SODIUM CHLORIDE 0.9%- sodium chloride injection, solution
Huaren Pharmaceutical (Rizhao) Co., Ltd.

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.

Sodium Chloride Injection (EUA)

SODIUM CHLORIDE INJECTION, USP BAG

Sodium Chloride Injection Instructions

Please read the instructions carefully and use under the guidance of a physician.

Check carefully before use. Do not use if leakage is found, the drug liquid is unclear, or there are visible particles, do not use.

INGREDIENTS

This product is an isotonic sterilizing aqueous solution of sodium chloride.

Chemical Name: Sodium chloride

Molecular Formula: NaCl Molecular Weight: 58.44 Osmolality: 260~320 mOsmol/kg.

CHARACTER

This product is a colorless and clear liquid.

INDICATIONS

It is used to regulate the balance of water and electrolytes in the body.

SPECIFICATION

50ml: 0.45g; 100ml: 0.9g; 250ml: 2.25g; 500ml: 4.5g; 1000ml: 9g

DOSAGE AND USAGE

Intravenous infusion, dosage according to the need of the disease.

ADVERSE REACTIONS

Excessive and rapid infusion can cause water and sodium retention, edema, elevated blood pressure, rapid heart rate, chest tightness, dyspnea, and even acute left heart failure.

PRECAUTIONS

Use with caution in the following cases:

1. CD Edematous diseases, such as nephrotic syndrome, cirrhosis, ascites, congestive heart failure, acute left heart failure, brain edema, and idiopathic edema
2. Acute renal failure, oliguria stage, chronic renal failure, urine volume decreased, and poor response to diuretic drugs
3. Hypertension
4. Hypokalemia

Follow-up examination:

1. CD Serum sodium, potassium, chlorine concentration
2. Blood acid-base balance index
3. Kidney function
4. Blood pressure
5. Cardiopulmonary function

MEDICATION IN PREGNANT WOMEN AND LACTATING WOMEN

Not clear.

MEDICATION IN CHILDREN

The amount and speed of fluid supplementation should be strictly controlled.

MEDICATION IN THE ELDERLY

The amount and speed of fluid supplementation should be strictly controlled.

DRUG INTERACTIONS

Should not be used with drugs with known incompatibility contraindications.

DRUG OVERDOSE

For those with existing acidosis, a large amount of this product can cause hyperchloric acidosis.

PHARMACOLOGY AND TOXICOLOGY

Sodium and chlorine are important electrolytes in the body, mainly in the extracellular fluid, and play a very important role in maintaining the normal blood and extracellular fluid volume and osmotic pressure of the human body. The normal serum sodium concentration is 135~145mmol/L, accounting for 92% of the plasma cation and 90% of the total osmotic pressure, so the amount of plasma sodium plays a decisive role in the osmotic pressure. The normal serum chlorine concentration is 98~106mmol/L, which is mainly regulated by the human body through the hypothalamus, posterior pituitary and

kidney to maintain the stability of body fluid volume and osmotic pressure.

PHARMACOKINETICS

In the gastrointestinal tract, sodium is absorbed almost entirely through the active transport of intestinal mucosal cells. Sodium is excreted primarily by the kidneys.

PACKAGE

1. Plastic infusion bag (non-PVC co-extruded film, double hard tube, easy to fold, double valve and double plug). 50ml/ bag, 100ml/ bag, 250ml/ bag, 500ml/ bag, 10O0ml/ bag.
2. Plastic infusion bag (non-PVC co-extruded film, double hard tube, easy to fold, double valve double plug, double aseptic packaging). 50ml/ bag, 100ml/ bag, 250ml/ bag, 500ml/ bag, 1000ml/ bag.

VALIDITY

1. The product of 50ml,100ml, and 1000ml specifications is valid for 24 months.
2. The validity period of 250ml,500ml is 36 months.

STORAGE

Store at 20° to 25°C (68° to 77°F) **[see USP Controlled Room Temperature]**. Protect from freezing.

OTHER INFORMATION

[EXECUTIVE STANDARD]

Pharmacopoeia of the People's Republic of China (2020, Volume 11)

[APPROVAL NUMBER]

GuoYaoZhunZi: H20033208 (50ml: 0.45g)

GuoYaoZhunZi: H20023682 (100ml: 0.9g)

GuoYaoZhunZi: H20023146 (250ml: 2.25g)

GuoYaoZhunZi: H20023145 (500ml: 4.5g)

GuoYaoZhunZi: H20023750 (1000ml: 9g)

[PHARMACEUTICAL MARKETING AUTHORIZATION HOLDER]

Name: Huaren Pharmaceutical Co., Ltd.

Registered Address: No. 187, Zhuzhou Road, Qingdao High-tech Park, China.

[MANUFACTURER]

Enterprise Name: Huaren Pharmaceutical Co., Ltd.

Production Address: No. 187, Zhuzhou Road, Qingdao High-tech Park, China. Zip code: 266101

Tel.: 400-0648885
Fax: 0532-67709071
Website: http//www.qdhuaren.com
Fax: 0532-88702625

HEALTH CARE PROVIDER LETTER pg.1

华仁药业 HUAREN PHARMACEUTICAL

Smith Associates

March 18, 2025

Subject: Temporary Importation of 0.9% Sodium Chloride Injection Products from Shandong Province, China to address drug shortages.

Dear Healthcare Provider,

To prevent the shortages of Sodium Chloride Injection, USP, in the United States, Smith Associates. is coordinating with the U.S. Food and Drug Administration (FDA) to temporarily import 0.9% Sodium Chloride Solution from HUAREN PHARMACEUTICAL CO., LTD's manufacturing facility in China. FDA has not approved these products manufactured by HUAREN.

At this time, no other entity except Smith Associates is authorized by the FDA to import or to distribute this HUAREN product in the United States.

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.

Effective immediately, and during this temporary period, Smith Associates will offer the following presentations of 0.9% Sodium Chloride Solution imported from Huaren's facility in Shandong Province, China:

Product Name and Description	Size	Product code	Bags per carton	NDC code of a single bag
0.9% Sodium Chloride Injection	1000mL			

It is important to note the following: (The first caution should be added if the product has a barcode; otherwise, remove it.

- Procedures should be followed to ensure the correct drug product is used in all systems and processes and administered to individual patients. For example, institutions should consider manually inputting the product into their systems and confirm that barcode systems do not provide incorrect information when the product is scanned.
- 0.9% Sodium Chloride Injection is available only by prescription in the U.S. However, the imported products do not have the "Rx only" statement on the labeling.
- USE A NEW CONTAINER IF PARTICULATES ARE VISIBLE OR IF THE IV CONTAINER CONTAINS A LEAK

CS

HEALTH CARE PROVIDER LETTER pg.2

华仁药业 HUAREN PHARMACEUTICAL

Smith Associates

Additional key differences between the FDA=approved product 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
- Table 2. Label images of the FDA-approved and imported 0.9% Sodium Chloride Injection

Please refer to the FDA-approved prescribing information as follows:

- **0.9% Sodium Chloride Injection, USP (insert link here)**

Reporting Adverse Events:
Healthcare providers should report adverse events associated with the use of Huaren 0.9% Sodium Chloride Solution for I.V. Infusion to **Smith Associates** by phone 888-729-9674 x203 email: kleigh@fdaconsultants.com and csmith@fdaconsultants.com

Adverse reactions or quality problems experienced with the use of this product may 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 https://www.accessdata.fda.gov/scripts/medwatch/index.cfm 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).

Please ensure that your staff and others in your institution who may be involved in administering 0.9% Sodium Chloride Solution for I.V. Infusion receive a copy of this letter and review the information.

To place an order:
please contact **Smith Associates** at _____
For all other inquiries please contact Smith Associates at 1-888-729-9674 x203 (phone); email: kleigh@fdaconsultants.com and csmith@fdaconsultants.com

CS

HEALTH CARE PROVIDER LETTER pg.3

Signature and title _____

Huaren Pharmaceutical

Email: _____

Contact Number: _____

Smith Associates

Signature and Title

Christian Smith

Smith Associates

Email: csmith@fdaconsultants.com

Phone: 888-729-9674 x203

This letter will require the manufacturer's signature, as well as your signature and email and phone contact. This information will also be provided in the amendment to the FDA.

PACKAGE LABEL– 0.9% Sodium Chloride 1000 mL Bag Label

氯化钠注射液 1000ml 100mmX135mm 2C

100mm

1000ml/0

Approval Number: GuoYaoZhunZi: H20023750

Non-PVC co-extruded film, double hard tube, easy to fold, double valv double plug

Sodium Chloride Injection

[Specification] 1000ml: 9g

[Indications]

It is used to regulate the balance of water and electrolytes in the body.

[Dosage and Usage]

Intravenous infusion, dosage according to the need of the disease.

[Precautions] [Adverse reactions] See the instructions for details.

[Storage] Sealed storage.

Check carefully before use. Do not use if leakage is found, the dru liquid is unclear,or there are visible particles, do not use.

[Pharmaceutical marketing authorization holder]
Ehuaen Pharmaceutical Co., Ltd.
[Manufacturer] Ehuaen Pharmaceutical Co., Ltd.

Batch No.: G2408061
Mfg.Date: 20240621
Exp.Date: July 2026

SODIUM CHLORIDE 0.9%

sodium chloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:85268-801
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 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85268-801-03	10 in 1 CASE	03/07/2025	
1	NDC:85268-801-02	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		03/07/2025	

Labeler - Huaren Pharmaceutical (Rizhao) Co., Ltd. (527866378)

Revised: 3/2025 Huaren Pharmaceutical (Rizhao) Co., Ltd.