

SYKES IV LYTE-R- sodium chloride, sodium gluconate, sodium acetate anhydrous, potassium chloride, magnesium 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 IV Lyte-R

STERILE NONPYROGENIC SOLUTION

For Animal Use Only

Description

Sykes IV Lyte-R Injection (Multiple Electrolytes Injection, Type 1, USP) is a sterile, non-pyrogenic isotonic solution intended for fluid and electrolyte replenishment in single dose containers. May be administered intravenously or subcutaneously using aseptic technique. It contains no antimicrobial agents. Discard any unused portion. The pH is adjusted with Hydrochloric Acid and/or Sodium Hydroxide. Composition, osmolarity, pH and ionic concentration are shown in Table 1.

Table 1

Composition (g/L)	Sodium Chloride	Sodium Gluconate	Sodium Acetate Anhydrous	Potassium Chloride	Magnesium Chloride, Hexahydrate
	5.26	5.02	2.22	0.37	0.30

Ionic Concentration (mEq/L)	Sodium	Potassium	Magnesium	Chloride	Acetate	Gluconate
	140	5	3	98	27	23

Osmolarity (mOsmol/L) (calc): 294 mOsmol per litre

pH: 6.6 (limit 4.0 to 8.0)

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

Clinical Pharmacology

A multiple electrolyte intravenous solution is intended to restore the electrolyte balance and water for hydration. It is capable of inducing diuresis depending on the clinical condition of the patient and produces a metabolic alkalizing effect. Acetate and gluconate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications and Usage

Sykes IV Lyte-R Injection (Multiple Electrolytes Injection, Type 1, USP) is indicated as a source of water and electrolytes for all species. It is also used as an alkalinizing agent.

Contraindications

None known

Warnings

The introduction of additives to any solution, regardless of type of container, requires special attention to ensure that no incompatibilities result. While some incompatibilities are readily absorbed, one must be aware that subtle physical, chemical and pharmacological incompatibilities can occur. The medical literature, the package insert and other available sources of information should be reviewed for thorough understanding of possible incompatibilities.

Sykes IV Lyte-R Injection (Multiple Electrolytes Injection, Type 1, USP) 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 and sodium retention.

Sykes IV Lyte-R Injection (Multiple Electrolytes Injection, Type 1, USP) 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.

Sykes IV Lyte-R Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of acetate or gluconate 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.

The intravenous administration of Sykes IV Lyte-R Injection (Multiple Electrolytes Injection, Type 1, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, over-hydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overloading 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 IV Lyte-R Injection (Multiple Electrolytes Injection, Type 1, USP) may result in sodium or potassium retention.

Adverse Reactions

Adverse reactions may occur due to the solution or the technique of administration including febrile response, infection at the site of injection or allergic reactions. Prolonged intravenous infusion of this type of product may cause venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

If an adverse reaction does occur, discontinue the infusion and 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 therapy or whenever the condition of the patient warrants such evaluation.

Sykes IV Lyte-R Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with caution.

Excess administration may result in metabolic alkalosis.

Caution must be exercised in the administration of Sykes IV Lyte-R Injection (Multiple Electrolytes Injection, Type 1, USP) to patients receiving corticosteroids or corticotropin.

Do not administer unless solution is clear and both seal and container are intact.

Solution must be warmed to body temperature prior to administration and administered 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.

If an adverse reaction does occur, discontinue the infusion and evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

To be used as directed by a licensed veterinarian. The dosage of the Sykes IV Lyte-R Injection (Multiple Electrolytes Injection, Type 1, USP) 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 IV Lyte-R Injection (Multiple Electrolytes Injection, Type 1, USP) in plastic container is available as follows:

Size (mL)	Item Code	NDC
250	FPILRUS25	86043-1010-1
500	FPILRUS50	86043-1010-2
1000	FPILRUS01	86043-1010-3
3000	FPILRUS03	86043-1010-4
5000	FPILRUS05	86043-1010-5

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 IV Lyte-R Injection (Multiple Electrolytes Injection, Type 1, USP) 250mL



Sykes IV Lyte – R Injection (Multiple Electrolytes Injection Type 1 USP)

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

KEEP OUT OF REACH OF CHILDREN

250 mL

Each 100mL contains:

SODIUM CHLORIDE	526mg
SODIUM GLUCONATE	502mg
SODIUM ACETATE ANHYDROUS	222mg
POTASSIUM CHLORIDE	37mg
MAGNESIUM CHLORIDE, HEXAHYDRATE	30mg
pH ADJUSTED WITH HYDROCHLORIC ACID AND/OR SODIUM HYDROXIDE	

mEq/L SODIUM 140, POTASSIUM 5, MAGNESIUM 3, CHLORIDE 98, ACETATE 27, GLUCONATE 23, pH: 6.6 (4.0 to 8.0), OSMOLARITY: 294 mOsmo/L (calc)

INDICATIONS: AS A SOURCE OF WATER AND ELECTROLYTES OR AS AN ALKALINIZING AGENT.

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 OR SUBCUTANEOUSLY USING STRICT ASEPTIC TECHNIQUE. SEE PACKAGE INSERT.

CAUTION: SOLUTION MUST BE WARMED TO BODY TEMPERATURE PRIOR TO ADMINISTRATION AND ADMINISTERED AT A SLOW RATE. 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 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. 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.
CUSTOMERSERVICE@SYPHARMA.COM.AU

FOR CUSTOMER SERVICE EMAIL:

NDC NUMBER: 86043-1010-1

BARCODE:



BATCH NUMBER:

EXPIRY:

Sykes IV Lyte-R Injection (Multiple Electrolytes Injection, Type 1, USP) 500mL



Sykes IV Lyte – R Injection (Multiple Electrolytes Injection Type 1 USP)

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

KEEP OUT OF REACH OF CHILDREN

500 mL

Each 100mL contains:

SODIUM CHLORIDE	526mg
SODIUM GLUCONATE	502mg
SODIUM ACETATE ANHYDROUS	222mg
POTASSIUM CHLORIDE	37mg
MAGNESIUM CHLORIDE, HEXAHYDRATE	30mg
pH ADJUSTED WITH HYDROCHLORIC ACID AND/OR SODIUM HYDROXIDE	

mEq/L SODIUM 140, POTASSIUM 5, MAGNESIUM 3, CHLORIDE 98, ACETATE 27, GLUCONATE 23, pH: 6.6 (4.0 to 8.0),
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NDC NUMBER: 86043-1010-2

BARCODE:



BATCH NUMBER:

EXPIRY:

Sykes IV Lyte-R Injection (Multiple Electrolytes Injection, Type 1, USP) 1000mL



Sykes IV Lyte – R Injection (Multiple Electrolytes Injection Type 1 USP)

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

KEEP OUT OF REACH OF CHILDREN

1000 mL

Each 100mL contains:

SODIUM CHLORIDE	526mg
SODIUM GLUCONATE	502mg
SODIUM ACETATE ANHYDROUS	222mg
POTASSIUM CHLORIDE	37mg
MAGNESIUM CHLORIDE, HEXAHYDRATE	30mg
pH ADJUSTED WITH HYDROCHLORIC ACID AND/OR SODIUM HYDROXIDE	

mEq/L SODIUM 140, POTASSIUM 5, MAGNESIUM 3, CHLORIDE 98, ACETATE 27, GLUCONATE 23,
pH: 6.6 (4.0 TO 8.0), OSMOLARITY: 294 mOSMOL/L (CALC)

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NDC NUMBER: 86043-1010-3

BARCODE:



BATCH NUMBER:

EXPIRY:

Sykes IV Lyte-R Injection (Multiple Electrolytes Injection, Type 1, USP) 3000mL



Sykes IV Lyte – R Injection (Multiple Electrolytes Injection Type 1 USP)

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

KEEP OUT OF REACH OF CHILDREN

3000 mL

Each 100mL contains:

SODIUM CHLORIDE	526mg
SODIUM GLUCONATE	502mg
SODIUM ACETATE ANHYDROUS	222mg
POTASSIUM CHLORIDE	37mg
MAGNESIUM CHLORIDE, HEXAHYDRATE	30mg
pH ADJUSTED WITH HYDROCHLORIC ACID AND/OR SODIUM HYDROXIDE	

mEq/L SODIUM 140, POTASSIUM 5, MAGNESIUM 3, CHLORIDE 98, ACETATE 27, GLUCONATE 23,
pH: 6.6 (4.0 TO 8.0), OSMOLARITY: 294 mOSMOL/L (CALC)

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NDC NUMBER: 86043-1010-4

BARCODE:



BATCH NUMBER:

EXPIRY:

Sykes IV Lyte-R Injection (Multiple Electrolytes Injection, Type 1, USP) 5000mL



Sykes IV Lyte – R Injection (Multiple Electrolytes Injection Type 1 USP)

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

KEEP OUT OF REACH OF CHILDREN

5000 mL

Each 100mL contains:

SODIUM CHLORIDE	526mg
SODIUM GLUCONATE	502mg
SODIUM ACETATE ANHYDROUS	222mg
POTASSIUM CHLORIDE	37mg
MAGNESIUM CHLORIDE, HEXAHYDRATE	30mg

pH ADJUSTED WITH HYDROCHLORIC ACID AND/OR SODIUM HYDROXIDE

mEq/L SODIUM 140, POTASSIUM 5, MAGNESIUM 3, CHLORIDE 98, ACETATE 27, GLUCONATE 23,
pH: 6.6 (4.0 TO 8.0), OSMOLARITY: 294 mOSMOL/L (CALC)

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NDC NUMBER: 86043-1010-5

BARCODE:



BATCH NUMBER:

EXPIRY:

SYKES IV LYTE-R

sodium chloride, sodium gluconate, sodium acetate anhydrous, potassium chloride, magnesium chloride injection, solution

Product Information

Product Type

PRESCRIPTION ANIMAL DRUG

Item Code (Source)

NDC:86043-1010

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	526 mg in 100 mL
SODIUM GLUCONATE (UNII: R6Q3791S76) (SODIUM CATION - UNII:LYR4M0NH37, GLUCONIC ACID - UNII:R4R8J0Q44B)	SODIUM GLUCONATE	502 mg in 100 mL
SODIUM ACETATE ANHYDROUS (UNII: NVG71ZZ7P0) (SODIUM CATION - UNII:LYR4M0NH37, ACETATE ION - UNII:569DQM74SC)	SODIUM ACETATE ANHYDROUS	222 mg in 100 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	37 mg in 100 mL
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CHLORIDE	30 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86043-1010-1	250 mL in 1 CONTAINER		
2	NDC:86043-1010-2	500 mL in 1 CONTAINER		
3	NDC:86043-1010-3	1000 mL in 1 CONTAINER		
4	NDC:86043-1010-4	3000 mL in 1 CONTAINER		
5	NDC:86043-1010-5	5000 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/10/2016	

Labeler - Sypharma Pty Ltd (753786292)

Registrant - Sypharma Pty Ltd (753786292)

Establishment

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