SODIUM CHLORIDE- sodium 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.

SODIUM CHLORIDE

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

Description

Sodium Chloride 0.9% Injection is a sterile, non-pyrogenic solution intended for water and electrolytes replenishment in single dose containers. May be administered intravenously using aseptic technique. It contains no antimicrobial agents. Discard any unused portion. Composition, osmolarity, pH and ionic concentration are shown in Table 1.

Table 1

Composition (g/L)	Osmolarity (mOsmol/L) (calc)	pH	Ionic Concentration (mEq/L)	
Sodium Chloride NaCl			Sodium	Chloride
9.0	308	5.5 (4 - 7)	150	150

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

Clinical Pharmacology

Sodium Chloride 0.9% Injection is intended to restore water and electrolytes. It is capable of inducing diuresis, depending on the clinical condition of the patient.

Indications

Sodium Chloride 0.9% Injection is indicated as a source of water and electrolytes.

Contraindications

None known.

Warnings

Sodium Chloride 0.9% Injection 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.

The intravenous administration of Sodium Chloride 0.9% Injection can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, over-hydration, congested states, or pulmonary edema. The risk of dilutive states is inversely proportional to the electrolyte concentration 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 Sodium Chloride 0.9% Injection may result in sodium 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

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 parenteral therapy or whenever the condition of the patient warrants such evaluation.

Caution must be exercised in the administration of Sodium Chloride 0.9% Injection to patients receiving corticosteroids or corticotrophin.
Do not administer unless solution is clear and seal is intact.

Solution must be warmed to body temperature prior to administration 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

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 discolouration prior to administration whenever solution and container permit.

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

Sodium Chloride 0.9% Injection 250mL

Sodium Chloride 0.9% Injection

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

KEEP OUT OF REACH OF CHILDREN

250mL (8.45 fl oz)

200

Each 100mL contains:
SODIUM CHLORIDE 900mg

mEq/L SODIUM 150, CHLORIDE 150, pH: 5.5 (4.0 to 7.0),
OSMOLARITY: 308mOsmol/L (calc)

150

INDICATIONS: AS A SOURCE OF WATER AND ELECTROLYTES 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.

100

CAUTION: 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 ADMINISTER SIMULTANEOUSLY WITH BLOOD. 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

50
Approx.

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: 46066-512-04

A533SPH

REV. 04/16

LOT:

EXP:

BARCODE: 0 99355 01343 8

Approx 50 100 150 200

Sodium Chloride 0.9% Injection 500mL

aspen

Sodium Chloride 0.9% Injection

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

KEEP OUT OF REACH OF CHILDREN

500mL (16.91 fl oz)

Each 100mL contains:
SODIUM CHLORIDE 900mg

mEq/L SODIUM 150, CHLORIDE 150, pH: 5.5 (4.0 to 7.0),
OSMOLARITY: 308mOsmol/L (calc)

INDICATIONS: AS A SOURCE OF WATER AND ELECTROLYTES 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: 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 ADMINISTER SIMULTANEOUSLY WITH BLOOD. 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: 46066-512-05

A534SPH

REV. 04/16

LOT:

BARCODE: 0 99355 01345 2

EXP:

400
300
200
100
Approx.

Approx.
100
200
300
400

Sodium Chloride 0.9% Injection 1000mL

Sodium Chloride 0.9% Injection

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

KEEP OUT OF REACH OF CHILDREN

1000mL (33.81 fl oz)

Each 100mL contains:
SODIUM CHLORIDE 900mg

mEq/L SODIUM 150, CHLORIDE 150, pH: 5.5 (4.0 to 7.0),
OSMOLARITY: 308mOsmol/L (calc)

INDICATIONS: AS A SOURCE OF WATER AND ELECTROLYTES 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: 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 ADMINISTER SIMULTANEOUSLY WITH BLOOD. 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: 46066-512-06

A535SPH

REV. 04/16

LOT:

EXP:

BARCODE:

0 99355 01347 6

Approx.

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:46066-512
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	900 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:46066-512-04	36 in 1 CASE		
1		250 mL in 1 CONTAINER		
2	NDC:46066-512-05	24 in 1 CASE		
2		500 mL in 1 CONTAINER		
3	NDC:46066-512-06	12 in 1 CASE		
3		1000 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

Revised: 12/2017 ASPEN VETERINARY