**PLASMA-LYTE 148 (PH 7.4)- sodium chloride, sodium gluconate, sodium acetate, potassium chloride, magnesium 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.*

---

**PLASMA-LYTE 148 (pH 7.4)**

**Healthcare Professional Letter**

Baxter

**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
- **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.



**Please refer to the FDA-approved prescribing information for the drug product listed below:**
• Plasma-Lyte A Injection pH 7.4 (click here)

• Complete and submit the report **Online**: http://www.fda.gov/medwatch/report.htm
• **Regular mail or Fax**: Download form 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

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

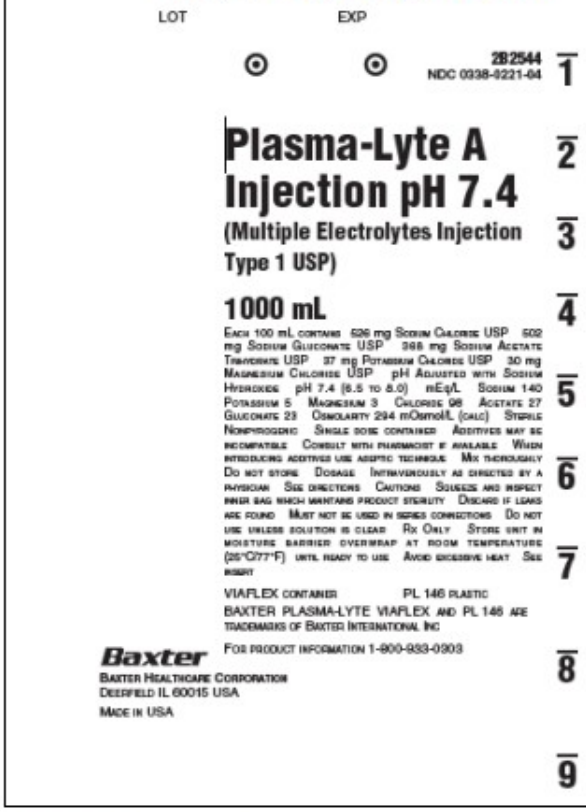
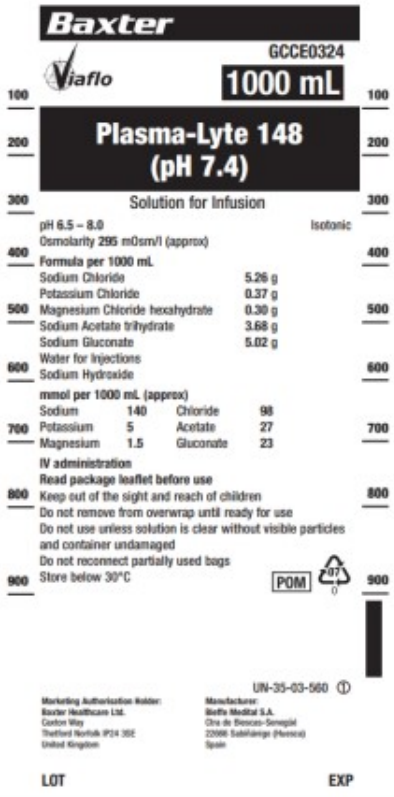
Lee Ann Schuette
VP Global and US Marketing IV solutions, Clinical Nutrition, Pharmacy Tools
Baxter Healthcare Corporation

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

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

**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 |
|---|---|
| **Plasma-Lyte A Injection pH 7.4 (Multiple Electrolytes Injection Type 1 USP)** | **Plasma-Lyte 148 (pH 7.4) Solution for Infusion** |
| Label Color: Black. Barcode, lot number, and expiry are not shown. | Label Color: Black. Lot number and expiration date are not shown. |
|  |  |





## PACKAGE/LABEL PRINCIPAL DISPLAY PANEL


Container Label

**Baxter**

**Viaflo**

**GCCE0324**

**1000 mL**

**100**

**200**

**300**

**400**

**500**

**600**

**700**

**800**

**900**

**Plasma-Lyte 148**
**(pH 7.4)**

Solution for Infusion

pH **6.5 – 8.0**
Isotonic
Osmolarity **295** m0sm/l (approx)

**Formula per 1000ml**
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 Hydroxide

**mmol per 100 mL (approx)**
Sodium 140 Chloride 98
Potassium 5 Acetate 27
Magnesium 1.5 Gluconate 23

**IV administration**
**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$^{o}$C

POM
07
0

UN-35-03-560
1

**Marketing Authorization Holder:**
**Baxter Healthcare Ltd.**
Caxton Way
Thetford Norfolk IP 24 3SE
United Kingdom

Manufacturer:
Bieffe Medital S.A.

Ctra de Biescas-Senegüé
22666 Sabiñánigo (Huesca)
Spain

**LOT**

**EXP**

## PLASMA-LYTE 148 (PH 7.4)

sodium chloride, sodium gluconate, sodium acetate, potassium chloride, magnesium chloride

injection, solution

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0338-9593 |
| **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 | 526 mg in 100 mL |
| **SODIUM GLUCONATE** (UNII: R6Q3791S76) (GLUCONIC ACID - UNII:R4R8J0Q44B, SODIUM CATION - UNII:LYR4M0NH37) | SODIUM GLUCONATE | 502 mg in 100 mL |
| **SODIUM ACETATE** (UNII: 4550K0SC9B) (ACETATE ION - UNII:569DQM74SC, SODIUM CATION - UNII:LYR4M0NH37) | SODIUM ACETATE | 368 mg in 100 mL |
| **POTASSIUM CHLORIDE** (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698) | POTASSIUM CHLORIDE | 37 mg in 100 mL |
| **MAGNESIUM CHLORIDE** (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698) | MAGNESIUM CHLORIDE | 30 mg in 100 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM HYDROXIDE** (UNII: 55X04QC32I) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0338-9593-10 | 10 in 1 CARTON | 11/08/2024 | |
| **1** | NDC:0338-9593-01 | 1000 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 | | 11/08/2024 | |

## Labeler - Baxter Healthcare Corporation (005083209)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Bieffe | | 464755693 | ANALYSIS(0338-9593) , LABEL(0338-9593) , MANUFACTURE(0338-9593) , |

| | | | |
|---|---|---|---|
| Medital SA | | 464755695 | PACK(0338-9593) , STERILIZE(0338-9593) |