COMPOUND SODIUM LACTATE- sodium chloride, potassium chloride, sodium lactate, and calcium chloride injection, solution
Baxter Healthcare Pty Ltd

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.

Electrolyte Solution
COMPOUND SODIUM LACTATE (HARTMANN'S SOLUTION) 5 L

For Animal Use Only

Description

COMPOUND SODIUM LACTATE (HARTMANN'S SOLUTION) Injection is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment. It is supplied in single dose VIAFLEX plastic containers for intravenous administration. It contains no antimicrobial agents. Any unused portion should be discarded.

The composition and ionic concentration of COMPOUND SODIUM LACTATE (HARTMANN'S SOLUTION) Injection are shown in Tables 1 and 2 below.

Table 1 - Composition (g/L)

Sodium chloride	6
Sodium lactate	3.22
Potassium chloride	0.4
Calcium chloride	0.27

Table 2 - Ionic concentration (mEq/L)

Sodium	131
Potassium	5
Calcium	4
Chloride	111
Lactate	29

Indications

COMPOUND SODIUM LACTATE (HARTMANN'S SOLUTION) Injection is indicated as a source of water and electrolytes or as an alkalinizing agent.

Warnings

COMPOUND SODIUM LACTATE (HARTMANN'S SOLUTION) Injection should be used with great care, if at all, in animals with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.
COMPOUND SODIUM LACTATE (HARTMANN'S SOLUTION) Injection should be used with great care, if at all, in animals with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

COMPOUND SODIUM LACTATE (HARTMANN'S SOLUTION) Injection should be used with great care in animals with metabolic or respiratory alkalosis. The administration of lactate 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.
COMPOUND SODIUM LACTATE (HARTMANN'S SOLUTION) Injection should not be administered simultaneously with blood through the same administration set because of the likelihood of coagulation.
The intravenous administration of COMPOUND SODIUM LACTATE (HARTMANN'S SOLUTION) Injection 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 injections. The risk of solute overload 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 COMPOUND SODIUM LACTATE (HARTMANN'S SOLUTION) Injection may result in sodium or potassium retention.
COMPOUND SODIUM LACTATE (HARTMANN'S SOLUTION) Injection is not for use in the treatment of lactic acidosis.

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 animal warrants such evaluation.
COMPOUND SODIUM LACTATE (HARTMANN'S SOLUTION) Injection must be used with caution. Excess administration may result in metabolic alkalosis.
Caution must be exercised in the administration of COMPOUND SODIUM LACTATE (HARTMANN'S SOLUTION) Injection to patients receiving corticosteroids or corticotropin.
Do not administer unless solution is clear and seal is intact.
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 animal, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

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 animal, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a veterinarian. Dosage is dependent upon the age, weight and clinical condition of the animal 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 animal and institute appropriate corrective measures. See Warnings, Precautions and Adverse Reactions.

How Supplied

COMPOUND SODIUM LACTATE (HARTMANN'S SOLUTION) Injection is supplied in following pack size:

- 5L solution in single dose VIAFLEX plastic containers.

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

Directions for Use of VIAFLEX plastic container

To Open

Tear overwrap down side 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 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.

To Add Medication

WARNING:**Additives may be incompatible.**

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge 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 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.

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

FOR ANIMAL TREATMENT ONLY

Baxter
VIAFLEX BAG
AHB8611

RESTRICTED VETERINARY MEDICINE IN NZ

5 Litre

ELECTROLYTE SOLUTION COMPOUND SODIUM LACTATE (HARTMANN'S SOLUTION)

ACTIVE CONSTITUENTS - EACH LITRE CONTAINS - SODIUM CHLORIDE 6.0 g - SODIUM LACTATE 3.22 g - POTASSIUM CHLORIDE 0.40 g - CALCIUM CHLORIDE 0.27 g

APPROXIMATE MILLIMOLES PER LITRE - SODIUM 131 - POTASSIUM 5 - CALCIUM 2 - CHLORIDE 111 - BICARBONATE (AS LACTATE) 29

APPROXIMATE OSMOLALITY 274 mOsm

FOR THE TREATMENT OF DEHYDRATION AND FOR THE ELECTROLYTE REPLACEMENT IN ALL SPECIES

DIRECTIONS FOR USE
DO NOT USE UNLESS SOLUTION IS CLEAR DO NOT REMOVE PLASTIC PACK OVERPOUCH UNTIL JUST BEFORE USE DISCONTINUE INFUSION IF ADVERSE REACTION OCCURS AVOID STORAGE OF SOLUTION PREPARED WITH ADDITIVES

TO BE USED BY OR UNDER THE SUPERVISION OF A REGISTERED VETERINARY SURGEON

REMOVE BLUE TOP AND INSERT PLASTIC DELIVERY SPIKE OF AN ADMINISTRATION SET THE VOLUME OF FLUID AND ROUTE OF ADMINISTRATION DEPEND ON SPECIES AGE AND DEGREE OF HYDRATION OF THE ANIMAL UNDER TREATMENT

WITHHOLDING PERIOD NIL

DISPOSAL
DISPOSE OF EMPTY CONTAINER AND OUTER PACKAGING BY WRAPPING WITH PAPER AND PLACING IN GARBAGE

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IN NEW ZEALAND REGISTERED TO BAXTER HEALTHCARE LTD
33 VESTEY DRIVE MT WELLINGTON AUCKLAND

REGISTERED PURSUANT TO THE ACVM ACT 1997 No A9422
SEE www.foodsafety.govt.nz FOR REGISTRATION CONDITIONS

STORE BELOW 30°C (ROOM TEMPERATURE) NRA 49590 / 01

BAXTER AND VIAFLEX ARE REGISTERED TRADEMARKS OF BAXTER INTERNATIONAL INC
BAXTER HEALTHCARE PTY LTD
1 BAXTER DRIVE OLD TOONGABBIE NSW AUSTRALIA 88-25-01-390C

COMPOUND SODIUM LACTATE

sodium chloride, potassium chloride, sodium lactate, and calcium chloride injection, solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:86046-8611
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	6 g in 1 L
SODIUM LACTATE (UNII: TU7HW0W0QT) (SODIUM CATION - UNII:LYR4M0NH37, LACTIC ACID - UNII:33X04XA5AT)	SODIUM LACTATE	3.22 g in 1 L
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	400 mg in 1 L
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	270 mg in 1 L

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:86046-8611-2	5 L in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/10/2015	

Labeler - Baxter Healthcare Pty Ltd (750455891)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Pty Ltd		750455891	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
US Salt		002246361	api manufacture

Revised: 3/2015 Baxter Healthcare Pty Ltd