



## Important Prescribing Information

November 5, 2024

### Subject: Temporary importation of Plasma-Lyte 148 (pH 7.4) Solution for Infusion from Sabiñánigo, Spain 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 Plasma-Lyte 148 (pH 7.4) Solution for Infusion (1,000 mL) from Baxter's manufacturing facility in Sabiñánigo, Spain. FDA has not approved this product manufactured by Baxter's Sabiñánigo 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
Plasma-Lyte 148 (pH 7.4) Solution for Infusion	1,000 mL	GCCE0324	10	0338-9593-01

#### It is important to note the following:

- 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 the products 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's administration port system is fully compatible with Baxter sets marketed in the United States.

- **The imported product does not contain a 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. A barcode containing the NDC number for the imported product will be made available online.
- Plasma-Lyte A Injection pH 7.4 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 tables at the end of this letter as follows:

Table 1 Key differences in FDA-approved Plasma-Lyte A Injection pH 7.4 and imported Plasma-Lyte 148 (pH 7.4) Solution for Infusion

Table 2 Label images of FDA-approved Plasma-Lyte A pH 7.4 and imported Plasma-Lyte 148 (pH 7.4) Solution for Infusion

**Please refer to the FDA-approved prescribing information for the drug product listed below:**

- Plasma-Lyte A Injection pH 7.4 (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](http://www.fda.gov/medwatch/report.htm)
- **Regular mail or Fax:** Download form [www.fda.gov/MedWatch/getforms.htm](http://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,



*Lee Ann Schuette*  
Electronically signed by: Lee  
Ann Schuette  
Reason: I approve this  
document  
Date: Nov 5, 2024 11:17 CST

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

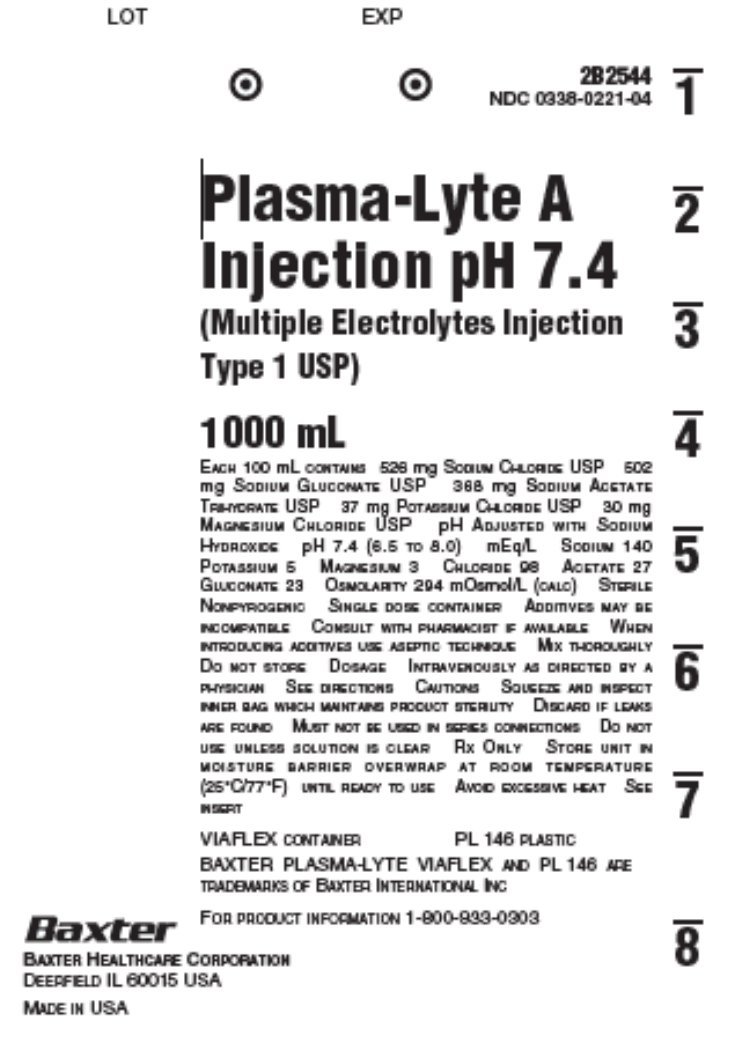
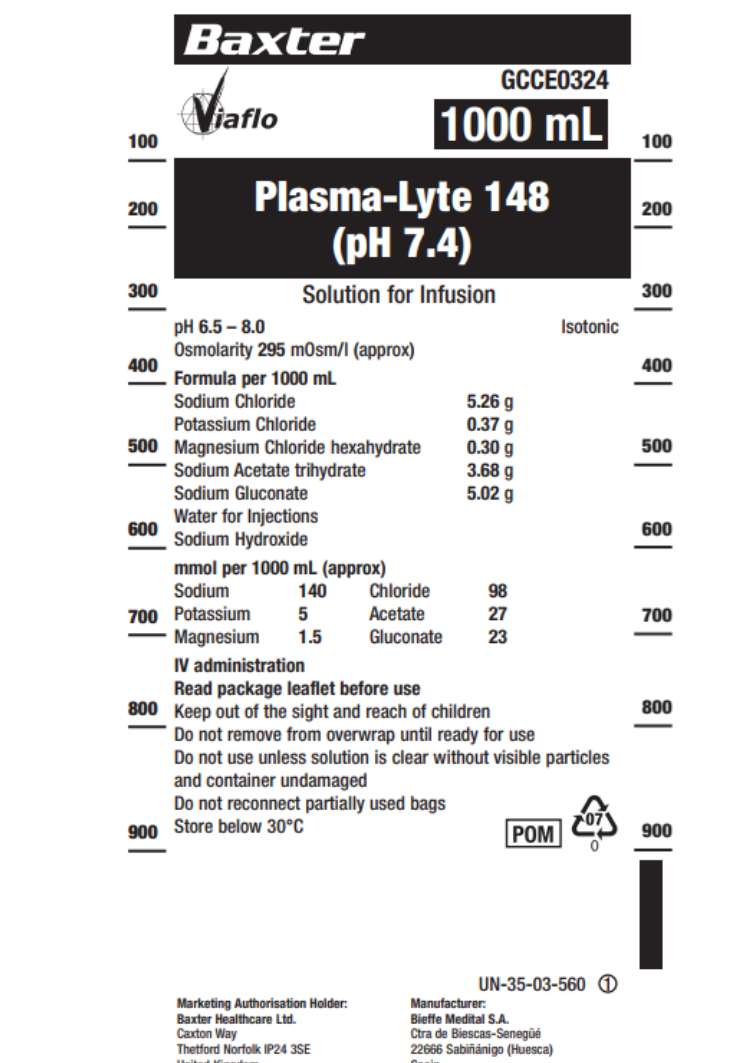

Baxter, Viaflo, and Viaflex are trademarks of Baxter International Inc.

**Table 1 Key differences in FDA-approved Plasma-Lyte A Injection pH 7.4 and imported Plasma-Lyte 148 (pH 7.4) Solution for Infusion**

	FDA-approved product	Imported product from Spain																								
<b>Product name</b>	<b>Plasma-Lyte A Injection pH 7.4 (Multiple Electrolytes Injection Type 1 USP)</b>	<b>Plasma-Lyte 148 (pH 7.4) Solution for Infusion</b>																								
<b>Label Volume</b>	1,000 mL	1,000 mL																								
<b>Indications</b>	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.	Plasma-Lyte 148 (pH 7.4) is indicated: - for fluid replacement (e.g. after burns, head injury, fracture, infection, and peritoneal irritation), - as intraoperative fluid replacement, - in haemorrhagic shock and clinical conditions requiring rapid blood transfusions (compatibility with blood), - in mild to moderate metabolic acidosis, also in case of lactate metabolism impairment.																								
<b>Active Ingredients</b>	<p>Each 100 mL contains</p> <p>526 mg Sodium Chloride 502 mg Sodium Gluconate 368 mg Sodium Acetate Trihydrate 37 mg Potassium Chloride 30 mg Magnesium Chloride Hexahydrate</p>	<p>Each 100 mL contains</p> <p>526 mg Sodium Chloride 502 mg Sodium Gluconate 368 mg Sodium Acetate Trihydrate 37 mg Potassium Chloride 30 mg Magnesium Chloride Hexahydrate</p>																								
<b>Additional information</b>	<p>pH 6.5 - 8.0</p> <p>Osmolarity 294 mOsmol/L (calc)</p> <p style="text-align: center;"><b>mEq/L</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Sodium</td> <td style="width: 10%;">140</td> <td style="width: 20%;">Chloride</td> <td style="width: 10%;">98</td> </tr> <tr> <td>Potassium</td> <td>5</td> <td>Acetate</td> <td>27</td> </tr> <tr> <td>Magnesium</td> <td>3</td> <td>Gluconate</td> <td>23</td> </tr> </table>	Sodium	140	Chloride	98	Potassium	5	Acetate	27	Magnesium	3	Gluconate	23	<p>pH 6.5 - 8.0</p> <p>Osmolarity 295 mOsmol/L (approx)</p> <p style="text-align: center;"><b>mEq/L</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Sodium</td> <td style="width: 10%;">140</td> <td style="width: 20%;">Chloride</td> <td style="width: 10%;">98</td> </tr> <tr> <td>Potassium</td> <td>5</td> <td>Acetate</td> <td>27</td> </tr> <tr> <td>Magnesium</td> <td>3</td> <td>Gluconate</td> <td>23</td> </tr> </table>	Sodium	140	Chloride	98	Potassium	5	Acetate	27	Magnesium	3	Gluconate	23
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<b>Storage Conditions</b>	Store at room temperature 25°C/77°F	Store below 30°C/86°F																								
<b>Container type</b>	VIAFLEX (PVC)	VIAFLO (nonPVC)																								

	FDA-approved product	Imported product from Spain
<b>Medication and Administration port closures</b>	<p>Contains medication port and administration port; Pull off port protector (blue color)</p> 	<p>Contains medication port and administration port; <b>Twist off port protector (natural color)</b></p> 

**Table 2 Label images of FDA-approved Plasma-Lyte A pH 7.4 and imported Plasma-Lyte 148 (pH 7.4) Solution for Infusion**

FDA-approved product	Imported product from Spain																								
<p align="center"><b>Plasma-Lyte A Injection pH 7.4</b> <b>(Multiple Electrolytes Injection Type 1 USP)</b></p>	<p align="center"><b>Plasma-Lyte 148 (pH 7.4)</b> <b>Solution for Infusion</b></p>																								
<p align="center">Label Color: Black. Barcode, lot number, and expiry are not shown.</p>	<p align="center">Label Color: Black. Lot number and expiration date are not shown.</p>																								
 <p>LOT                      EXP</p> <p align="right">2B2544 NDC 0338-0221-04</p> <p><b>Plasma-Lyte A Injection pH 7.4</b> <b>(Multiple Electrolytes Injection Type 1 USP)</b></p> <p><b>1000 mL</b></p> <p>EACH 100 mL CONTAINS 528 mg SODIUM CHLORIDE USP 502 mg SODIUM GLUCONATE USP 388 mg SODIUM ACETATE TRIHYDRATE USP 37 mg POTASSIUM CHLORIDE USP 30 mg MAGNESIUM CHLORIDE USP pH ADJUSTED WITH SODIUM HYDROXIDE pH 7.4 (6.5 TO 8.0) mEq/L SODIUM 140 POTASSIUM 5 MAGNESIUM 3 CHLORIDE 08 ACETATE 27 GLUCONATE 23 OSMOLARITY 294 mOsm/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 SOLICITS 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</p> <p>VIAFLEX CONTAINER                      PL 148 PLASTIC BAXTER PLASMA-LYTE VIAFLEX AND PL 148 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> <p><b>Baxter</b> FOR PRODUCT INFORMATION 1-800-933-0903 BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA</p>	 <p align="center"><b>Baxter</b></p> <p align="right">GCCE0324</p> <p align="center"><b>Viaflo</b>                      <b>1000 mL</b></p> <p><b>Plasma-Lyte 148</b> <b>(pH 7.4)</b></p> <p align="center"><b>Solution for Infusion</b></p> <p>pH 6.5 – 8.0                      Isotonic Osmolarity 295 mOsm/l (approx)</p> <p><b>Formula per 1000 mL</b></p> <table border="0"> <tr> <td>Sodium Chloride</td> <td>5.26 g</td> </tr> <tr> <td>Potassium Chloride</td> <td>0.37 g</td> </tr> <tr> <td>Magnesium Chloride hexahydrate</td> <td>0.30 g</td> </tr> <tr> <td>Sodium Acetate trihydrate</td> <td>3.68 g</td> </tr> <tr> <td>Sodium Gluconate</td> <td>5.02 g</td> </tr> <tr> <td>Water for Injections</td> <td></td> </tr> </table> <p><b>mmol per 1000 mL (approx)</b></p> <table border="0"> <tr> <td>Sodium</td> <td>140</td> <td>Chloride</td> <td>98</td> </tr> <tr> <td>Potassium</td> <td>5</td> <td>Acetate</td> <td>27</td> </tr> <tr> <td>Magnesium</td> <td>1.5</td> <td>Gluconate</td> <td>23</td> </tr> </table> <p><b>IV administration</b> Read package leaflet before use Keep out of the sight and reach of children Do not remove from overwrap until ready for use Do not use unless solution is clear without visible particles and container undamaged Do not reconnect partially used bags Store below 30°C</p> <p align="right">POM </p> <p align="right">UN-35-03-560 ①</p> <p>Marketing Authorisation Holder: Baxter Healthcare Ltd. Caxton Way Theford Norfolk IP24 3SE United Kingdom</p> <p>Manufacturer: Bieffe Medital S.A. Ctra de Biescas-Senegüé 22666 Sabiñánigo (Huesca) Spain</p> <p align="center">LOT                      EXP</p>	Sodium Chloride	5.26 g	Potassium Chloride	0.37 g	Magnesium Chloride hexahydrate	0.30 g	Sodium Acetate trihydrate	3.68 g	Sodium Gluconate	5.02 g	Water for Injections		Sodium	140	Chloride	98	Potassium	5	Acetate	27	Magnesium	1.5	Gluconate	23
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