (e.g., corticosteroids).

(2) Risk of hyponatremia: Monitoring of serum sodium is important for all fluids. The osmolarity of this product is 260-320 mOsmol/kg. High 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. 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.

(3) Check the concentration of sodium, potassium, and chloride ions in the serum; the acid-base concentration balance index, renal function, blood pressure, and cardiopulmonary function in the blood as clinically necessary.

(4) Check the packaging carefully before use to make sure that it is intact; squeeze and check the inner bag, and discard it if

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there is any leakage; the solution inside should be clear, without visible particles or discoloration, and should be used once.

(5) It is not recommended to add a medication; if necessary, please squeeze the bag after adding a medication to check carefully for leakage.

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

(7) When other electrolytes or drugs are added to this solution, the dose and infusion rate will also be dictated by the additives dose regime.

(8) Stop the infusion immediately if signs or symptoms of hypersensitivity /infusion reactions develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

(9) Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte balance, and acid-base balance for patients requiring long-term injection therapy or whenever the condition of the patient or the rate of administration warrants such evaluation.

(10) Do not connect flexible plastic containers 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.

(11) 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.

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

[Pregnancy and Lactation]
There are no adequate data from the use of sodium chloride injection in pregnant or lactating women. Sodium chloride injection is contraindicated in patients with pregnancy-induced hypertension. The potential risks and benefits for each specific patient should be carefully considered before using sodium chloride injection in pregnant or lactating women.

[Pediatrics Use]
The volume and rate of fluid replacement should be strictly controlled. Plasma electrolyte concentrations should be closely monitored in the pediatric population.

hypernatremia (which can lead to CNS manifestations, including seizures, coma, cerebral edema, and death), sodium overload (which can lead to central and/or peripheral edema), and hypokalemia. It can also cause bicarbonate loss. When assessing an overdose, any additives in the solution must also be considered.

[Pharmacology and Toxicology]
Sodium chloride is an electrolyte supplement. Sodium and chlorine 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. The normal serum sodium concentration is 135-145 mmol/L, accounting for 92% of plasma cations and 90% of the total osmotic pressure. Therefore, the amount of plasma sodium plays a decisive role in the osmotic pressure. The normal serum chloride concentration is 98-106 mmol/L. The sodium and chloride ions in the human body are mainly regulated by the hypothalamus, posterior pituitary gland, and kidneys to maintain the stability of fluid volume and osmotic pressure.

[Pharmacokinetics]
After intravenous injection, sodium chloride directly enters the blood circulation and is widely distributed in the body, but mainly exists in extracellular fluid. Both sodium and chloride ions can be filtered by the glomerulus and partially reabsorbed by the renal tubules. It is excreted by the kidneys in urine, and only a small amount is excreted through sweat.

[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 1000ml/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 specially 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 1000ml/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 specially designed polyisoprene rubber stopper, and special valves for special purposes.

[Geriatrics Use]
The volume and rate of fluid replacement should be strictly controlled. 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.

[Drug Interactions]
When sodium chloride injection is used as a drug solvent or diluent, attention should be paid to the incompatibility between drugs. Caution is advised during coadministration of sodium chloride injection with lithium preparations, as it may 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 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]
Excessive administration of sodium chloride injection may lead to hypernatremia (which can lead to CNS manifestations, including seizures, coma, cerebral edema, and death), sodium overload (which can lead to central and/or peripheral edema), and hypokalemia.

[Shelf Life] 24 months
[Executive Standard] Pharmacopoeia of the People's Republic of China, Volume II, 2020 Edition

[License Number]

Product	Strength	License Number
Sodium Chloride Injection	50ml:0.45g	H19993745
Sodium Chloride Injection	100ml:0.9g	H19994067
Sodium Chloride Injection	250ml:2.25g	H19994066
Sodium Chloride Injection	500ml:4.5g	H19983148

[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

Container Label

Baxter Logo Trademark

A6C1322

SODIUM CHLORIDE INJECTION

50

100

150

200

250ml
0.9% Sodium Chloride

[Strength] 250ml: 2.25g
[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

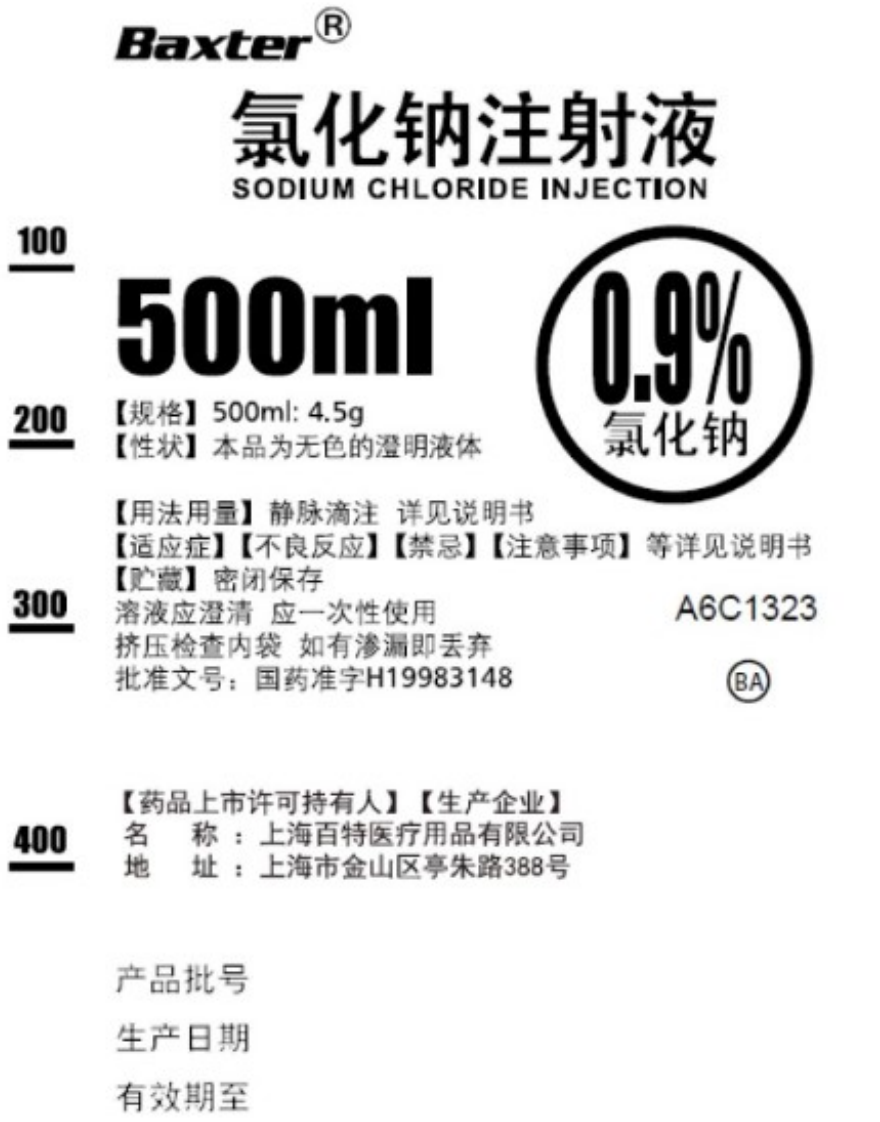
The solution should be clear and should be used up at one time
Inspect the inner bag by squeezing it and discard solution if leakage occurs
License Number: H19994066

AA

[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



Container Label

Baxter Logo Trademark

A6C1323

SODIUM CHLORIDE INJECTION

100

200

300

400

500ml
0.9% Sodium Chloride

[Strength] 500ml: 4.5g
[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

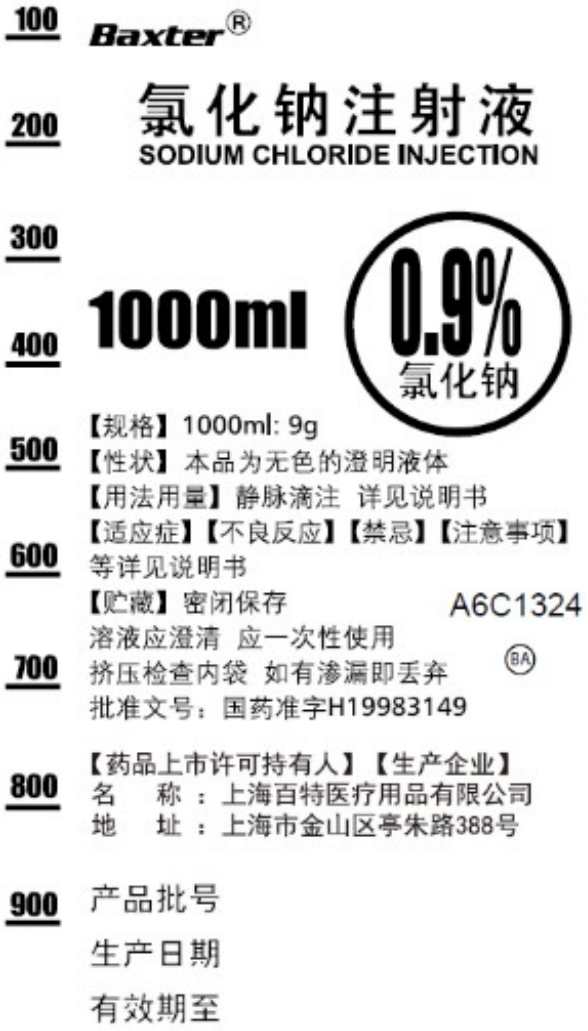
The solution should be clear and should be used up at one time
Inspect the inner bag by squeezing it and discard solution if leakage occurs
License Number: H19983148

AA

[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



Container Label

Baxter Logo Trademark

A6C1324

SODIUM CHLORIDE INJECTION

100

200

300

400

500

600

700

800

900

1000ml
0.9% Sodium Chloride

[Strength] 1000ml: 9g
[Description] This product is a clear, colorless liquid
[Dosage and Administration] Intravenous drip See the package insert for details
For details of [Indications], [Adverse Reactions], [Contraindications], and [Precautions], please refer to the package insert

[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: H19983149

AA

[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

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-9804
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	9 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:0338-9804-40	40 in 1 CARTON	10/18/2024	
1	NDC:0338-9804-01	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		10/18/2024	

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-9806
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	9 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:0338-9806-12	12 in 1 CARTON	10/18/2024	
1	NDC:0338-9806-01	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			

Unapproved drug for use in drug shortage		10/18/2024	

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-9810
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	9 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:0338-9810-24	24 in 1 CARTON	10/18/2024	
1	NDC:0338-9810-01	500 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		10/18/2024	

Labeler - Baxter Healthcare Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare (Shanghai) Co. Ltd.		527191860	MANUFACTURE(0338-9804, 0338-9806, 0338-9810) , ANALYSIS(0338-9804, 0338-9806, 0338-9810) , LABEL(0338-9804, 0338-9806, 0338-9810) , PACK(0338-9804, 0338-9806, 0338-9810) , STERILIZE(0338-9804, 0338-9806, 0338-9810)