OSMOSOL-R- multiple electrolyte injection type 1 injection, solution
MWI (VetOne)

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.

OsmoSol-R

Assembled in U.S.A.

Manufactured for:

MWI, Boise, ID 83705
www.VetOne.net

NDC 86136-008-05

V1 501206

5000 mL (169.07 fl oz)

18-827

RMS# 92-2123

Iss. 08/21

For animal use only

Keep out of reach of children.

RX Only

CAUTION:

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

Active Ingredients:

Each 100 mL contains Sodium Chloride 526 mg; Sodium Acetate 222 mg; Sodium Gluconate 502 mg; Potassium Chloride 37 mg; Magnesium Chloride 30 mg in water for Injection. May contain HCl or NaOH for pH adjustment.

mEq/liter: Sodium 140; Potassium 5; Magnesium 3; Chloride 98; Acetate 27; Gluconate 23.

Osmolarity: 294 mOsmol/liter (calc).

pH: 7.4 (6.5 - 8.0).

CAUTION:

Sterile nonpyrogenic solution. Use only if solution is clear and container is undamaged. This is a single dose unit. For Intravenous or subcutaneous use. It contains no

preservatives. Use promptly upon initial entry. If entire contents are not used, discard unused portion. Must not be used in series connections. Additives may be incompatible. Squeeze and inspect inner bag which maintains product sterility. Discard if leaks are found or if the solution contains visible solid particles.

Usual dose:

SEE INSERT.

STORAGE:

Store between 15°C - 30°C. Keep from freezing.

Description:

OsmoSol-R 7.4 is a sterile, nonpyrogenic isotonic solution of balanced electrolytes in water for injection. The solution is administered by intravenous infusion for parenteral replacement of acute losses of extracellular fluid. Each 100 mL of OsmoSol-R 7.4 contains sodium chloride, 526 mg; sodium acetate, 222 mg; sodium gluconate, 502 mg; potassium chloride, 37 mg; magnesium chloride, 30 mg. May contain HCL and/or NaOH for pH adjustment. pH 7.4 (6.5 - 8.0); 294 mOsmol/liter (calc.). Electrolytes per 1000 mL (not including pH adjustment): sodium 140 mEq; potassium 5 mEq; magnesium 3 mEq; chloride 98 mEq; acetate 27 mEq; gluconate 23 mEq. The solution contains no bacteriostat, antimicrobial agent or added buffer (except for pH adjustment) and is intended only for use as a single-dose injection. When smaller doses are required the unused portion should be discarded. OsmoSol-R 7.4 is a parenteral fluid and electrolyte replenisher.

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 deeemed necessary.

Indications:

OsmoSol-R 7.4 is indicated for replacement of acute extracellular fluid volume losses in surgery, trauma, burns or shock. OsmoSol-R 7.4 can be used as an adjunct to restore a decrease in circulatory volume in patients with moderate blood loss. OsmoSol-R 7.4 is not intended to supplant transfusion of whole blood or packed red cells in the presence of uncontrolled hemorrhage or severe reductions of red cell volume.

Contraindications:

None known.

Precautions:

OsmoSol-R 7.4 should be used with caution in severe renal impairment because of the danger of hyperkalemia. As with all intravenous solutions, care should be taken to avoid circulatory overload, especially in patients with cardiac or pulmonary disorders. OsmoSol-R 7.4 is not intended to correct acidosis or large deficits of individual electrolytes, nor to replace blood or plasma expanders when these are indicated. Do not administer unless solution is clear and container is undamaged. Discard unused portion. 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. Caution must be exercised in the administration of parenteral fluids, especially those containing sodium ions, to patients receiving corticosteroids or corticotropin. Solutions containing acetate or gluconate ions should be used with caution, as excess administration may result in metabolic alkalosis.

Warnings:

Solutions containing sodium ions 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. Solutions which contain potassium 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. In patients with diminished renal function, administration of solutions containing sodium or potassium ions may result in sodium or potassium retention. Solutions containing acetate or gluconate ions should be used with great care in patients with metabolic or respiratory alkalosis. Acetate or gluconate should be administered with great care in those conditions in which there is an increased level or an impaired initialization of these ions, such as severe hepatic insufficiency. The intravenous administration of this solution 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 administered parenteral solutions. The risk if solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.

Dosage and Administration:

Administer by intravenous infusion. It may also be administered subcutaneously. The amount to be infused is based on replacement of losses of extracellular fluid volume in the individual patient. Up to 3 times the volume of estimated blood loss during and after surgery can be given to correct ciruculatory volume when there is only a moderate loss of blood.

Overdosage:

In the event of overhydration or solute overload, re-evaluate the patient and institute

appropriate corrective measures. See WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

Warnings:

Do Not Use flexible container in series connections.

Manufactured by: Nova-Tech, Inc.

RMS#92-2126

Iss. 08/21

Sterile nonpyrogenic solution

VET one

OsmoSol™-R 7.4

Multiple Electrolyte Injection Type I, USP

STERILE NONPYROGENIC SOLUTION
FOR VETERINARY USE ONLY

DESCRIPTION: OsmoSol-R 7.4 is a sterile, nonpyrogenic isotonic solution of balanced electrolytes in water for injection. The solution is administered by intravenous infusion for parenteral replacement of acute losses of extracellular fluid. Each 100 mL of OsmoSol-R 7.4 contains sodium chloride, 526 mg; sodium acetate, 222 mg; sodium gluconate, 502 mg; potassium chloride, 37 mg; magnesium chloride, 30 mg. May contain HCl and/or NaOH for pH adjustment. pH 7.4 (6.5 – 8.0); 294 mOsmol/liter (calc.). Electrolytes per 1000 mL (not including pH adjustment): sodium 140 mEq; potassium 5 mEq; magnesium 3 mEq; chloride 98 mEq; acetate 27 mEq; gluconate 23 mEq. The solution contains no bacteriostat, antimicrobial agent or added buffer (except for pH adjustment) and is intended only for use as a single-dose injection. When smaller doses are required the unused portion should be discarded. OsmoSol-R 7.4 is a parenteral fluid and electrolyte replenisher.

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.

INDICATIONS: OsmoSol-R 7.4 is indicated for replacement of acute extracellular fluid volume losses in surgery, trauma, burns or shock. OsmoSol-R 7.4 can be used as an adjunct to restore a decrease in circulatory volume in patients with moderate blood loss. OsmoSol-R 7.4 is not intended to supplant transfusion of whole blood or packed red cells in the presence of uncontrolled hemorrhage or severe reductions of red cell volume.

CONTRAINDICATIONS: None known.

PRECAUTIONS: OsmoSol-R 7.4 should be used with caution in severe renal impairment because of the danger of hyperkalemia. As with all intravenous solutions, care should be taken to avoid circulatory overload, especially in patients with cardiac or pulmonary disorders. OsmoSol-R 7.4 is not intended to correct acidosis or large deficits of individual electrolytes, nor to replace blood or plasma expanders when these are indicated. Do not administer unless solution is clear and container is undamaged. Discard unused portion. 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. Caution must be exercised in the administration of parenteral fluids, especially those containing sodium ions, to patients receiving corticosteroids or corticotropin. Solutions containing acetate or gluconate ions should be used with caution, as excess administration may result in metabolic alkalosis.

WARNINGS: Solutions containing sodium ions 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. Solutions which contain potassium 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. In patients with diminished renal function, administration of solutions containing sodium or potassium ions may result in sodium or potassium retention. Solutions containing acetate or gluconate ions should be used with great care in patients with metabolic or respiratory alkalosis. Acetate or gluconate should be administered with great care in those conditions in which there is an increased level or an impaired initialization of these ions, such as severe hepatic insufficiency. The intravenous administration of this solution 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 administered parenteral solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.

DOSAGE AND ADMINISTRATION: Administer by intravenous infusion. It may also be administered subcutaneously. The amount to be infused is based on replacement of losses of extracellular fluid volume in the individual patient. Up to 3 times the volume of estimated blood loss during and after surgery can be given to correct circulatory volume when there is only a moderate loss of blood.

OVERDOSAGE: In the event of overhydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. See WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

STORAGE: Store at 15°C - 30°C (59°F - 86°F).

WARNINGS: DO NOT USE FLEXIBLE CONTAINER IN SERIES CONNECTIONS.

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

Manufactured by: Nova-Tech, Inc.

Manufactured For:
MWI, Boise, ID 83705
www.VetOne.net

18-827
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VETone

OsmoSol™-R 7.4

Multiple Electrolyte Injection Type I, USP

FOR ANIMAL USE ONLY

5000 mL (169.07 fl oz)

Approx.

1000

2000

ACTIVE INGREDIENTS: EACH 100 mL CONTAINS SODIUM CHLORIDE 526 mg; SODIUM ACETATE 222 mg; SODIUM GLUCONATE 502 mg; POTASSIUM CHLORIDE 37 mg; MAGNESIUM CHLORIDE 30 mg IN WATER FOR INJECTION. MAY CONTAIN HCl OR NaOH FOR pH ADJUSTMENT.

mEq/LITER: SODIUM 140; POTASSIUM 5; MAGNESIUM 3; CHLORIDE 98; ACETATE 27; GLUCONATE 23.

OSMOLARITY: 294 mOsmol/LITER (CALC.).

pH: 7.4 (6.5 – 8.0).

USUAL DOSE: SEE INSERT.

3000

CAUTION: STERILE NONPYROGENIC SOLUTION. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. THIS IS A SINGLE DOSE UNIT. FOR INTRAVENOUS OR SUBCUTANEOUS USE. IT CONTAINS NO PRESERVATIVES. USE PROMPTLY UPON INITIAL ENTRY. IF ENTIRE CONTENTS ARE NOT USED, DISCARD UNUSED PORTION. MUST NOT BE USED IN SERIES CONNECTIONS. ADDITIVES MAY BE INCOMPATIBLE. SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY. DISCARD IF LEAKS ARE FOUND OR IF THE SOLUTION CONTAINS VISIBLE SOLID PARTICLES.

STORAGE: STORE BETWEEN 15°C - 30°C. KEEP FROM FREEZING.

KEEP OUT OF REACH OF CHILDREN

RX ONLY

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

ASSEMBLED IN U.S.A.

4000

5 PP

LATEX

V1 501206

Manufactured For:
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18-827
RMS# 92-2123
Iss. 08/21

NDC 86136-008-05

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OSMOSOL-R

multiple electrolyte injection type 1 injection, solution

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:86136-008
Route of Administration	INTRAVENOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	526 mg in 100 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CATION	37 mg in 100 mL
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	30 in 100 mL
SODIUM ACETATE ANHYDROUS (UNII: NVG71ZZ7P0) (ACETATE ION - UNII:569DQM74SC)	SODIUM ACETATE ANHYDROUS	222 in 100 mL
SODIUM GLUCONATE (UNII: R6Q3791S76) (GLUCONIC ACID - UNII:R4R8J0Q44B)	SODIUM GLUCONATE	502 in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86136-008-05	5000 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/23/2022	

Labeler - MWI (VetOne) (019926120)

Registrant - MWI (VetOne) (019926120)

Establishment

Name	Address	ID/FEI	Business Operations
Nova-Tech, Inc.		196078976	manufacture, analysis

Establishment

Name	Address	ID/FEI	Business Operations
Macco Organiques Inc		246200364	api manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Ruibang laboratories		544807456	api manufacture

Revised: 12/2022

MWI (VetOne)