Important Prescribing Information

[November 6, 2024]

Subject: Temporary importation of 0.9% Sodium Chloride Injection, 5% Dextrose Injection, Lactated Ringer's Injection, and Plasma-Lyte A Injection from Alliston, Canada 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 the following products from Baxter's manufacturing facility in Alliston, Canada:

- 0.9% Sodium Chloride Injection, USP (250 mL, 500 mL, and 1,000 mL)
- 5% Dextrose Injection, USP (250 mL and 1,000 mL)
- Lactated Ringer's Injection, USP (500 mL and 1,000 mL)
- Plasma-Lyte A Injection, USP (1,000 mL)

FDA has not approved these products manufactured by Baxter's Alliston 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 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, USP	250 mL	JB1322	30	0338-9604-01
	500 mL	JB1323	24	0338-9608-01
	1,000 mL	JB1324	12	0338-9612-01
5% Dextrose Injection, USP	250 mL	JB0062	30	0338-9830-01
	1,000 mL	JB0064	12	0338-9588-01
Lactated Ringer's Injection, USP	500 mL	JB2323	24	0338-9596-01
	1,000 mL	JB2324	12	0338-9600-01
Plasma-Lyte A Injection, USP	1,000 mL	JB2544	12	0338-9591-01

It is important to note the following:

- **The imported products do not have a linear barcode on the bag, rather they have a 2D barcode that contains the product Global Trade Identification Number (GTIN), lot number, and expiration date. The barcode on the imported product labels may not register accurately in U.S. scanning systems.** Alternative procedures should be followed to ensure 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 ensure that barcode systems provide correct information when the product is scanned. Barcodes containing the NDC number for each imported product will additionally be made available online.
- These products are available only by prescription in the U.S. However, the imported products do not have the statement "Rx only" on the labeling.
- The 250 mL products (0.9% Sodium Chloride Injection, USP and 5% Dextrose Injection, USP are **not** compatible for admixing with Baxter's Vial-mate product.
- USE A NEW BAG IF PARTICULATES ARE VISIBLE OR IF THE IV BAG 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 USP
Table 2 Label images of FDA-approved and imported 0.9% Sodium Chloride Injection USP
Table 3 Key differences between FDA-approved and imported 5% Dextrose Injection USP
Table 4 Label images of FDA-approved and imported 5% Dextrose Injection USP
Table 5 Key differences between FDA-approved and imported Lactated Ringer's Injection, USP
Table 6 Label images of FDA-approved and imported Lactated Ringer's, USP
Table 7 Key differences between FDA-approved and imported Plasma-Lyte A Injection, USP
Table 8 Label images of FDA-approved and imported Plasma-Lyte A Injection, USP

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/).

Please refer to the FDA-approved prescribing information for each drug product as follows:

- 5% Dextrose Injection, USP (click here)
- 0.9% Sodium Chloride Injection, USP (click here)
- Lactated Ringers Injection, USP (click here)

- Plasma-Lyte Injection, USP (click here)

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 at 1-888-229-0001.

Sincerely,

Lee Ann Schuette

Lee Ann Schuette (Nov 6, 2024 16:07 CST)

Lee Ann Schuette
VP Global and US Marketing IV solutions, Clinical Nutrition, Pharmacy Tools
Baxter Healthcare Corporation

Attachments:

Product Comparison Tables 1-8

Product Comparison Table

Table 1 Key differences between FDA-approved and imported 0.9% Sodium Chloride Injection USP

	FDA-approved product	Imported product from Alliston, Canada
Product name	0.9% Sodium Chloride Injection, USP	0.9% Sodium Chloride Injection, USP
Label volume	**100 mL, 150 mL, 250 mL, 500 mL, 1000 mL**	**250 mL, 500 mL, 1000 mL**
Language of the Labels	English	English, **French**
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.	0.9% Sodium Chloride Injection, USP is indicated as a source of water and electrolytes. 0.9% Sodium Chloride Injection, USP can be used as a vehicle or diluent for compatible products for parenteral administration. 0.9% Sodium Chloride Injection, USP is also indicated for use as a priming solution in hemodialysis procedures
Active ingredients	Each 100 mL contains 900 mg Sodium Chloride, USP	Each 100 mL contains 900 mg Sodium Chloride, USP
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 25°C/77°F.
Container type	VIAFLEX (PVC)	VIAFLEX (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 (blue color), right side 

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

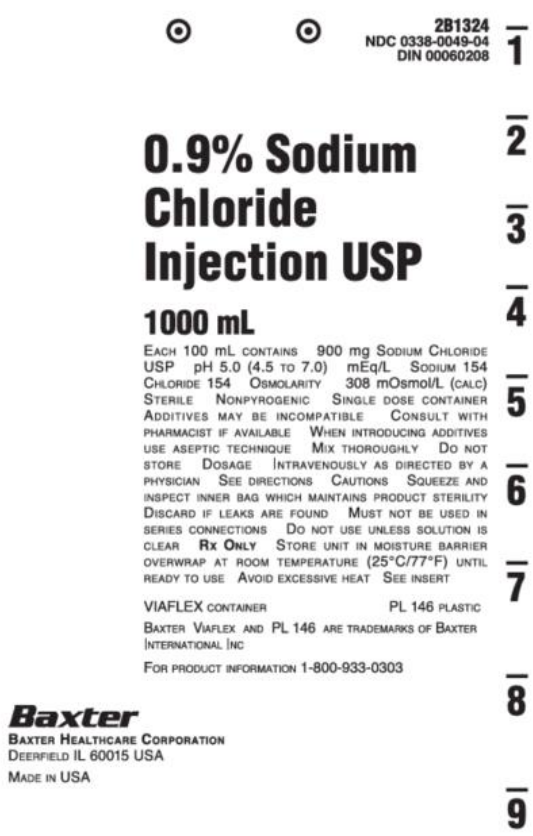
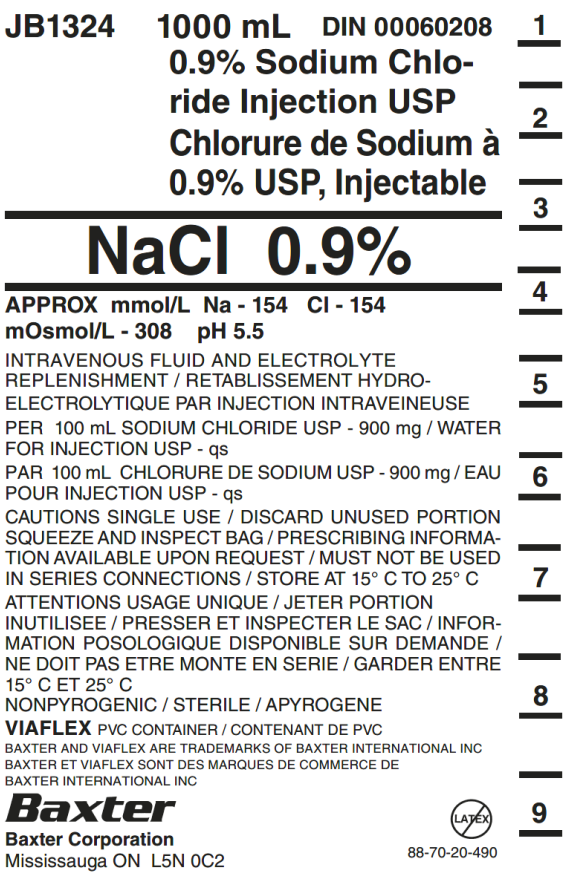
US-FDA approved product	Imported product from Alliston, Canada
0.9% Sodium Chloride Injection, USP	0.9% Sodium Chloride Injection, USP
Label Color: Black. **1000 mL shown as representative label.** Barcode, lot number, and expiry are not shown.	Label Color: Black. **1000 mL shown as representative label**. Barcode, lot number, and expiration date are not shown.
	

Table 3 Key differences between FDA-approved and imported 5% Dextrose Injection USP

	US-FDA approved product	Imported product from Alliston, Canada
Product name	5% Dextrose Injection, USP	5% Dextrose Injection, USP
Label volume	**150 mL, 250 mL, 500 mL, 1000 mL**	**250 mL, 1000 mL**
Language of the Labels	English	English, **French**
Indications	Dextrose Injection, USP is indicated as a source of water and calories.	5% Dextrose Injection, USP is indicated as a source of water and calories
Active ingredients	Each 100 mL contains 5 g Dextrose Hydrous USP	Each 100 mL contains 5 g Dextrose Hydrous USP
Additional information	pH 4.0 (3.2 to 6.5) Osmolarity 252 mOsmol/L (calc)	pH 4.0 (3.2 to 6.5) Osmolarity 252 mOsmol/L (calc)
Caloric content	170 kcal/L	170 kcal/L
Storage conditions	Store at room temperature 25°C/77°F.	Store at room temperature 15°C/59°F. to 25°C/77°F.
Container type	VIAFLEX (PVC)	VIAFLEX (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 (blue color), right side 

Table 4 Label images of FDA-approved and imported 5% Dextrose Injection USP

US-FDA approved product	Imported product from Alliston, Canada
5% Dextrose Injection, USP	5% Dextrose Injection, USP
Label Color: Black. **1000 mL shown as representative label.** Barcode not shown.	Label Color: Black**. 1000 mL shown as representative label**. Barcode, lot number, and expiration date not shown.

LOT EXP

2B0064
NDC 0338-0017-04

5% Dextrose Injection USP

1000 mL

EACH 100 mL CONTAINS 5 g DEXTROSE HYDROUS USP pH 4.0 (3.2 TO 6.5) OSMOLARITY 252 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 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

1 2 3 4 5 6 7 8 9

JB0064 1000 mL DIN 00060348

5% Dextrose Injection USP
Dextrose à 5% USP, Injectable

D5W

APPROX mOsmol/L - 252 pH 4.0

INTRAVENOUS FLUID AND NUTRIENT REPLENISHMENT / RECHARGE LIQUIDIENNE ET NUTRIMENT PAR INJECTION INTRAVEINEUSE

PER **100** mL DEXTROSE HYDROUS USP - **5** g / WATER FOR INJECTION USP - qs / pH MAY BE ADJUSTED WITH SODIUM HYDROXIDE

PAR **100** mL DEXTROSE HYDRATE USP - **5** g / EAU POUR INJECTION USP - qs / pH PEUT ETRE AJUSTE AVEC DE L'HYDROXYDE DE SODIUM

CAUTIONS SINGLE USE / DISCARD UNUSED PORTION SQUEEZE AND INSPECT BAG / SEE DIRECTIONS FOR USE MUST NOT BE USED IN SERIES CONNECTIONS / DO NOT ADMINISTER SIMULTANEOUSLY WITH BLOOD / STORE AT 15°C TO 25°C

ATTENTIONS USAGE UNIQUE / JETER PORTION INUTILISEE PRESSER ET INSPECTER LE SAC / VOIR MODE D'EMPLOI NE DOIT PAS ETRE MONTE EN SERIE / NE PAS ADMINISTRER SIMULTANEMENT AVEC LE SANG / GARDER ENTRE 15°C ET 25°C

NONPYROGENIC / STERILE / APYROGENE

VIAFLEX PVC CONTAINER / CONTENANT DE PVC

BAXTER AND VIAFLEX ARE TRADEMARKS OF BAXTER INTERNATIONAL INC
BAXTER ET VIAFLEX SONT DES MARQUES DE COMMERCE DE BAXTER INTERNATIONAL INC

Baxter
Baxter Corporation
Mississauga ON L5N 0C2

LATEX
07-25-77-316

1 2 3 4 5 6 7 8 9

Table 5 Key differences between FDA-approved and imported Lactated Ringer's Injection, USP

	US FDA approved product	Imported product from Alliston, Canada
Product name	Lactated Ringer's Injection, USP	Lactated Ringer's Injection, USP
Label volume	**250 mL, 500 mL, 1000 mL**	**500 mL, 1000 mL**
Language of the Labels	English	English, **French**
Indications	Lactated Ringer's Injection, USP is indicated as a source of water and electrolytes or as an alkalinizing agent	Lactated Ringer's Injection, USP is indicated as a source of water and electrolytes or as an alkalinizing agent
Active ingredients	Each 100 mL contains: 600 mg Sodium Chloride, USP 310 mg Sodium Lactate, USP 30 mg Potassium Chloride, USP 20 mg Magnesium Chloride, USP (mEq/L: 130 mEq Sodium, 4 mEq Potassium, 2.7 mEq Calcium, 109 mEq Chloride, 28 mEq Lactate)	Each 100 mL contains: 600 mg Sodium Chloride, USP 310 mg Sodium Lactate, USP 30 mg Potassium Chloride, USP 20 mg Magnesium Chloride, USP (mEq/L: 130 mEq Sodium, 4 mEq Potassium, 2.7 mEq Calcium, 109 mEq Chloride, 28 mEq Lactate)
Additional information	pH 6.5 (6.0 to 7.5) Osmolarity 273 mOsmol/L (calc)	pH 6.5 (6.0 to 7.5) Osmolarity 273 mOsmol/L (calc)
Caloric content	9 kcal/L	9 kcal/L
Storage conditions	Store at room temperature 25°C/77°F.	Store at room temperature 15°C/59°F. to 25°C/77°F.
Container type	VIAFLEX (PVC)	VIAFLEX (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 (blue color), right side 

Table 6 Label images of FDA-approved and imported Lactated Ringer's, USP

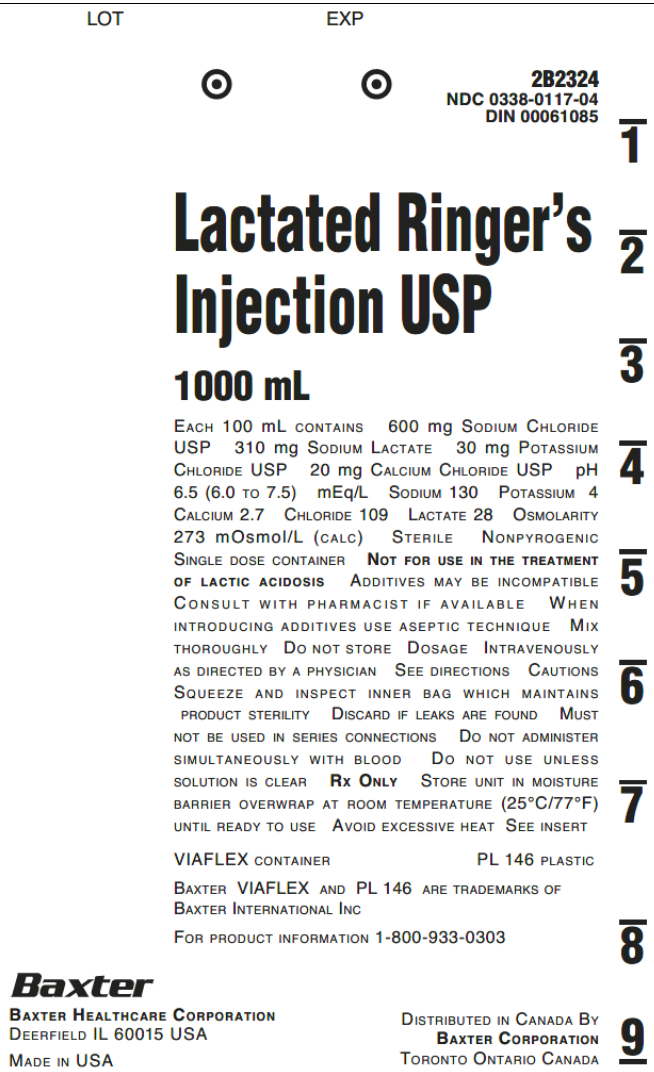
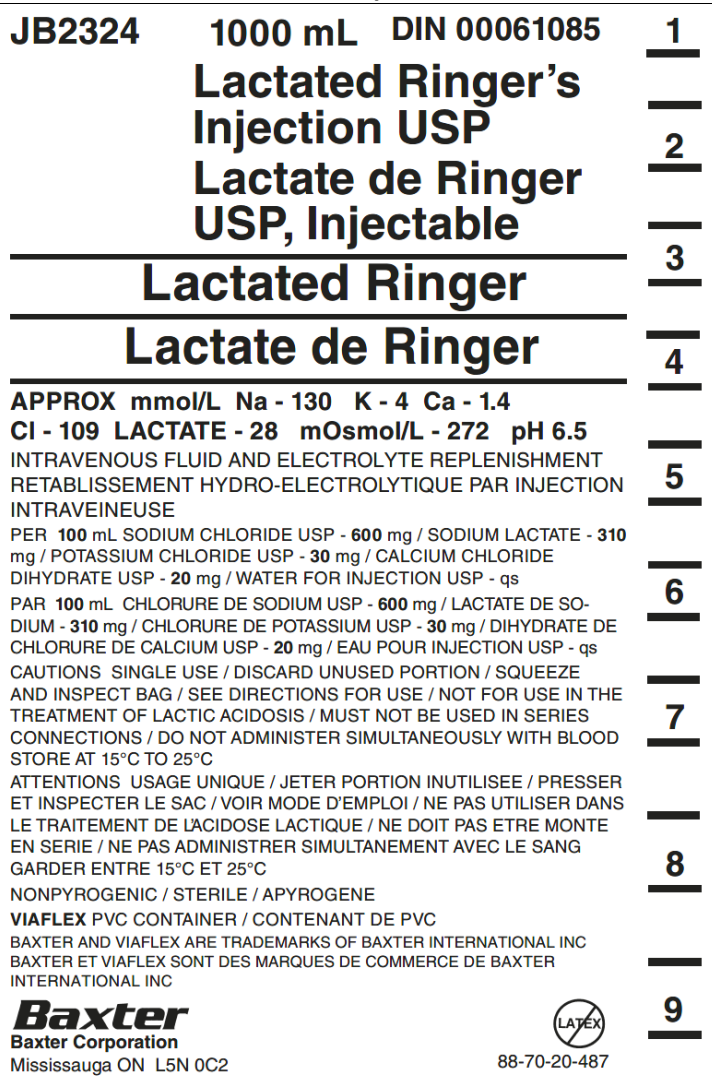
US-FDA approved product	Imported product from Alliston, Canada
Lactated Ringer's, USP	Lactated Ringer's, USP
Label Color: Black. Barcode not shown. **1000 mL shown as representative label.**	Label Color: Black**.** Barcode, lot number, and expiration date not shown. **1000 mL shown as representative label.**
	

Table 7 Key differences between FDA-approved and imported Plasma-Lyte A Injection, USP

	US FDA approved product	Imported product from Alliston, Canada
Product name	Plasma-Lyte A Injection, USP	Plasma-Lyte A Injection, USP
Label volume	**500 mL, 1000 mL**	**1000 mL**
Language of the Labels	English	English, **French**
Indications	PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is indicated as a source of water and electrolytes or as an alkalinizing agent. Furthermore, it is compatible with blood or blood components.	PLASMA-LYTE A Injection is indicated for volume replacement, as a source of water and electrolytes, and as an alkalinizing agent
Active ingredients	Each 100 mL contains: 526 mg Sodium Chloride, USP 502 mg Sodium Gluconate, USP 368 mg Sodium Acetate, USP 37 mg Potassium Chloride, USP 30 mg Magnesium Chloride, USP (mEq/L: 140 mEq sodium, 5 mEq potassium, 3 mEq magnesium, 98 mEq chloride, 27 mEq acetate, 23 mEq gluconate)	Each 100 mL contains: 526 mg Sodium Chloride, USP 502 mg Sodium Gluconate, USP 368 mg Sodium Acetate, USP 37 mg Potassium Chloride, USP 30 mg Magnesium Chloride, USP (mEq/L: 140 mEq sodium, 5 mEq potassium, 3 mEq magnesium, 98 mEq chloride, 27 mEq acetate, 23 mEq gluconate)
Additional information	pH 7.4 (6.5 to 8.0) Osmolarity 294 mOsm/L (calc)	pH 7.4 (6.5 to 8.0) Osmolarity 294 mOsm/L (calc)
Caloric content	21 kcal/L	21 kcal/L
Storage conditions	Store at room temperature 25°C/77°F.	Store at room temperature 15°C/59°F. to 25°C/77°F.
Container type	VIAFLEX (PVC)	VIAFLEX (PVC)

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 (blue color), right side 

Table 8 Label images of FDA-approved and imported Plasma-Lyte A Injection, USP

US-FDA approved product	Imported product from Alliston, Canada
Plasma-Lyte A Injection, USP	Plasma-Lyte A Injection, USP
Label Color: Black. Barcode not shown.	Label Color: Black. Barcode, lot number, and expiration date not shown.