Important Prescribing Information

Nov 18, 2024

Subject: Temporary importation of 0.9% Sodium Chloride Injection Products from Chengdu, China, labeled in Chinese, to address drug shortages

Dear Healthcare Professional,

To prevent a shortage of large volume parenteral fluid drug products, Sichuan Kelun Pharmaceutical Co., Ltd. (Kelun) is coordinating with the U.S. Food and Drug Administration (FDA), to temporarily import 0.9% Sodium Chloride Injection (250 mL) from Kelun's manufacturing facility in Chengdu, China. FDA has not approved this product manufactured by Kelun's Chengdu, China 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 Kelun is authorized by the FDA to import or distribute these products in the United States.

Effective immediately, and during this temporary period, Kelun will offer the following imported products from Kelun's facility in Chengdu, China:

Product Name and Description	Size	Containers per Carton	Unapproved Drug for Use in Drug Shortage NDC
0.9% Sodium Chloride Injection (UniFlex)	250mL	40	84898-911-02

Lot Number	Exp. mm/yyyy
A24072906	06/2027
A24072907	06/2027
A24072908	06/2027
A24072909	06/2027
A24072910	06/2027
A24072911	06/2027
A24072912	06/2027
A24100908	09/2027
A24100909	09/2027
A24100910	09/2027
A24100911	09/2027
A24100912	09/2027

Lot Number	Exp. mm/yyyy
A24101001	09/2027
A24101002	09/2027
A24101003	09/2027
A24101004	09/2027
A24101005	09/2027
A24101006	09/2027
A24101007	09/2027
A24101008	09/2027
A24101009	09/2027
A24101010	09/2027
A24101011	09/2027
A24101012	09/2027

It is important to note the following:

- The imported products' administration port system is fully compatible with BD IV sets marketed in the United States.
- Procedures should be followed to assure that the correct drug product is being 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 statement "Rx only" on the labeling.

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

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

Reporting Adverse Events / Product Quality Issues

To report **adverse events** associated with this imported product, please call ApiJect at 855-826-4885. Adverse events or quality problems experienced with the use of this product 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 this imported product, please contact ApiJect Systems Corp, Kelun distributor in the U.S. for Medical Information Service at 855-826-4885.

Please refer to the FDA-approved prescribing information for 0.9% Sodium Chloride Injection (click here).

If you have any questions about the information contained in this letter or the use of the imported products, please contact ApiJect Systems Corp, Kelun distributor in USA for Medical Information Service at 855-826-4885.

Sincerely,

Zhu Huiling

Zhu Huiling

Dept. Manager, International Affairs & Foreign Trade
Sichuan Kelun Pharmaceutical Co., Ltd.

Uniflex ™ is the proposed trademarks of Sichuan Kelun Pharmaceutical Co., Ltd

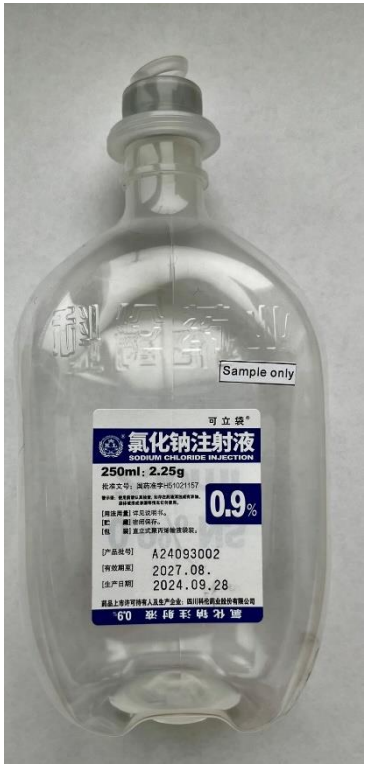
Attachments:

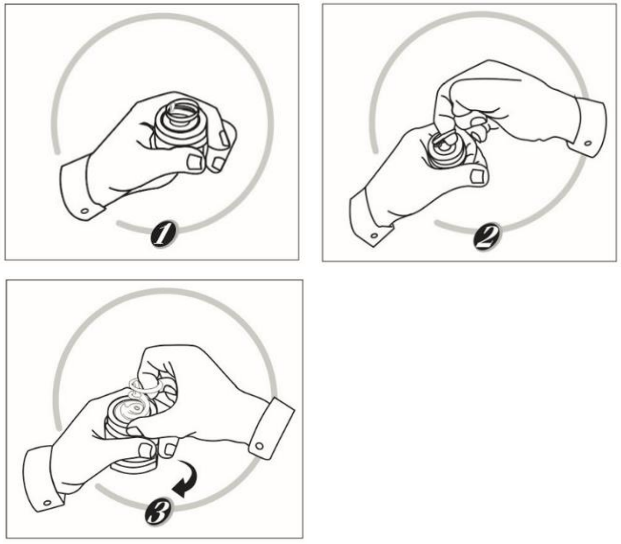
Product Comparison Tables 1 and 2

Product Comparison Table

Table 1. Key Differences between FDA-approved and Imported 0.9% Sodium Chloride Injection

	U.S. FDA Approved Product	Imported Product
Product name	**0.9% Sodium Chloride Injection**	**0.9% Sodium Chloride Injection**
Volume	250mL	250mL
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.	Water loss due to various causes, including hypotonic, isotonic and hyperosmolar water loss; hyperosmolar nonketotic diabetic coma can be corrected by isotonic or hypotonic sodium chloride; hypochlorine metabolic alkalosis; irrigation of eyes with topical normal saline, washing wounds, etc.; it is also used in obstetric water sacs to induce labor.
Active ingredients	Sodium 154 mEq/L Chloride 154 mEq/L Each 100 mL contains 900 mg Sodium chloride USP	Sodium 154 mEq/L Chloride 154 mEq/L Each 100 mL contains 900 mg Sodium chloride Ch. P.
Additional information	pH is 5.0 (4.5 to 7.0) Osmolarity 308 mOsmol/L (calc)	pH 4.5 to 7.0 Osmolarity 308 mOsmol/L (calc) pH and Osmolarity not indicated on label
Storage conditions	Store at room temperature 25°C/77°F	Store in well-closed containers. Storage temperature prescribed in Ch. P. for this label: Room temperature (10°C to 30°C)
Specification	USP	Ch. P.

	VIAFLEX (PVC) Pull off port protector (blue color) 	UniFlex (PP)   

	U.S. FDA Approved Product	Imported Product
Administration port closures	 How to open: Remove the plastic protector from outlet port at bottom of container.	Top view of PP cap (ring-pull type, intact)  How to open: Pull off the ring on top of the closure in clockwise direction. 

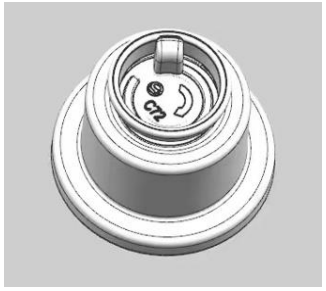
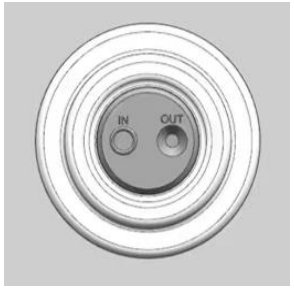
	U.S. FDA Approved Product	Imported Product
		After removing pull ring, two ports are shown on top of rubber stopper. OUT port is for the administration set and IN port is a medication addition site. Two-port rubber stopper   

Table 2. Label images of FDA-Approved and Imported 0.9% Sodium Chloride Injection

FDA Approved Product	Proposed Import Product	
VIAFLEX PVC) LOT EXP 2B1323 NDC 0338-0049-03 DIN 00060208 **0.9% Sodium Chloride Injection USP** **500 mL** EACH 100 mL CONTAINS 900 mg SODIUM CHLORIDE USP pH 5.0 (4.5 TO 7.0) mEq/L SODIUM 154 CHLORIDE 154 OSMOLARITY 308 mOsmol/L (CALC) STERILE NONPYROGENIC SINGLE DOSE CONTAINER ADDITIVES MAY BE INCOMPATIBLE CONSULT WITH PHARMACIST IF AVAILABLE WHEN INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE MIX THOROUGHLY DO NOT STORE DOSAGE INTRAVENOUSLY AS DIRECTED BY A PHYSICIAN SEE DIRECTIONS CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND MUST NOT BE USED IN SERIES CONNECTIONS DO NOT USE UNLESS SOLUTION IS CLEAR RX ONLY STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT VIAFLEX CONTAINER PL 146 PLASTIC BAXTER VIAFLEX AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC FOR PRODUCT INFORMATION 1-800-933-0303 1 2 3 4 **Baxter** BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA DISTRIBUTED IN CANADA BY BAXTER CORPORATION MISSISSAUGA ON L5N 0C2	**UniFlex (PP)** Front view 40*50mm  Back view 40*50mm 	**Translation** UniFlex SODIUM CHLORIDE INJECTION 2.25g / 250ml, 0.9% Registration Approval No.: GYZZ H51021157 ATTENTION: Visually inspect the container. Check for minute leaks by squeezing bag firmly. If leaks are found, discard solution. Do not use the drug solution if particulate matter is visible. [Usage] See product insert [Storage] in a closed environment [Packaging] UniFlex Polypropylene Bag [LOT] [EXP] [MFG] Manufacturer: Sichuan Kelun Pharmaceutical Co., Ltd. SODIUM CHLORIDE INJECTION 0.9%