Important Prescribing Information

December 3, 2024

Subject: Temporary importation of Sodium Lactate Ringer's 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 Sodium Lactate Ringer's Injection (500 mL) from Baxter's manufacturing facility in Shanghai, China. FDA has not approved this product 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 this imported product in the United States.

Effective immediately, and during this temporary period, Baxter will offer the following imported product:

Product name and description	Size	Product code	Bags per carton	NDC code of a single bag
Sodium Lactate Ringer's Injection	500 mL	A6E2323	24	0338-9832-01

It is important to note the following:

- The imported Sodium Lactate Ringer's Injection is identical in composition to the US product Lactated Ringer's Injection.
- 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 product 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 product has primary container label written in Chinese. The primary container label contains the active pharmaceutical ingredient, concentration, volume, and product code in English.

- The imported product's administration port system is fully compatible with Baxter sets marketed in the United States.
- 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.
- **The imported product does not contain barcode on the unit label.** Institutions should manually input the product into their systems and take appropriate precautions to ensure accurate product identification in processes and workflows. Alternative procedures should be followed to ensure that the correct drug product and concentration is being used in all systems and processes and administered to individual patients.
- Lactated Ringer's Injection, USP is available only by prescription in the United States. However, the imported product does not have the statement "Rx only" on the labeling.

Additional key differences in the labeling between the FDA-approved product and the imported product are stated in the product comparison table at the end of this letter as follows:

Table 1. Key differences between FDA-approved Lactated Ringer's Injection, USP and imported Sodium Lactate Ringer's Injection
Table 2. Label images of FDA-approved Lactated Ringer's Injection, USP and imported Sodium Lactate Ringer's Injection

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

- Lactated Ringer's Injection, USP (click here)

Reporting Adverse Events or Product Quality Issues

To report **adverse events** associated with this imported product, please call Baxter at 1-866-888-2472, or fax: 1-800-759-1801. Adverse events or quality problems experienced with the use of this imported 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 (1-800-332-0178).

To report **product quality issues** associated with this imported product, 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 product, 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.

Sincerely,

Electronically signed by: Maria Soriano
Reason: I approve this document
Date: Dec 3, 2024 09:41 EST

Cecilia Soriano
President, Infusion Therapies & Technologies
Baxter Healthcare Corporation

Attachments:

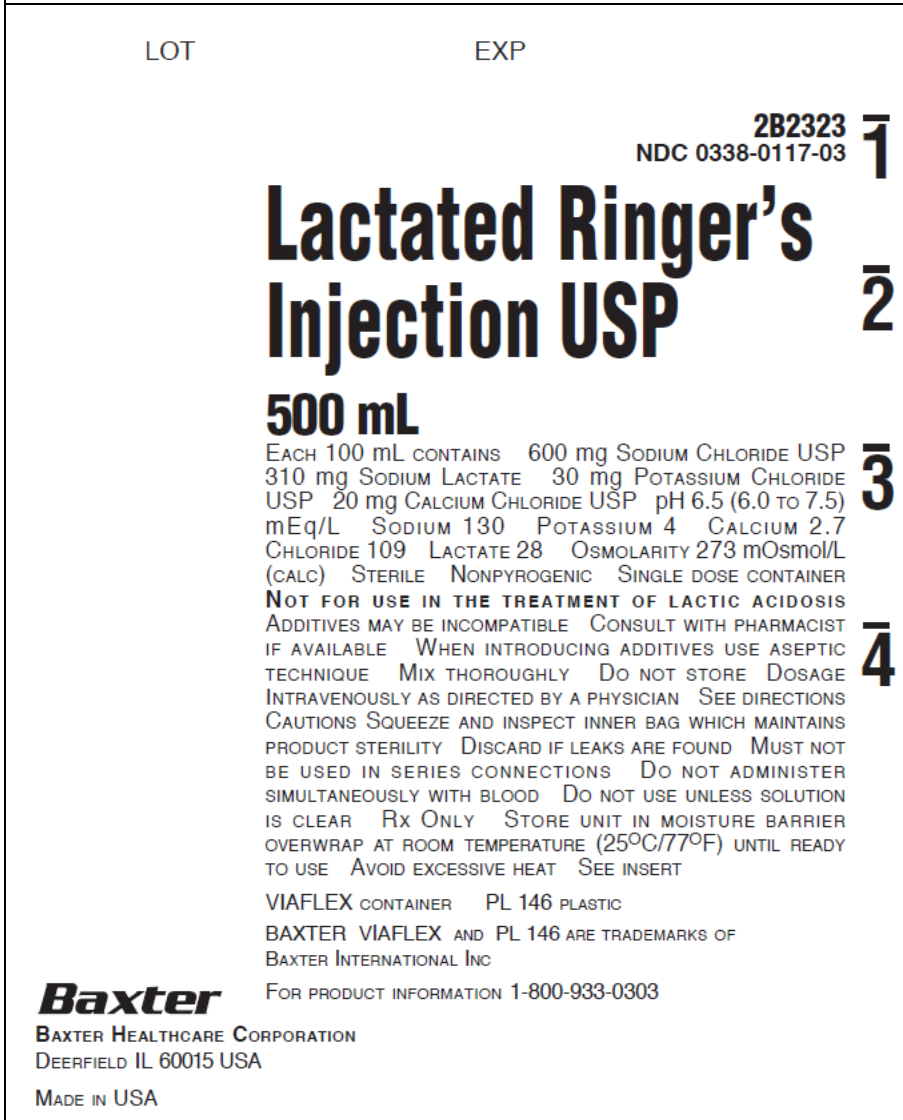
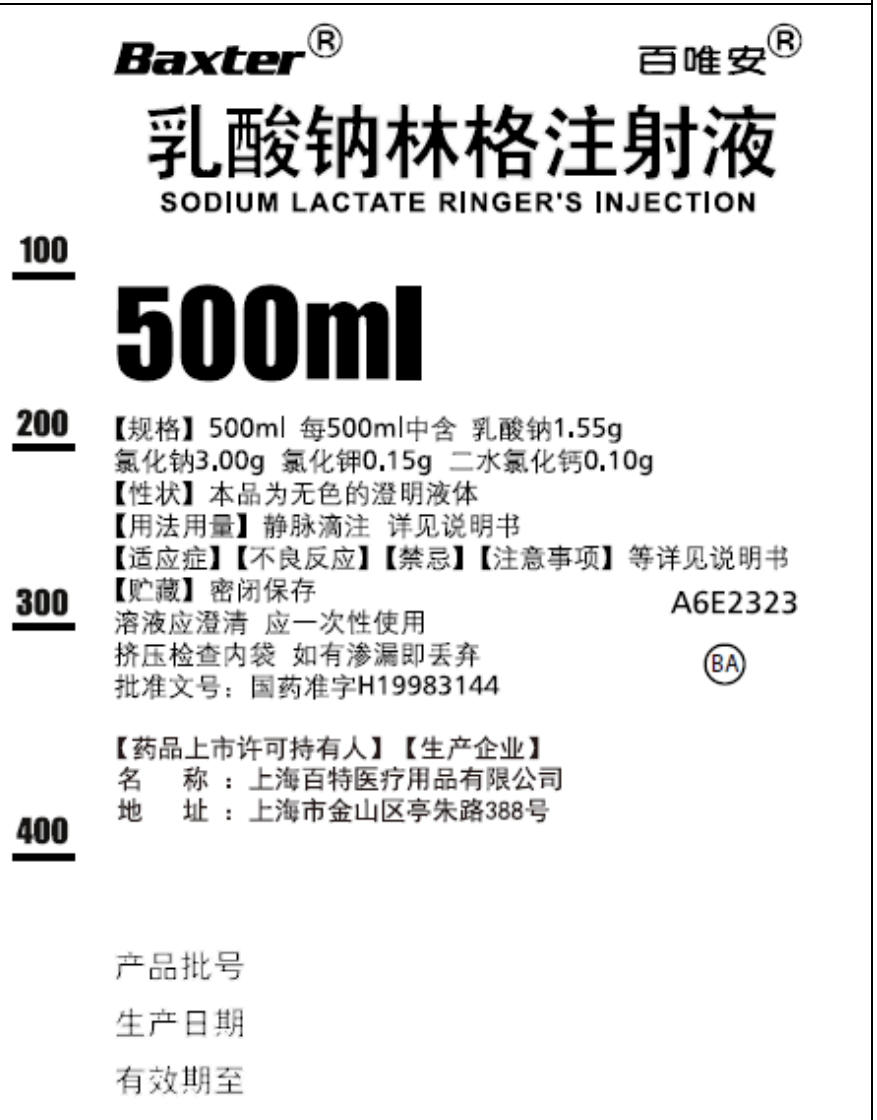
Product Comparison Tables 1 and 2

Product Comparison Tables

Table 1. Key differences between FDA-approved Lactated Ringer's Injection, USP and imported Sodium Lactate Ringer's Injection

	FDA-approved product 2B2323	Imported product from Shanghai, China A6E2323
Product name	Lactated Ringer's Injection, USP	Sodium Lactate Ringer's Injection
Label volume	500 mL	500 mL
Language of the Labels	English	Chinese
Indications	Lactated Ringer's Injection, USP is indicated as a source of water and electrolytes or as an alkalinizing agent	It is indicated for regulating body fluid, electrolyte, and acid-base equilibrium; this solution is also used for metabolic acidosis or dehydration cases with metabolic acidosis.
Active ingredients	Each 100ml contains 310mg Sodium Lactate, 600mg Sodium Chloride, 30mg Potassium Chloride and 20mg Calcium Chloride Dihydrate, USP	Each 100mL contains 310mg Sodium Lactate, 600mg sodium chloride, 30mg Potassium Chloride and 20mg Calcium Chloride Dihydrate, ChP
Additional information	pH: 6.0 to 7.5 Osmolarity 273 mOsm/L (calc)	pH: 6.0 to 7.5 Osmolarity 273 mOsm/L (calc)
Storage conditions	Store at room temperature 25°C/77°F.	Store at room temperature 10°C/50°F. to 30°C/86°F.
Container type	VIAFLEX (PVC)	AVIVA (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; Pull off port protector (yellow color), left side 

Table 2. Label images of FDA-approved Lactated Ringer's Injection, USP and imported Sodium Lactate Ringer's Injection

FDA-approved product 2B2323	Imported product from Shanghai, China A6E2323
Lactated Ringer's Injection, USP	Sodium Lactate Ringer's Injection
Label Color: Black. Barcode not shown (white).	Label Color: Black. (No barcode)
	

	English translation
	Baxter ® A6E2323 **SODIUM LACTATE RINGER'S INJECTION** **100** **500ml** [Strength] 500ml Each 500ml contains 1.55g Sodium Lactate, 3.00g Sodium Chloride, 0.15g Potassium Chloride, and 0.10g Calcium Chloride Dihydrate **200** [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 **300** 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: H19983144 [Drug Marketing Authorization Holder] [Manufacturer] Name: Baxter Healthcare (Shanghai) Co., Ltd. **400** Address: No. 388, Tingzhu Road, Jinshan District, Shanghai LOT MFG EXP