VETERINARY PLASMA-LYTE A- 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.

VETERINARY PLASMA-LYTE A

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. It contains no antimicrobial agents. Discard unused portion. The pH is adjusted with sodium hydroxide. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

Table 1

	Size (mL)	Composition (g/L)					Osmolarity (mOsmol/L) (calc)	pH	Ionic Concentration (mEq/L)						Caloric Content (kcal/L)
		Sodium Chloride, USP, (NaCl)	Sodium Gluconate, ($C_6H_{11}NaO_7$)	Sodium Acetate Trihydrate, USP, ($C_2H_3NaO_2 \cdot 3H_2O$)	Potassium Chloride, USP (KCl)	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)			Sodium	Potassium	Magnesium	Chloride	Acetate	Gluconate	
Veterinary Plasma-Lyte A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP)	5000	5.26	5.02	3.68	0.37	0.30	294	7.4 (6.5 to 8.0)	140	5	3	98	27	23	21

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. Normal physiologic osmolarity range is 280 to 310 mOsmol/L.
Administration of substantially hypertonic solutions may cause vein damage.
The plastic container is fabricated from a specially formulated polyvinyl chloride. 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.
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.

CONTRAINDICATIONS

None known

WARNINGS

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.
PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.
PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of acetate or gluconate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.
The intravenous administration of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.
In patients with diminished renal function, administration of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) may result in sodium or potassium retention.

ADVERSE REACTIONS

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia. If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

PRECAUTIONS

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid

balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.
PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be used with caution. Excess administration may result in metabolic alkalosis.
Caution must be exercised in the administration of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) to patients receiving corticosteroids or corticotropin.
Do not administer unless solution is clear and seal is intact.

DOSAGE AND ADMINISTRATION

As directed by a veterinarian. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.
All injections in plastic containers are intended for intravenous administration using sterile equipment.
Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the
veterinarian, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

OVERDOSAGE

In an event of overhydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. See Warnings, Precautions and Adverse Events.

HOW SUPPLIED

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

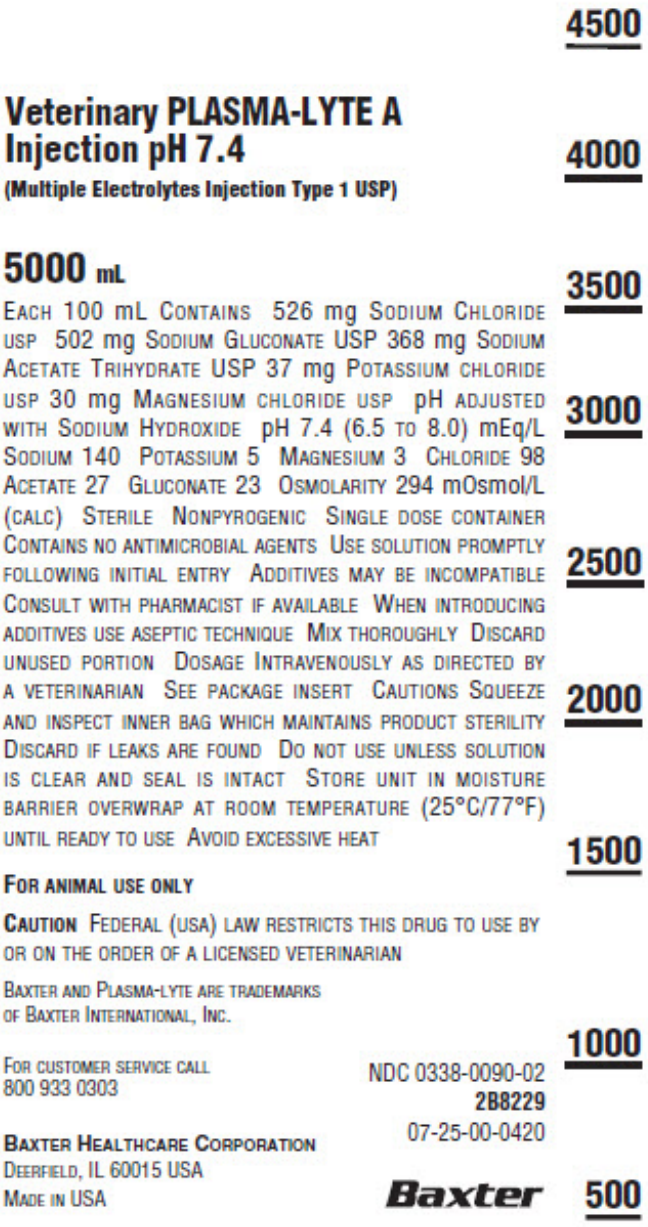
Size (mL)	Code	NDC
5000	2B8229	NDC 0338-0090-02

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C/77°F); brief exposure up to 40°C/104°F does not adversely affect the product.

Directions for use of plastic container

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 plastic protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.



Container Label

Veterinary PLASMA-LYTE A
Injection pH 7.4
(Multiple Electrolytes Injection Type 1 USP)

5000 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 SinglGLe dose container Contains no antimicrobial agents Use solution promptly Following initial entry Additives may be incompatible Consult with pharmacist if available When introducing

additives use aseptic technique Mix thoroughly Discard unused portion Dosage Intravenously as directed by a veterinarian See package insert Cautions Squeeze and inspect inner bag which maintains product sterility Discard if leaks are found Do not use unless solution is clear and seal is intact Store unit in moisture barrier overwrap at room temperature (25°C/77°F) until ready to use Avoid excessive heat

For animal use only
Caution Federal (usa) law restricts this drug to use by or on the order of a licensed veterinarian

Baxter and Plasma-lyte are trademarks of Baxter International, Inc.

For customer service call

NDC 0338-0090-02

800 933 0303

2B8229

Baxter Healthcare Corporation
Deerfield, IL 60015 USA

Made in USA

Baxter Logo

4500

4000

3500

3000

2500

2000

1500

1000

500

VETERINARY PLASMA-LYTE A

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

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:0338-0090
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698, SODIUM	SODIUM	526 mg

CATION - UNII:LYR4M0NH37)	CHLORIDE	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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-0090-02	2 in 1 CARTON		
1		5000 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/21/2019	

Labeler - Baxter Healthcare Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		059140764	analysis, label, manufacture, pack, sterilize, api manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		194684502	analysis

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