SYKES 5% DEXTROSE AND 0.9% SODIUM CHLORIDE- dextrose monohydrate and 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 5% Dextrose and 0.9% Sodium Chloride

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

Description

Sykes 5% Dextrose and 0.9% Sodium Chloride Injection is a sterile, non-pyrogenic solution intended for fluid and electrolyte replenishment and caloric supply in single dose containers. May be administered intravenously using aseptic technique. It contains no antimicrobial agents. Discard any unused portion. Composition, osmolarity, pH and caloric content are shown in Table 1.

Table 1

	Composition (g/L)		Osmolarity (mOsmol/L) (calc)	pH	Concentration (mEq/L)		Caloric Content (kcal/L)
	Dextrose Hydrous ($C_6H_{12}O_6 \cdot H_2O$)	Sodium Chloride (NaCl)			Sodium	Chloride	
5% Dextrose and 0.9% Sodium Chloride Injection	50	9	560	4.5 (3.2 to 6.5)	154	154	170

Normal physiologic osmolarity range is approximately 560 to 620 mOsmol/L.
Administration of substantially hypertonic solutions (≥600 mOsmol/L) may cause vein damage.
The container is free of PVC and phthalates. The container meets the requirements of USP and is registered with US FDA.

Clinical Pharmacology

Sykes 5% Dextrose and 0.9% Sodium Chloride Injection has value as a source of water, electrolytes and calories. It will induce diuresis depending on the clinical condition of the patient.

Indications

Sykes 5% Dextrose and 0.9% Sodium Chloride Injection is indicated as a source of water and calories for all species.

Contraindications

Sykes 5% Dextrose and 0.9% Sodium Chloride Injection is contraindicated in patients with a known allergy to corn or corn products.

Warnings

Excessive administration of Sykes 5% Dextrose and 0.9% Sodium Chloride Injection may result in significant hypokalemia.

Sykes 5% Dextrose and 0.9% Sodium Chloride 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.

Sykes 5% Dextrose and 0.9% Sodium Chloride Injection should not be administered simultaneously with blood through the same infusion set because of the possibility that pseudoagglutination of red cells may occur.

The intravenous administration of Sykes 5% Dextrose and 0.9% Sodium Chloride Injection can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema.

The risk of dilutive 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 Sykes 5% Dextrose and 0.9% Sodium Chloride Injection may result in sodium retention.

Adverse Reactions

Reactions which may occur because of the injection 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 Sykes 5% Dextrose and 0.9% Sodium Chloride Injection to patients receiving corticosteroids or corticotropin.

Sykes 5% Dextrose and 0.9% Sodium Chloride Injection should be used with caution in patients with known subclinical or overt diabetes mellitus.
Do not administer unless solution is clear and both seal and container are intact.

Dosage and Administration

To be used as directed by a licensed veterinarian. The dosage of the Sykes 5% Dextrose and 0.9% Sodium Chloride Injection 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. 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 5% Dextrose and 0.9% Sodium Chloride Injection is available in containers in various sizes as follows:

Size (mL)	Item Code	NDC
250	FPDSCUS25	86043-1012-1
500	FPDSCUS50	86043-1012-2
1000	FPDSCUS01	86043-1012-3
3000	FPDSCUS03	86043-1012-4
5000	FPDSCUS05	86043-1012-5

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 5% Dextrose and 0.9% Sodium Chloride Injection 250mL

SYKES

Sykes 5% Dextrose and 0.9% Sodium Chloride Injection

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

KEEP OUT OF REACH OF CHILDREN

250 mL

Each 100mL contains:

Dextrose Hydrous	5g
Sodium Chloride	0.9g
Water for Injection	q.s.

mEq/L Sodium 154, Chloride 154

pH: 4.5 (3.2 – 6.5); Osmolarity: 560 mOsmol/L (calc)

INDICATIONS: As a source of water, electrolytes and calories 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 pharmacist, if available. When introducing additives, use aseptic technique, mix thoroughly and do not store. 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 (USA) 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

NDC Number: 86043-1012-1

Barcode: 9 317643 192636

Batch Number:

Expiry:

Sykes 5% Dextrose and 0.9% Sodium Chloride Injection 500mL

Sykes 5% Dextrose and 0.9% Sodium Chloride Injection

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

KEEP OUT OF REACH OF CHILDREN

500 mL

Each 100mL contains:

DEXTROSE HYDROUS	5g
SODIUM CHLORIDE	0.9g
WATER FOR INJECTION	q.s.

mEq/L SODIUM 154, CHLORIDE 154

PH: 4.5 (3.2 – 6.5); OSMOLARITY: 560 mOsmol/L (calc)

INDICATIONS: AS A SOURCE OF WATER, ELECTROLYTES AND CALORIES 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 PHARMACIST, IF AVAILABLE. WHEN INTRODUCING ADDITIVES, USE ASEPTIC TECHNIQUE, MIX THOROUGHLY AND DO NOT STORE. 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 (USA) 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

NDC NUMBER: 86043-1012-2

BARCODE:

9 317643 192643

BATCH NUMBER:

EXPIRY:

Sykes 5% Dextrose and 0.9% Sodium Chloride Injection 1000mL

SYKES

Sykes 5% Dextrose and 0.9% Sodium Chloride Injection

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

KEEP OUT OF REACH OF CHILDREN

1000 mL

Each 100mL contains:

Dextrose Hydrous	5g
Sodium Chloride	0.9g
Water for Injection	q.s.

mEq/L Sodium 154, Chloride 154

pH: 4.5 (3.2 – 6.5); Osmolarity: 560 mOsmol/L (calc)

INDICATIONS: As a source of water, electrolytes and calories 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 pharmacist, if available. When introducing additives, use aseptic technique, mix thoroughly and do not store. 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 (USA) 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

NDC Number: 86043-1012-3

Barcode:

9 317643 192650

Batch Number:

Expiry:

Sykes 5% Dextrose and 0.9% Sodium Chloride Injection 3000mL

SYKES

Sykes 5% Dextrose and 0.9% Sodium Chloride Injection

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

KEEP OUT OF REACH OF CHILDREN

3000 mL

Each 100mL contains:

Dextrose Hydrous	5g
Sodium Chloride	0.9g
Water for Injection	q.s.

mEq/L Sodium 154, Chloride 154

pH: 4.5 (3.2 – 6.5); Osmolarity: 560 mOsmol/L (calc)

INDICATIONS: As a source of water, electrolytes and calories 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.

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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

NDC Number: 86043-1012-4

Barcode: 9 317643 192667

Batch Number:

Expiry:

Sykes 5% Dextrose and 0.9% Sodium Chloride Injection 5000mL

SYKES

Sykes 5% Dextrose and 0.9% Sodium Chloride Injection

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

KEEP OUT OF REACH OF CHILDREN

5000 mL

Each 100mL contains:

Dextrose Hydrous	5g
Sodium Chloride	0.9g
Water for Injection	q.s.

mEq/L Sodium 154, Chloride 154

pH: 4.5 (3.2 – 6.5); Osmolarity: 560 mOsmol/L (calc)

INDICATIONS: As a source of water, electrolytes and calories 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.

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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

NDC Number: 86043-1012-5

Barcode:

9 317643 192674

Batch Number:

Expiry:

SYKES 5% DEXTROSE AND 0.9% SODIUM CHLORIDE

dextrose monohydrate and sodium chloride injection solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:86043-1012
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	5 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	0.9 g in 100 mL

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:86043-1012-1	250 mL in 1 CONTAINER		
2	NDC:86043-1012-2	500 mL in 1 CONTAINER		
3	NDC:86043-1012-3	1000 mL in 1 CONTAINER		
4	NDC:86043-1012-4	3000 mL in 1 CONTAINER		
5	NDC:86043-1012-5	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: 12/2017 Sypharma Pty Ltd