

PLASMA-LYTE A- sodium chloride, sodium gluconate, sodium acetate, potassium chloride and magnesium chloride injection, solution
Baxter Healthcare Company

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 a Injection

Health Care Provider Letter



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

Baxter, Viaflex, and Plasma-Lyte are trademarks of Baxter International Inc.

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. |
|  <p>281324 NDC 0228-0248-04 DIN 00062028</p> <p>1 2 3 4 5 6 7 8 9</p> <p>0.9% Sodium Chloride Injection USP 1000 mL</p> <p>Each 100 mL contains 900 mg Sodium Chloride USP pH 5.0 (4.5 to 7.0) mEq/L Sodium 154 Chloride 154 Osmolality 308 mOsmol/L (300) Sterile Nonpyrogenic Single Dose Container Additives may be incompatible Consult with pharmacist if available. When introducing solutions use aseptic technique Mix thoroughly. Do not store. Dosage Intravenously as directed by a physician. See directions. Caution Squeeze and inspect lines and check markings product sterility. Discard if leaks are found. Must not be used in series connections. Do not use unless solution is clear. For Only Store unit in horizontal position. Overmap at room temperature (25°C/77°F) until ready to use. Avoid excessive heat. See insert.</p> <p>VIAFLEX CONTAINER PL 148 PLASTIC BAXTER VIAFLEX AND PL 148 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC. FOR PRODUCT INFORMATION 1-800-933-0303</p> <p>Baxter BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA</p> |  <p>JB1324 1000 mL DIN 00062028</p> <p>1 2 3 4 5 6 7 8 9</p> <p>0.9% Sodium Chloride Injection USP Chlorure de Sodium à 0.9% USP, Injectable NaCl 0.9%</p> <p>APPROX mmol/L Na - 154 Cl - 154 mOsmol/L - 308 pH 5.5</p> <p>INTRAVENOUS FLUID AND ELECTROLYTE REPLENISHMENT / RETABLISSEMENT HYDRO-ELECTROLYTIQUE PAR INJECTION INTRAVEINEUSE PER 100 mL SODIUM CHLORIDE USP - 900 mg / WATER FOR INJECTION USP - qs PAR 100 mL CHLORURE DE SODIUM USP - 900 mg / EAU POUR INJECTION USP - qs</p> <p>CAUTIONS SINGLE USE / DISCARD UNUSED PORTION SQUEEZE AND INSPECT BAG / PRESCRIBING INFORMATION AVAILABLE UPON REQUEST / MUST NOT BE USED IN SERIES CONNECTIONS / STORE AT 15° C TO 25° C ATTENTIONS USAGE UNIQUE / JETER PORTION INUTILISEE / PRESSER ET INSPECTER LE SAC / INFORMATION POSOLOGIQUE DISPONIBLE SUR DEMANDE / NE DOIT PAS ETRE MONTE EN SERIE / GARDER ENTRE 15° C ET 25° C</p> <p>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</p> <p>Baxter Baxter Corporation Mississauga ON L5N 0C2</p> <p>00-70-00-490</p> |

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. |

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

280064
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

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


07-25-77-316

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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 alkalizing agent | Lactated Ringer's Injection, USP is indicated as a source of water and electrolytes or as an alkalizing 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 Label Color: Black. Barcode not shown. 1000 mL shown as representative label. | Lactated Ringer's, USP Label Color: Black. Barcode, lot number, and expiration date not shown. 1000 mL shown as representative label. |
| <p>LOT EXP</p> <p style="text-align: right;">282324 NDC 0338-0117-04 DIN 00061085</p> <p style="text-align: right;">1</p> <p style="text-align: right;">2</p> <p style="text-align: right;">3</p> <p style="text-align: right;">4</p> <p style="text-align: right;">5</p> <p style="text-align: right;">6</p> <p style="text-align: right;">7</p> <p style="text-align: right;">8</p> <p style="text-align: right;">9</p> <p>Lactated Ringer's Injection USP</p> <p>1000 mL</p> <p>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 Osmolality 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.</p> <p>VIAFLEX CONTAINER PL 146 PLASTIC BAXTER, VIAFLEX AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC. FOR PRODUCT INFORMATION 1-800-933-0303</p> <p>Baxter BAXTER HEALTHCARE CORPORATION DEERFIELD, IL 60015 USA MADE IN USA</p> <p>DISTRIBUTED IN CANADA BY BAXTER CORPORATION TORONTO, ONTARIO, CANADA</p> | <p>JB2324 1000 mL DIN 00061085</p> <p style="text-align: right;">1</p> <p style="text-align: right;">2</p> <p style="text-align: right;">3</p> <p style="text-align: right;">4</p> <p style="text-align: right;">5</p> <p style="text-align: right;">6</p> <p style="text-align: right;">7</p> <p style="text-align: right;">8</p> <p style="text-align: right;">9</p> <p>Lactated Ringer's Injection USP</p> <p>Lactate de Ringer USP, Injectable</p> <hr/> <p>Lactated Ringer</p> <hr/> <p>Lactate de Ringer</p> <hr/> <p>APPROX mmol/L Na - 130 K - 4 Ca - 1.4 Cl - 109 LACTATE - 28 mOsmol/L - 272 pH 6.5</p> <p>INTRAVENOUS FLUID AND ELECTROLYTE REPLENISHMENT RETABLISSEMENT HYDRO-ELECTROLYTIQUE PAR INJECTION INTRAVEINEUSE</p> <p>PER 100 mL SODIUM CHLORIDE USP - 600 mg / SODIUM LACTATE - 310 mg / POTASSIUM CHLORIDE USP - 30 mg / CALCIUM CHLORIDE DIHYDRATE USP - 20 mg / WATER FOR INJECTION USP - qs</p> <p>PAR 100 mL CHLORURE DE SODIUM USP - 600 mg / LACTATE DE SODIUM - 310 mg / CHLORURE DE POTASSIUM USP - 30 mg / DIHYDRATE DE CHLORURE DE CALCIUM USP - 20 mg / EAU POUR INJECTION USP - qs</p> <p>CAUTIONS: SINGLE USE / DISCARD UNUSED PORTION / SQUEEZE AND INSPECT BAG / SEE DIRECTIONS FOR USE / NOT FOR USE IN THE TREATMENT OF LACTIC ACIDOSIS / MUST NOT BE USED IN SERIES CONNECTIONS / DO NOT ADMINISTER SIMULTANEOUSLY WITH BLOOD. STORE AT 15°C TO 25°C</p> <p>ATTENTIONS: USAGE UNIQUE / JETER PORTION INUTILISEE / PRESSER ET INSPECTER LE SAC / VOIR MODE D'EMPLOI / NE PAS UTILISER DANS LE TRAITEMENT DE L'ACIDOSE LACTIQUE / NE DOIT PAS ETRE MONTE EN SERIE / NE PAS ADMINISTRER SIMULTANEMENT AVEC LE SANG. GARDER ENTRE 15°C ET 25°C</p> <p>NONPYROGENIC / STERILE / APYROGENE</p> <p>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.</p> <p>Baxter Baxter Corporation Mississauga ON L5N 0C2</p> <p style="text-align: right;">88-70-20-487</p> |

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 | <p>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.</p> <p>Furthermore, it is compatible with blood or blood components.</p> | <p>PLASMA-LYTE A Injection is indicated for volume replacement, as a source of water and electrolytes, and as an alkalinizing agent</p> |
| Active ingredients | <p>Each 100 mL contains:</p> <p>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)</p> | <p>Each 100 mL contains:</p> <p>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)</p> |
| Additional information | <p>pH 7.4 (6.5 to 8.0) Osmolarity 294 mOsm/L (calc)</p> | <p>pH 7.4 (6.5 to 8.0) Osmolarity 294 mOsm/L (calc)</p> |
| 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 Plasma-Lyte A Injection, USP | Imported product from Alliston, Canada Plasma-Lyte A Injection, USP |
|--|--|
| <p>Label Color: Black. Barcode not shown.</p> <p>LOT EXP</p> <p style="text-align: right;">282544 NDC 0338-0221-04</p>  <p style="text-align: right;">1</p> <p style="text-align: right;">2</p> <p style="text-align: right;">3</p> <p style="text-align: right;">4</p> <p style="text-align: right;">5</p> <p style="text-align: right;">6</p> <p style="text-align: right;">7</p> <p style="text-align: right;">8</p> <p style="text-align: right;">9</p> <p>Plasma-Lyte A Injection pH 7.4 (Multiple Electrolytes Injection Type 1 USP)</p> <p>1000 mL</p> <p><small>EACH 100 mL CONTAINS 526 mg SODIUM CHLORIDE USP 502 mg SODIUM GLUCONATE USP 368 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 98 ACETATE 27 GLUCONATE 23 Osmolality 294 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 USER 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</small></p> <p><small>VIAFLEX CONTAINER PL 146 PLASTIC BAXTER PLASMA-LYTE VIAFLEX AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</small></p> <p>Baxter BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA</p> <p><small>FOR PRODUCT INFORMATION 1-800-933-0303</small></p> | <p>Label Color: Black. Barcode, lot number, and expiration date not shown.</p> <p>JB2544 1000 mL DIN 02339358</p> <p style="text-align: right;">1</p> <p style="text-align: right;">2</p> <p style="text-align: right;">3</p> <p style="text-align: right;">4</p> <p style="text-align: right;">5</p> <p style="text-align: right;">6</p> <p style="text-align: right;">7</p> <p style="text-align: right;">8</p> <p style="text-align: right;">9</p> <p>PLASMA-LYTE A Injection PLASMA-LYTE A, Injectable</p> <p><small>Norme Baxter Std</small></p> <p>APPROX mmol/L Na - 140 K - 5 Mg - 1.5 Cl - 98 ACETATE - 27 GLUCONATE - 23 mOsmol/L - 294 pH 7.4</p> <p><small>INTRAVENOUS FLUID AND ELECTROLYTE REPLENISHMENT RETABLISSEMENT HYDRO-ELECTROLYTIQUE PAR INJECTION INTRAVEINEUSE</small></p> <p><small>PER 100 mL SODIUM CHLORIDE USP - 526 mg / SODIUM GLUCONATE - 502 mg / SODIUM ACETATE TRIHYDRATE USP - 368 mg / POTASSIUM CHLORIDE USP - 37 mg / MAGNESIUM CHLORIDE HEXAHYDRATE USP - 30 mg / WATER FOR INJECTION USP - qs / pH MAY BE ADJUSTED WITH SODIUM HYDROXIDE</small></p> <p><small>PAR 100 mL CHLORURE DE SODIUM USP - 526 mg / GLUCONATE DE SODIUM - 502 mg / ACETATE DE SODIUM TRIHYDRATE USP - 368 mg CHLORURE DE POTASSIUM USP - 37 mg / CHLORURE DE MAGNESIUM HEXAHYDRATE - 30 mg / EAU POUR INJECTION USP - qs / LE pH AJUSTE AVEC L'HYDROXYDE DE SODIUM</small></p> <p><small>CAUTIONS SINGLE USE / DISCARD UNUSED PORTION / SQUEEZE AND INSPECT BAG / SEE DIRECTIONS FOR USE / MUST NOT BE USED IN SERIES CONNECTIONS / STORE AT 15°C TO 25°C ATTENTION USAGE UNIQUE / JETER PORTION INUTILISEE / PRESSER ET INSPECTER LE SAC / VOIR MODE D'EMPLOI / NE DOIT PAS ETRE MONTE EN SERIE / GARDER ENTRE 15°C ET 25°C NONPYROGENIC / STERILE / APYROGENE</small></p> <p><small>VIAFLEX PVC CONTAINER / CONTENANT DE PVC BAXTER PLASMA-LYTE AND VIAFLEX ARE TRADEMARKS OF BAXTER INTERNATIONAL INC BAXTER PLASMA-LYTE ET VIAFLEX SONT DES MARQUES DE COMMERCE DE BAXTER INTERNATIONAL INC</small></p> <p>Baxter Baxter Corporation Mississauga ON L5N 0C2</p> <p style="text-align: right;"> 07-25-77-284</p> |

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

JB2544 1000 mL DIN 02339358 **1**

PLASMA-LYTE A
Injection **2**

PLASMA-LYTE A,
Injectable **3**

Norme Baxter Std

APPROX mmol/L Na - 140 K - 5 Mg - 1.5 Cl - 98
ACETATE - 27 GLUCONATE - 23 mOsmol/L - 294
pH 7.4 **4**

INTRAVENOUS FLUID AND ELECTROLYTE REPLENISHMENT
RETABLISSEMENT HYDRO-ELECTROLYTIQUE PAR INJECTION
INTRA VEINEUSE **5**

PER **100 mL SODIUM CHLORIDE USP - 526 mg / SODIUM GLUCONATE**
- 502 mg / SODIUM ACETATE TRIHYDRATE USP - 368 mg /
POTASSIUM CHLORIDE USP - 37 mg / MAGNESIUM CHLORIDE
HEXAHYDRATE USP - 30 mg / WATER FOR INJECTION USP - qs /
pH MAY BE ADJUSTED WITH SODIUM HYDROXIDE **6**

PAR **100 mL CHLORURE DE SODIUM USP - 526 mg / GLUCONATE DE**
SODIUM - 502 mg / ACETATE DE SODIUM TRIHYDRATE USP - 368 mg
CHLORURE DE POTASSIUM USP - 37 mg / CHLORURE DE MAGNESIUM
HEXAHYDRATE - 30 mg / EAU POUR INJECTION USP - qs /
LE pH AJUSTE AVEC L'HYDROXYDE DE SODIUM **7**

CAUTIONS SINGLE USE / DISCARD UNUSED PORTION / SQUEEZE
AND INSPECT BAG / SEE DIRECTIONS FOR USE / MUST NOT BE
USED IN SERIES CONNECTIONS / 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 / GARDER ENTRE 15°C ET 25°C
NONPYROGENIC / STERILE / APYROGENE **8**

VIAFLEX PVC CONTAINER / CONTENANT DE PVC
BAXTER PLASMA-LYTE AND VIAFLEX ARE TRADEMARKS OF BAXTER
INTERNATIONAL INC
BAXTER PLASMA-LYTE ET VIAFLEX SONT DES MARQUES DE
COMMERCE DE BAXTER INTERNATIONAL INC **9**

Baxter
Baxter Corporation
Mississauga ON L5N 0C2



07-25-77-284

Container Label

JB2544 1000 mL DIN 02339358

PLASMA-LYTE A
INJECTION

PLASMA-LYTE A,
Injectable

Norme Baxter Std

APPROX mmol/L Na - 140 K - 5 Mg - 1.5 Cl - 98
ACETATE - 27 GLUCONATE - 23 mOsmol/L - 294
pH 7.4

INTRAVENOUS FLUID AND ELECTROLYTE REPLENISHMENT
RETABLISSEMENT HYDRO-ELECTROLYTIQUE PAR INJECTION

INTRAVEINEUSE

PER **100** mL SODIUM CHLORIDE USP – **526** mg / SODIUM GLUCONATE
- **502** mg / SODIUM ACETATE TRIHYDRATE USP – **368** mg /
POTASSIUM CHLORIDE USP – **37** mg / MAGNESIUM CHLORIDE
HEXAHYDRATE USP – **30** mg / WATER FOR INJECTION USP – qs
pH MAY BE ADJUSTED WITH SODIUM HYDROXIDE

PAR **100** mL CHLORURE DE SODIUM USP – **526** mg / GLUCONATE DE
SODIUM - **502** mg / ACETATE DE SODIUM TRIHYDRATE USP – **368** mg
CHLORURE DE POTASSIUM USP – **37** mg / CHLORURE DE MAGNESIUM
HEXAHYDRATE USP – **30** mg / EAU POUR INJECTION USP – qs
LE pH AJUSTE AVEC 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 / 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 / GARDER ENTRE ET 15°C ET 25°C

NONPYROGENIC / STERILE / APYROGENE

VIAFLEX PVC CONTAINER / CONTENANT DE PVC

BAXTER PLASMA-LYTE AND VIAFLEX ARE TRADEMARKS OF BAXTER
INTERNATIONAL INC

BAXTER PLASMA-LYTE ET VIAFLEX SONT DES MARQUES DE
COMMERCE DE BAXTER INTERNATIONAL INC

Baxter Logo

Baxter Corporation

Mississauga ON L5C 0C2

No LATEX Label

07-25-77-284

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PLASMA-LYTE A

sodium chloride, sodium gluconate, sodium acetate, potassium chloride and magnesium chloride injection, solution

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:0338-9591 |
| 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:R4R8JOQ44B, SODIUM CATION - UNII:LYR4M0NH37) | SODIUM GLUCONATE | 502 ug 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:0338-9591-12 | 12 in 1 CARTON | 11/06/2024 | |
| 1 | NDC:0338-9591-01 | 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 | | 11/06/2024 | |

Labeler - Baxter Healthcare Company (005083209)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|--|
| Baxter Corporation | | 205087968 | ANALYSIS(0338-9591) , LABEL(0338-9591) , MANUFACTURE(0338-9591) , STERILIZE(0338-9591) , PACK(0338-9591) |

Revised: 10/2024

Baxter Healthcare Company