SYKES 0.9% SODIUM CHLORIDE- sodium chloride injection solution
Sypharma 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.

Sykes 0.9% Sodium Chloride

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

Description

Sykes 0.9% Sodium Chloride Intravenous Infusion 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 (4.5- 7)	154	154

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

Clinical Pharmacology

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

Indications and Usage

Sykes 0.9% Sodium Chloride Intravenous Infusion is indicated as a source of water and electrolytes.

Contraindications

None known.

Warnings

Sykes 0.9% Sodium Chloride Intravenous Infusion 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 Sykes 0.9% Sodium Chloride Intravenous Infusion 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 Sykes 0.9% Sodium Chloride Intravenous Infusion 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

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 Sykes 0.9% Sodium Chloride Intravenous Infusion to patients receiving corticosteroids or corticotrophin.

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 discolouration 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 judgement 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.

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 Events.

Packs Supplied

Sykes 0.9% Sodium Chloride Intravenous Infusion in plastic container is available as follows:

Size (mL)	Item Code	NDC
250	FP09SUS25	86043-1002-1
500	FP09SUS50	86043-1002-2
1000	FP09SUS01	86043-1002-3
3000	FP09SUS03	86043-1002-4
5000	FP09SUS05	86043-1002-5

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.

Made in Australia

Manufactured and distributed by:
Sypharma Pty Ltd
27 Healey Road Dandenong
Victoria 3175 Australia

For customer service email:
customerservice@sypharma.com.au

Version: US_01

Sykes 0.9% Sodium Chloride Intravenous Infusion 250mL

Sykes 0.9% Sodium Chloride Intravenous Infusion 500mL

Sykes 0.9% Sodium Chloride Intravenous Infusion 1000mL

Sykes 0.9% Sodium Chloride Intravenous Infusion 3000mL

Sykes 0.9% Sodium Chloride Intravenous Infusion 5000mL

SYKES 0.9% SODIUM CHLORIDE

sodium chloride injection solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:86043-1002
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:86043-1002-1	250 mL in 1 CONTAINER		
2	NDC:86043-1002-2	500 mL in 1 CONTAINER		
3	NDC:86043-1002-3	1000 mL in 1 CONTAINER		
4	NDC:86043-1002-4	3000 mL in 1 CONTAINER		
5	NDC:86043-1002-5	5000 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/09/2016	

Labeler - Sypharma Pty Ltd (753786292)

Registrant - Sypharma Pty Ltd (753786292)

Establishment

Name	Address	ID/FEI	Business Operations
Sypharma Pty Ltd		753786292	manufacture, pack, sterilize

Revised: 2/2018 Sypharma Pty Ltd