LACTATED RINGERS- sodium chloride, potassium chloride, sodium lactate and calcium 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.

SODIUM LACTATE RINGER'S INJECTION

HEALTH CARE PROFESSIONAL LETTER

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/).

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

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=dad7735c-709b-40ea-ab7a-15577e24a966)

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 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

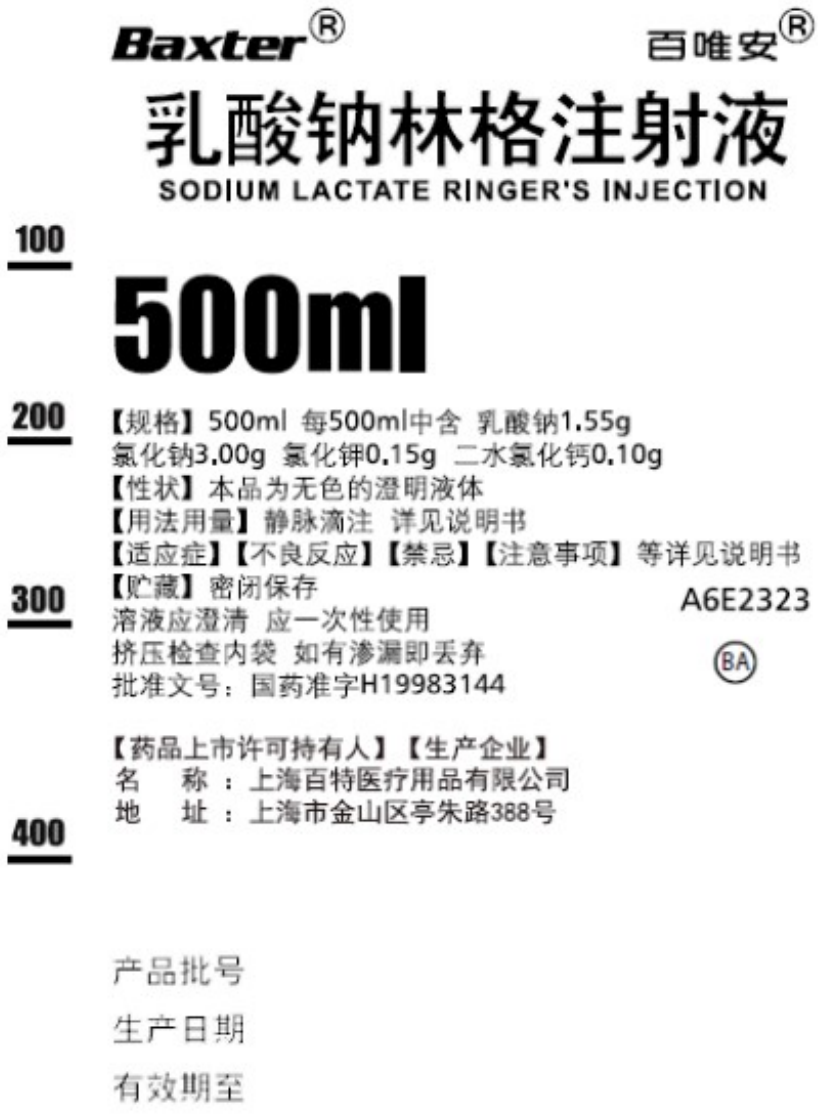
	FDA-approved product 2B2323	**Imported product from Shanghai, China A6E2323**
Product name	Lactated Ringer's Injection, USP	Sodium Lactate Ringer's Injection
Label volume	500 mL	500 mL
Language of the Labels	English	Chinese
Indications	Lactated Ringer's Injection, USP is indicated as a source of water 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)
LOT EXP 2B2323 NDC 0338-0117-03 **Lactated Ringer's Injection USP** **500 mL** Each 100 mL contains 600 mg Sodium Chloride USP 310 mg Sodium Lactate 30 mg Potassium Chloride USP 20 mg Calcium Chloride USP pH 6.5 (6.0 to 7.5) mEq/L Sodium 130 Potassium 4 Calcium 2.7 Chloride 109 Lactate 28 Osmolarity 273 mOsmol/L (calc) Sterile Nonpyrogenic Single dose container **Not for use in the treatment of lactic acidosis** 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 VIAFLEX container PL 146 plastic BAXTER VIAFLEX and PL 146 are trademarks of Baxter International Inc For product information 1-800-933-0303 Baxter Baxter Healthcare Corporation Deerfield IL 60015 USA Made in USA	Baxter® 百唯安® **乳酸钠林格注射液** **SODIUM LACTATE RINGER'S INJECTION** **500ml** 【规格】500ml 每500ml中含 乳酸钠1.55g 氯化钠3.00g 氯化钾0.15g 二水氯化钙0.10g 【性状】本品为无色的澄明液体 【用法用量】静脉滴注 详见说明书 【适应症】【不良反应】【禁忌】【注意事项】等详见说明书 【贮藏】密闭保存 溶液应澄清 应一次性使用 挤压检查内袋 如有渗漏即丢弃 批准文号：国药准字H19983144 A6E2323 BA 【药品上市许可持有人】【生产企业】 名 称：上海百特医疗用品有限公司 地 址：上海市金山区亭朱路388号 产品批号 生产日期 有效期至

	English translation
	

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL



Baxter Logo Trademark

A6E2323

SODIUM LACTATE RINGER’S INJECTION

100

200

300

400

500ml

[Strength] 500ml
Each 500ml contains 1.55g Sodium Lactate,
3.00g Sodium Chloride, 0.15g Potassium Chloride, and 0.10g Calcium Chloride Dihydrate
[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: H19983144

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

LOT
MFG
EXP

LACTATED RINGERS

sodium chloride, potassium chloride, sodium lactate and calcium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-9832
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	600 mg in 100 mL
SODIUM LACTATE (UNII: TU7HW0W0QT) (SODIUM CATION - UNII:LYR4M0NH37, LACTIC ACID, UNSPECIFIED FORM - UNII:33X04XA5AT)	SODIUM LACTATE	310 mg in 100 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	30 mg in 100 mL
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	20 mg in 100 mL

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
	NDC:0338-9832			

1	NDC:0338-9832-24	24 in 1 CARTON	12/03/2024	
1	NDC:0338-9832-01	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		12/03/2024	

Labeler - Baxter Healthcare Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare (Shanghai) Co. Ltd.		527191860	ANALYSIS(0338-9832) , LABEL(0338-9832) , MANUFACTURE(0338-9832) , PACK(0338-9832) , STERILIZE(0338-9832)

Revised: 12/2024 Baxter Healthcare Corporation