**ELECTROSOL PH 7.4- sodium chloride, sodium gluconate, sodium acetate, potassium chloride, and magnesium chloride injection, solution**
**ASPEN VETERINARY**

*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.*

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**ELECTROSOL pH 7.4**

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

## Description

ElectroSol™ Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is a sterile, non-pyrogenic isotonic solution intended for fluid and electrolyte replenishment in single dose containers. May be administered intravenously using aseptic technique. It contains no antimicrobial agents. Discard any unused portion. The pH is adjusted with Sodium Hydroxide. Composition, osmolarity, pH and ionic concentration and caloric content are shown in Table 1.

Table 1

| Composition (g/L) | Sodium Chloride | Sodium Gluconate | Sodium Acetate Trihydrate | Potassium Chloride | Magnesium Chloride |
|---|---|---|---|---|---|
| | 5.26 | 5.02 | 3.68 | 0.37 | 0.30 |

| Ionic Concentration (mEq/L) | Sodium | Potassium | Magnesium | Chloride | Acetate | Gluconate |
|---|---|---|---|---|---|---|
| | 140 | 5 | 3 | 98 | 27 | 23 |

Osmolarity (mOsmol/L) (calc): 294 mOsmol per liter
pH: 7.4 (limit 6.5 to 8.0)
Caloric Content (kcal/L): 21

The container is free of PVC and phthalates. The container meets the requirements of USP and is registered with FDA.

## Clinical Pharmacology

A multiple electrolyte intravenous solution is intended to restore the electrolyte balance and water for hydration. It is capable of inducing diuresis depending on the clinical condition of the patient and 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

ElectroSol™ Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is indicated as a source of water and electrolytes for all species. It is also used as an alkalinizing agent.

ElectroSol™ 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.

**Contraindications**

None known

**Warnings**

The introduction of additives to any solution, regardless of type of container, requires special attention to ensure that no incompatibilities result. While some incompatibilities are readily absorbed, one must be aware that subtle physical, chemical and pharmacological incompatibilities can occur. The medical literature, the package insert and other available sources of information should be reviewed for thorough understanding of possible incompatibilities.

ElectroSol™ 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 and sodium retention; in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present; 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 ElectroSol™ Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, over-hydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overloading causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.

In patients with diminished renal function, administration of ElectroSol™ Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) may result in sodium or potassium retention.

**Adverse Reactions**

Adverse reactions may occur due to the solution or the technique of administration including febrile response, infection at the site of injection or allergic reactions. Prolonged intravenous infusion of this type of product may cause venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

If an adverse reaction does occur, discontinue the infusion and evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

**Precautions**

This is a single dose unit. It contains no preservatives. Use entire contents when first opened.

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged therapy or whenever the condition of the patient warrants such evaluation.

ElectroSol™ 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 ElectroSol™ Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) to patients receiving corticosteroids or corticotropin.

Do not administer unless solution is clear and both seal and container are intact.

Solution must be warmed to body temperature prior to administration and administered at a slow rate. Use solution promptly following initial entry.

Reactions which may occur because of the solution or the technique of administration, include febrile response, infection at the site of injection, extravasation, and hypervolemia.

**Dosage and Administration**

To be used as directed by a licensed veterinarian. The dosage of the ElectroSol™ Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is dependent upon the age, weight and clinical conditions of the patient as well as laboratory determinations. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

For use in one patient on one occasion only. Discard any unused portion. Care should be taken with administration technique to avoid administration site reactions and infection.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

**Over-dosage**

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

**Storage**

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (86°F/30°C). Protect from freezing.

**Directions for use of plastic container**

**To Open**

Tear overwrap at slit and remove solution container. 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 solution container 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 inlet/outlet port at bottom of container.
3. Attach administration set.

**To Add Medication**
**WARNING: Additives may be incompatible.**

**To add medication before solution administration**

1. Prepare medication site.

2. Using syringe with 0.63mm to 0.80mm needle, puncture 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 the clamp on the administration set.
2. Prepare medication site.
3. Using syringe with 0.63mm to 0.80mm needle, puncture 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.

**CAUTION:** FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN.

**Manufactured for:**
Aspen Veterinary Resources® Ltd.
Liberty, MO 64068, USA
www.aspenveterinaryresources.com

**Manufactured by:**
Sypharma Pty Ltd
27 Healey Road, Dandenong
Victoria 3175 Australia

For customer service email:
info@aspenveterinaryresources.com

Rev. 04/16

**ElectroSol™ Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) 500mL**

# ElectroSol™ Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP)

**STERILE NONPYROGENIC SOLUTION**
**For Animal Use Only**

**KEEP OUT OF REACH OF CHILDREN**

## 500mL (16.91 fl oz)

**Each 100mL contains:**

| | |
|---|---|
| Sodium Chloride | 526mg |
| Sodium Gluconate | 502mg |
| Sodium Acetate Trihydrate | 368mg |
| Potassium Chloride | 37mg |
| Magnesium Chloride | 30mg |

pH adjusted with Sodium Hydroxide

mEq/L Sodium 140, Potassium 5, Magnesium 3, Chloride 98, Acetate 27, Gluconate 23, pH: 7.4 (6.5 to 8.0), Osmolarity: 294 mOsmol/L (calc)

**INDICATIONS:** As a source of water and electrolytes or as an alkalinizing agent in all species.

**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. Administer intravenously using strict aseptic technique. See Package Insert.

**CAUTION:** Solution must be warmed to body temperature prior to administration and administered at a slow rate. This is a single dose unit. It contains no preservatives. Use solution promptly following initial entry. Use entire contents when first opened. Squeeze and inspect inner bag which maintains product sterility. Discard if leaks are found or if the solution contains visible solid particles. Do not use unless solution is clear and seal is intact.

**WARNING:** Additives may be incompatible, Consult with veterinarian if available. When introducing additives use aseptic technique. Mix thoroughly. If entire contents are not used, discard the unused portion.

**STORAGE:** Store below 86ºF/30ºC (room temperature) in barrier over-pouch until ready for use. Protect from freezing.

**CAUTION:** FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN

**Manufactured For:** Aspen Veterinary Resources® LTD., Liberty, MO 64068, USA
www.aspenveterinaryresources.com

**Manufactured By:** Sypharma Pty Ltd, 27 Healey Road, Dandenong Victoria 3175 Australia.

**For Customer Service Email:** info@aspenveterinaryresources.com

**NDC Number:** 46066-511-05

A530SPH

**Rev.** 04/16

**Barcode:** 0 99355 01337 7

**Lot:**

**Exp:**

400 300 200 100 Approx.

**ElectroSol™ Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) 1000mL**

ElectroSol™ Injection pH 7.4 (Multiple Electrolytes Injection,

100 Approx.

VETERINARY RESOURCES,® LTD.

# Type 1, USP)

## STERILE NONPYROGENIC SOLUTION
**For Animal Use Only**

**KEEP OUT OF REACH OF CHILDREN**

# 1000mL (33.81 fl oz)

**Each 100mL contains:**

| | |
|---|---|
| Sodium Chloride | 526mg |
| Sodium Gluconate | 502mg |
| Sodium Acetate Trihydrate | 368mg |
| Potassium Chloride | 37mg |
| Magnesium Chloride | 30mg |
| pH adjusted with Sodium Hydroxide | |

mEq/L Sodium 140, Potassium 5, Magnesium 3, Chloride 98, Acetate 27, Gluconate 23, pH: 7.4 (6.5 to 8.0), Osmolarity: 294 mOsmol/L (calc)

**INDICATIONS:** As a source of water and electrolytes or as an alkalinizing agent in all species.

**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. Administer intravenously using strict aseptic technique. See Package Insert.

**CAUTION:** Solution must be warmed to body temperature prior to administration and administered at a slow rate. This is a single dose unit. It contains no preservatives. Use solution promptly following initial entry. Use entire contents when first opened. Squeeze and inspect inner bag which maintains product sterility. Discard if leaks are found or if the solution contains visible solid particles. Do not use unless solution is clear and seal is intact.

**WARNING:** Additives may be incompatible, Consult with veterinarian if available. When introducing additives use aseptic technique. Mix thoroughly. If entire contents are not used, discard the unused portion.

**STORAGE:** Store below 86°F/30°C (room temperature) in barrier over-pouch until ready for use. Protect from freezing.

**CAUTION:** FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN


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www.aspenveterinaryresources.com

**Manufactured By:** Sypharma Pty Ltd, 27 Healey Road, Dandenong Victoria 3175 Australia.

**For Customer Service Email:** info@aspenveterinaryresources.com

NDC NUMBER: 46066-511-06

100
Approx.

A531SPH

REV. 04/16

LOT:

BARCODE:


EXP:

**ElectroSol™ Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) 5000mL**

# ElectroSol™ Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP)

**STERILE NONPYROGENIC SOLUTION**
**For Animal Use Only**

**KEEP OUT OF REACH OF CHILDREN**

## 5000mL (169.07 fl oz)

**Each 100mL contains:**

| | |
|---|---|
| Sodium Chloride | 526mg |
| Sodium Gluconate | 502mg |
| Sodium Acetate Trihydrate | 368mg |
| Potassium Chloride | 37mg |
| Magnesium Chloride | 30mg |
| pH adjusted with Sodium Hydroxide | |

mEq/L Sodium 140, Potassium 5, Magnesium 3, Chloride 98, Acetate 27, Gluconate 23, pH: 7.4 (6.5 to 8.0), Osmolarity: 294 mOsmol/L (calc)

**INDICATIONS:** As a source of water and electrolytes or as an alkalinizing agent in all species.

**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. Administer intravenously using strict aseptic technique. See Package Insert.

**CAUTION:** Solution must be warmed to body temperature prior to administration and administered at a slow rate. This is a single dose unit. It contains no preservatives. Use solution promptly following initial entry. Use entire contents when first opened. Squeeze and inspect inner bag which maintains product sterility. Discard if leaks are found or if the solution contains visible solid particles. Do not use unless solution is clear and seal is intact.

**WARNING:** Additives may be incompatible, Consult with veterinarian if available. When introducing additives use aseptic technique. Mix thoroughly. If entire contents are not used, discard the unused portion.

**STORAGE:** Store below 86°F/30°C (room temperature) in barrier over-pouch until ready for use. Protect from freezing.

**CAUTION:** FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN

**Manufactured For:** Aspen Veterinary Resources® LTD., Liberty, MO 64068, USA
www.aspenveterinaryresources.com

**Manufactured By:** Sypharma Pty Ltd, 27 Healey Road, Dandenong Victoria 3175 Australia.

**For Customer Service Email:** info@aspenveterinaryresources.com

**NDC Number:** 46066-511-09

A532SPH

**Rev.** 04/16

**Lot:**

**Barcode:** 0 99355 01341 4

**Exp:**

4000 1000 Approx. 3000 2000 1000 Approx. 2000 3000 4000

# ELECTROSOL PH 7.4

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

**Product Information**

| | | | |
|---|---|---|---|
| **Product Type** | PRESCRIPTION ANIMAL DRUG | **Item Code (Source)** | NDC:46066-511 |
| **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) (SODIUM CATION - UNII:LYR4M0NH37, GLUCONIC ACID - UNII:R4R8J0Q44B) | SODIUM GLUCONATE | 502 mg in 100 mL |
| **SODIUM ACETATE** (UNII: 4550K0SC9B) (SODIUM CATION - UNII:LYR4M0NH37, ACETATE ION - UNII:569DQM74SC) | 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:46066-511-05 | 24 in 1 CASE | | |
| **1** | | 500 mL in 1 CONTAINER | | |
| **2** | NDC:46066-511-06 | 12 in 1 CASE | | |
| **2** | | 1000 mL in 1 CONTAINER | | |
| **3** | NDC:46066-511-09 | 2 in 1 CASE | | |
| **3** | | 5000 mL in 1 CONTAINER | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 05/25/2016 | |

## Labeler - ASPEN VETERINARY (627265361)

## Registrant - SYPHARMA PTY LTD (753786292)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| SYPHARMA PTY LTD | | 753786292 | manufacture, pack, sterilize |