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

PLASMA-LYTE A Injection
pH 7.4 (Multiple Electrolytes Injection, Type 1, USP)
in VIAFLEX Plastic Container

DESCRIPTION

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is a sterile, nonpyrogenic isotonic solution in a single dose container for intravenous administration. Each 100 mL contains 526 mg of Sodium Chloride, USP (NaCl); 502 mg of Sodium Gluconate ($C_6H_{11}NaO_7$); 368 mg of Sodium Acetate Trihydrate, USP ($C_2H_3NaO_2 \cdot 3H_2O$); 37 mg of Potassium Chloride, USP (KCl); and 30 mg of Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$). It contains no antimicrobial agents. The pH is adjusted with sodium hydroxide. The pH is 7.4 (6.5 to 8.0).

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 140 mEq sodium, 5 mEq potassium, 3 mEq magnesium, 98 mEq chloride, 27 mEq acetate, and 23 mEq gluconate. The osmolarity is 294 mOsmol/L (calc). Normal physiologic osmolarity range is 280 to 310 mOsmol/L. The caloric content is 21 kcal/L.

The VIAFLEX plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

CLINICAL PHARMACOLOGY

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) produces a metabolic alkalinizing effect. Acetate and gluconate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

INDICATIONS AND USAGE

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.

CONTRAINDICATIONS

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is contraindicated in patients with a known hypersensitivity to the product. See **WARNINGS**.

WARNINGS

Hypersensitivity Reactions

Hypersensitivity and infusion reactions have been reported with PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP). See **ADVERSE REACTIONS**.

Stop the infusion immediately if signs or symptoms of a hypersensitivity reaction develop, such as tachycardia, chest pain, dyspnea and flushing. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Electrolyte Imbalances

Fluid Overload

Depending on the volume and rate of infusion, the intravenous administration of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) can cause electrolyte disturbances such as overhydration, and congested states, including pulmonary congestion and edema.

Avoid PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in patients with or at risk for fluid and/or solute overloading. If use cannot be avoided, monitor fluid balance, electrolyte concentrations, and acid base balance, as needed and especially during prolonged use.

Hyponatremia

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) may cause hyponatremia. Hyponatremia can lead to acute hyponatremic encephalopathy characterized by headache, nausea, seizures, lethargy, and vomiting. Patients with brain edema are at particular risk of severe, irreversible and life-threatening brain injury.

The risk of hospital-acquired hyponatremia is increased in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH) treated with high volume of hypotonic PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP).

Avoid PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in hypervolemic or overhydrated patients. If use cannot be avoided, monitor serum sodium concentrations.

Hypernatremia

Hypernatremia may occur with PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP)). Conditions that may increase the risk of hypernatremia, fluid overload and edema (central and peripheral), include patients with: primary hyperaldosteronism; secondary hyperaldosteronism associated with, for example,

hypertension, congestive heart failure, liver disease (including cirrhosis), renal disease (including renal artery stenosis, nephrosclerosis); and pre-eclampsia.

Certain medications, such as corticosteroids or corticotropin, may also increase risk of sodium and fluid retention, see **PRECAUTIONS**.

Avoid PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in patients with, or at risk for, hypernatremia. If use cannot be avoided, monitor serum sodium concentrations.

Hypermagnesemia

Avoid solutions containing magnesium including PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in patients with or predisposed to hypermagnesemia, including patients with severe renal impairment and those patients receiving magnesium therapy (e.g., treatment of eclampsia and myasthenia gravis).

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is not indicated for the treatment of hypomagnesemia.

Acidosis

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is not for use for the treatment of lactic acidosis or severe metabolic acidosis in patients with severe liver and/or renal impairment.

Alkalosis

Excess administration of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) can result in metabolic alkalosis. Avoid PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in patients with alkalosis or at risk for alkalosis.

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is not indicated for the treatment of hypochloremic hypokalemic alkalosis. Avoid use in patients with hypochloremic hypokalemic alkalosis.

Hypocalcemia

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) contains no calcium, and an increase in plasma pH due to its alkalinizing effect may lower the concentration of ionized (not protein-bound) calcium. Avoid PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in patients with hypocalcemia.

Hyperkalemia

Potassium-containing solutions, including PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) may increase the risk of hyperkalemia.

Patient’s at increased risk of developing hyperkalemia include those:

- With conditions predisposing to hyperkalemia and/or associated with increased sensitivity to potassium, such as patients with severe renal impairment, acute dehydration, extensive tissue injury or burns, certain cardiac disorders such as congestive heart failure.
- Treated concurrently or recently with agents or products that cause or increase the risk of hyperkalemia (see **PRECAUTIONS**).

Avoid PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in patients with, or at risk for hyperkalemia. If use cannot be avoided, monitor serum potassium concentrations.

Although PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) has a potassium concentration in plasma, it is insufficient to produce a useful effect in case of severe potassium deficiency; therefore, it is not indicated for correction of severe potassium deficiency.

PRECAUTIONS

Patients with Renal Impairment

In patients with renal impairment, administration of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) may result in sodium and/or potassium or magnesium retention (see WARNINGS). PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in patients with severe renal impairment or conditions that may cause sodium and/or potassium retention or magnesium retention, fluid overload, or edema. If use cannot be avoided, monitor patients with severe renal impairment for development of these adverse reactions.

Drug Interactions

Other Products that Affect Fluid and/or Electrolyte Balance

Administration of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) to patients treated concomitantly with drugs associated with sodium and fluid retention, may increase the risk of hypernatremia and volume overload. Avoid use of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in patients receiving such products, such as corticosteroids or corticotropin. If use cannot be avoided, monitor serum electrolytes, fluid balance and acid-base balance.

Other Drugs that Increase the Risk of Hyponatremia

Administration of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in patients treated concomitantly with medications associated with hyponatremia may increase the risk of developing hyponatremia.

Avoid use of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in patients receiving products, such as diuretics, and certain antiepileptic and psychotropic medications. Drugs that increase the vasopressin effect reduce renal electrolyte free water excretion and may also increase the risk of hyponatremia following treatment with intravenous fluids. If use cannot be avoided, monitor serum sodium concentrations.

Lithium

Renal clearance of lithium may be increased during administration of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP). Monitor serum lithium concentrations during concomitant use.

Other Products that Increase the Risk of Hyperkalemia

Because of its potassium content, avoid use of PLASMA-LYTE A Injection pH 7.4 (Multiple

Electrolytes Injection, Type 1, USP) in patients receiving products that can cause hyperkalemia or increase the risk of hyperkalemia, such as potassium sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, or the immunosuppressants tacrolimus and cyclosporine. If use cannot be avoided, monitor serum potassium concentrations.

Drugs with pH Dependent Renal Elimination

Due to its alkalinizing effect (formation of bicarbonate), PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) may interfere with the elimination of drugs with pH dependent renal elimination. Renal clearance of acidic drugs may be increased. Renal clearance of alkaline drugs may be decreased.

Drug/Laboratory Test Interactions

There have been reports of positive test results using the Bio-Rad Laboratories Platelia *Aspergillus* EIA test in patients receiving Baxter gluconate containing PLASMA-LYTE solutions. These patients were subsequently found to be free of *Aspergillus* infection. Therefore, positive test results for this test in patients receiving Baxter gluconate containing PLASMA-LYTE solutions should be interpreted cautiously and confirmed by other diagnostic methods.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies with PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy

Teratogenic Effects

Animal reproduction studies have not been conducted with PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP). It is also not known whether PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is administered to a nursing mother.

Pediatric Use

The use of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in pediatric patients is based on clinical practice.

Geriatric Use

Geriatric patients are at increased risk of developing electrolyte imbalances. PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is known to be

substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Therefore, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. Consider monitoring renal function in elderly patients.

ADVERSE REACTIONS

Post-Marketing Adverse Reactions

The following adverse reactions associated with the use of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) were identified in clinical trials or postmarketing reports. Because postmarketing reactions were reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency, reliably, or to establish a causal relationship to drug exposure.

Hypersensitivity and Infusion Reactions: tachycardia, chest pain, chest discomfort, dyspnea, flushing, hyperemia, asthenia, pyrexia, hypotension, wheezing, urticaria, cold sweat, chills.

General Disorders and Administration Site Conditions: infusion site pain, burning sensation.

Metabolism and nutrition disorders: hyperkalemia, hyponatremia.

Nervous System Disorders: hyponatremic encephalopathy.

Overdose

Excessive administration of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) can cause:

- fluid overload with a risk of edema (peripheral and/or pulmonary), particularly when renal sodium excretion is impaired.
- hypernatremia and hyperkalemia, especially in patients with severe renal impairment.
- hypermagnesemia. See **WARNINGS** and **ADVERSE REACTIONS**
- metabolic alkalosis with or without hypokalemia and decreased ionized serum calcium and magnesium concentrations.

When assessing an overdose, any additives in the solution must also be considered.

The effects of an overdose may require immediate medical attention and treatment.

Interventions include discontinuation of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP), dose reduction, and other measures as indicated for the specific clinical constellation (e.g., monitoring of fluid balance, electrolyte concentrations and acid base balance).

DOSAGE AND ADMINISTRATION

Important Administration Instructions

- PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is intended for intravenous administration using sterile equipment.
- Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container.
- Set the vent to the closed position on a vented intravenous administration set to prevent air embolism.
- Use a dedicated line without any connections to avoid air embolism.
- Do not pressurize intravenous solutions contained in flexible plastic containers to increase flow rates in order to avoid air embolism due to incomplete evacuation of residual air in the container.
- Prior to infusion, visually inspect the solution for particulate matter and discoloration. The solution should be clear and there should be no precipitates. Do not administer unless solution is clear, and container is undamaged.
- PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is compatible with blood or blood components. It may be administered prior to or following the infusion of blood through the same administration set (i.e., as a priming solution), added to or infused concurrently with blood components, or used as a diluent in the transfusion of packed erythrocytes. PLASMA-LYTE A Injection and 0.9% Sodium Chloride Injection, USP are equally compatible with blood or blood components.

Dosing Information

The choice of product, dosage, volume, rate, and duration of administration is dependent upon the age, weight and clinical condition of the patient and concomitant therapy, and administration should be determined by a physician experienced in intravenous fluid therapy.

Introduction of Additives

Additives may be incompatible.

Evaluate all additions to the plastic container for compatibility and stability of the resulting preparation. Consult with a pharmacist, if available.

If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. After addition, if there is a discoloration and/or the appearance of precipitates, insoluble complexes or crystals, do not use. Do not store solutions containing additives. Discard any unused portion.

HOW SUPPLIED

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in VIAFLEX plastic containers is available as shown below:

Code	Size (mL)	NDC
2B2544	1000	NDC 0338-0221-04
2B2543	500	NDC 0338-0221-03

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

DIRECTIONS FOR USE OF VIAFLEX PLASTIC CONTAINER

For Information on Risk of Air Embolism – see **DOSAGE AND ADMINISTRATION**

To Open

Tear overwrap down side at slit and remove solution container. Visually inspect the container. If the outlet port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

Baxter Healthcare Corporation
Deerfield, IL 60015 USA

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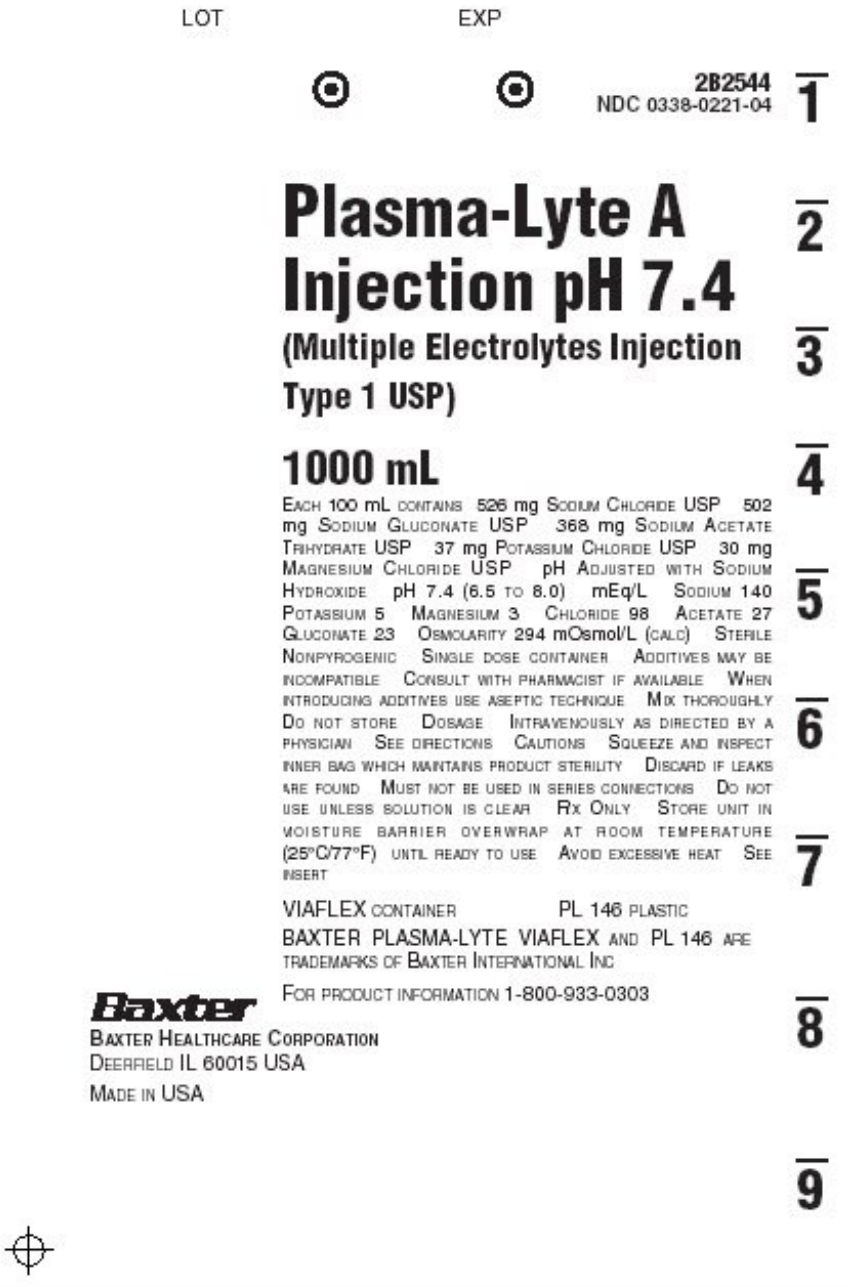
PACKAGE LABEL - PRINCIPAL DISPLAY PANEL



Plasma-Lyte A Injection pH 7.4 (Multiple Electrolytes Injection Type 1 USP) 1000mL Container Label

Plasma-Lyte A Injection pH 7.4 (Multiple Electrolytes Injection Type 1 USP) 1000mL Container Label

2B2544

NDC 0338-0221-04

Plasma-Lyte A

Injection pH 7.4

(Multiple Electrolytes Injection

Type 1 USP)

1000 mL

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 Osmolarity 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 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

VIAFLEX container PL 146 plastic

For product information 1-800-933-0303

Baxter

Baxter Healthcare Corporation

Deerfield IL 60015 USA

Made in USA

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:0338-0221
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:0338-0221-03	500 mL in 1 BAG; Type 0: Not a Combination Product	02/02/1979	
2	NDC:0338-0221-04	1000 mL in 1 BAG; Type 0: Not a Combination Product	02/02/1979	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017378	02/02/1979	

Labeler - Baxter Healthcare Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		059140764	ANALYSIS(0338-0221) , LABEL(0338-0221) , MANUFACTURE(0338-0221) , PACK(0338-0221) , STERILIZE(0338-0221)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		194684502	ANALYSIS(0338-0221)