SYKES ELECTROLYTE SOLUTION COMPOUND SODIUM LACTATE HARTMANNS-
sodium chloride, potassium chloride, sodium lactate and calcium chloride 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 Electrolyte Solution Compound Sodium Lactate Hartmanns

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

Description

Sykes Electrolyte Solution Compound Sodium Lactate (Hartmanns Solution) is a sterile, non-pyrogenic solution intended for fluid and electrolyte replenishment in single dose containers. May be administered intravenously, subcutaneously or intraperitoneally (except in horses) 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)	Sodium Chloride	Potassium Chloride	Calcium Chloride	Sodium Lactate*	
	6.0	0.40	0.28	3.24	
Ionic Concentration (mEq/L)	Sodium	Potassium	Calcium	Chloride	Lactate
	131	5	2	111	29

*Sodium Lactate USP *(S)*-enantiomer

Osmolarity (mOsmol/L) (calc): 280mOsmol per litre

pH: 6.5 (limit 6.0 to 7.0)

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. A combination of multiple electrolytes and sodium lactate, an alkalinizing agent, will provide electrolyte balance and normalize the pH of the acid-base of the physiological system.

Indications

Sykes Electrolyte Solution Compound Sodium Lactate (Hartmann’s Solution) is indicated as a source of water and electrolytes for all species. It is also used as an alkalinizing agent.

Contraindications

Sykes Electrolyte Solution Compound Sodium Lactate (Hartmann’s Solution) is contraindicated in patients with a known hypersensitivity to sodium lactate; congestive heart failure or severe impairment of renal function; clinical states in which the administration of sodium and chloride is detrimental.

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 Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution) 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 Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution) 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 Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of lactate 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.

Sykes Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution) should not be administered simultaneously with blood through the same administration set because of likelihood of coagulation.

The intravenous administration of Sykes Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution) 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 injections. 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 Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution) may result in sodium or potassium retention.

Do not administer to horses by intraperitoneal injection. Do not administer to animals with inadequate renal function. Not for use in lactic acidosis.

Adverse Reactions

Adverse reactions may occur due to the solution or the technique of administration including fever 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 Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution) should be used with caution. Excess administration may result in metabolic alkalosis.

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 Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution) 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 doctor, 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 Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution) in plastic container is available as follows:

Size (mL)	Item Code	NDC
250	FPHARTUS25	86043-1001-1
500	FPHARTUS50	86043-1001-2
1000	FPHARTUS01	86043-1001-3
3000	FPHARTUS03	86043-1001-4
5000	FPHARTUS05	86043-1001-5

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (30°C/86°F). 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

Australian Label

FOR ANIMAL TREATMENT ONLY

Sykes Electrolyte Solution Compound Sodium Lactate
(HARTMANN'S SOLUTION)

ACTIVE CONSTITUENTS	g/L
Sodium Chloride	6.0
Potassium Chloride	0.40
Calcium Chloride Dihydrate	0.28
Sodium Lactate	3.24

Approximate millimoles per litre: Sodium (131), Potassium (5), Calcium (2), Chloride (111), Bicarbonate (as lactate) 29

For the treatment of dehydration and for electrolyte replacement in all species.

Contents: 250 ml / 500 ml / 700 ml / 1000 ml / 3000 ml / 5000 ml

Directions for use:
To be used under the supervision of a registered veterinary surgeon.

Caution:
Do not use in series connection. Do not use unless solution is clear. Do not remove plastic overpouch until immediately prior to use. Before use, check for leaks by squeezing the bag firmly. Discard if leakage is detected or if the solution contains visible solid particles. Discard unused portion after use. Discontinue infusion if an adverse reaction occurs. Additives may be incompatible. Add to inverted container (ports uppermost) with a 0.63 to 0.80 mm needle, squeeze ports and mix thoroughly. Avoid storage of solutions so prepared.

Withholding period: Nil

TRADE ADVICE
EXPORT SLAUGHTER INTERVAL (ESI): A period of zero (0) days is required between last treatment of animals and slaughter for export.

Storage:
Store below 30°C (room temperature).

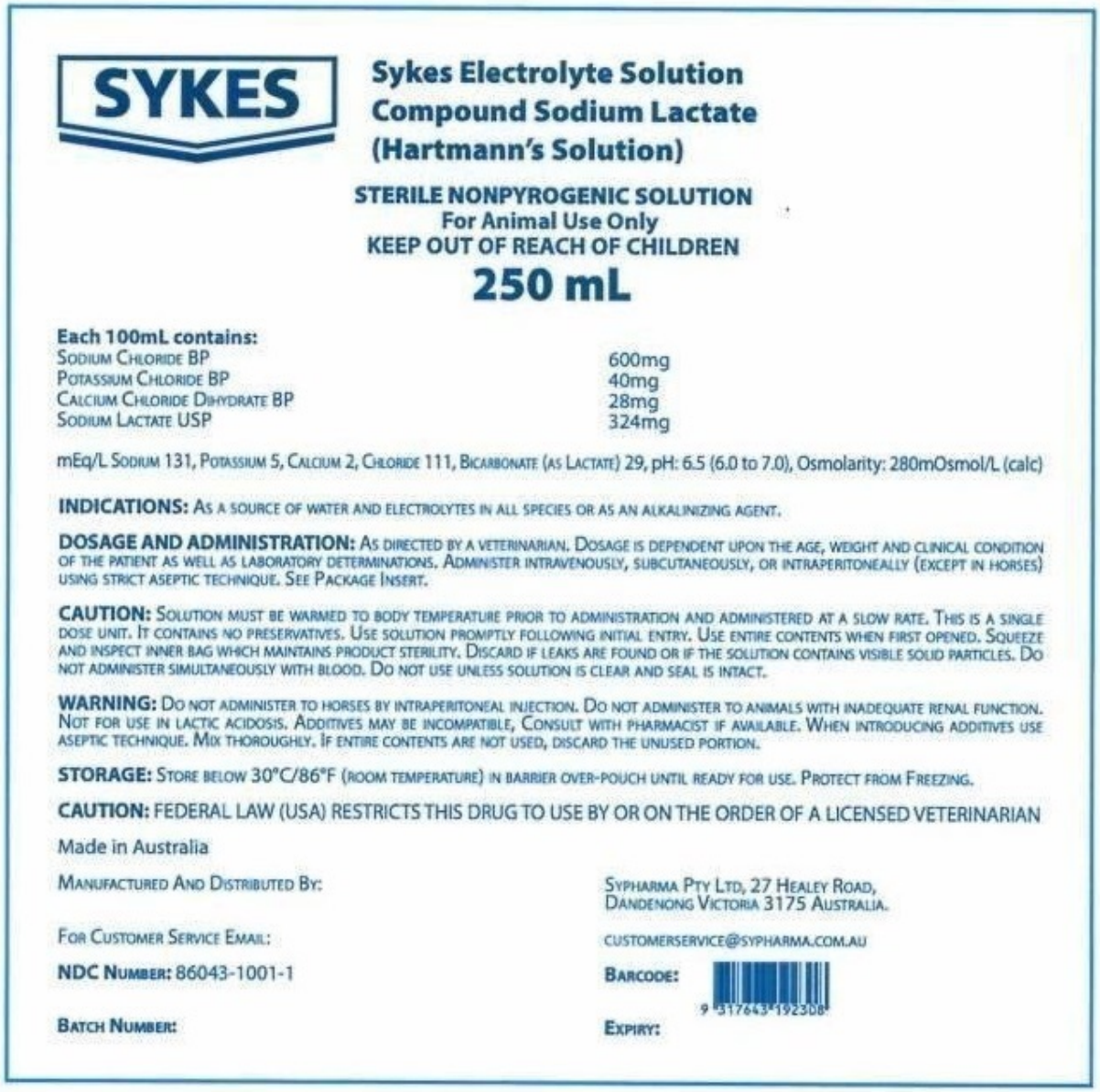
Disposal:
Dispose of empty container and outer packaging by wrapping with paper and placing in garbage.

Sykes Vet International Pty Ltd
27 Healey Road
Dandenong VIC 3174

APVMA: 63359/51322

Batch no:
Expiry:

Sykes Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution) 250mL Label



SYKES

Sykes Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution)

STERILE NONPYROGENIC SOLUTION
For Animal Use Only
KEEP OUT OF REACH OF CHILDREN

250 mL

Each 100mL contains:

Sodium Chloride BP	600mg
Potassium Chloride BP	40mg
Calcium Chloride Dihydrate BP	28mg
Sodium Lactate USP	324mg

mEq/L Sodium 131, Potassium 5, Calcium 2, Chloride 111, Bicarbonate (as Lactate) 29, pH: 6.5 (6.0 to 7.0), Osmolarity: 280mOsmol/L (calc)

INDICATIONS: As a source of water and electrolytes in all species 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, subcutaneously, or intraperitoneally (except in horses) 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 administer simultaneously with blood. Do not use unless solution is clear and seal is intact.

WARNING: Do not administer to horses by intraperitoneal injection. Do not administer to animals with inadequate renal function. Not for use in lactic acidosis. 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 30°C/86°F (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: 86043-1001-1

Barcode: 9 317643 192308

Batch Number:

Expiry:

Sykes Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution) 500mL Label

SYKES

Sykes Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution)

STERILE NONPYROGENIC SOLUTION
For Animal Use Only
KEEP OUT OF REACH OF CHILDREN

500 mL

Each 100mL contains:

Sodium Chloride BP	600mg
Potassium Chloride BP	40mg
Calcium Chloride Dihydrate BP	28mg
Sodium Lactate USP	324mg

mEq/L Sodium 131, Potassium 5, Calcium 2, Chloride 111, Bicarbonate (as Lactate) 29, pH: 6.5 (6.0 to 7.0), Osmolarity: 280mOsmol/L (calc)

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For Customer Service Email:

customerservice@sypharma.com.au

NDC Number: 86043-1001-2

Barcode: 9 317643 192315

Batch Number:

Expiry:

Sykes Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution) 1000mL Label

SYKES

Sykes Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution)

STERILE NONPYROGENIC SOLUTION
For Animal Use Only
KEEP OUT OF REACH OF CHILDREN

1000 mL

Each 100mL contains:

Sodium Chloride BP	600mg
Potassium Chloride BP	40mg
Calcium Chloride Dihydrate BP	28mg
Sodium Lactate USP	324mg

mEq/L Sodium 131, Potassium 5, Calcium 2, Chloride 111, Bicarbonate (as Lactate) 29, pH: 6.5 (6.0 to 7.0), Osmolarity: 280mOsmol/L (calc)

INDICATIONS: As a source of water and electrolytes in all species or as an alkalinizing agent.

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For Customer Service Email:

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NDC Number: 86043-1001-3

Barcode: 9 317643 192322

Batch Number:

Expiry:

Sykes Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution) 3000mL Label

SYKES

Sykes Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution)

STERILE NONPYROGENIC SOLUTION

For Animal Use Only

KEEP OUT OF REACH OF CHILDREN

3000 mL

Each 100mL contains:

Sodium Chloride BP	600mg
Potassium Chloride BP	40mg
Calcium Chloride Dihydrate BP	28mg
Sodium Lactate USP	324mg

mEq/L Sodium 131, Potassium 5, Calcium 2, Chloride 111, Bicarbonate (as Lactate) 29, pH: 6.5 (6.0 to 7.0), Osmolarity: 280mOsmol/L (calc)

INDICATIONS: As a source of water and electrolytes in all species or as an alkalinizing agent.

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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: 86043-1001-4

Barcode: 9 317643 192339

Batch Number:

Expiry:

Sykes Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution) 5000mL Label Version 2

SYKES

Sykes Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution)

STERILE NONPYROGENIC SOLUTION

For Animal Use Only

KEEP OUT OF REACH OF CHILDREN

5000 mL

Each 100mL contains:

Sodium Chloride BP	600mg
Potassium Chloride BP	40mg
Calcium Chloride Dihydrate BP	28mg
Sodium Lactate USP	324mg

mEq/L Sodium 131, Potassium 5, Calcium 2, Chloride 111, Bicarbonate (as Lactate) 29, pH: 6.5 (6.0 to 7.0), Osmolarity: 280mOsmol/L (calc)

INDICATIONS: As a source of water and electrolytes in all species 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, subcutaneously, or intraperitoneally (except in horses) using strict aseptic technique. See Package Insert.

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Made in Australia

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For Customer Service Email: customerservice@sypharma.com.au

NDC Number: 86043-1001-5

Barcode: 9 317643 192346

Batch Number:

Expiry:

Sykes Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution) 5000mL Label Version 1

Sykes Electrolyte Solution Compound Sodium Lactate (Hartmann's Solution)

STERILE NONPYROGENIC SOLUTION

For Animal Use Only

KEEP OUT OF REACH OF CHILDREN

5000 mL

Each 100mL contains:

Sodium Chloride BP	600mg
Potassium Chloride BP	40mg
Calcium Chloride Dihydrate BP	28mg
Sodium Lactate USP	324mg

mEq/L Sodium 131, Potassium 5, Calcium 2, Chloride 111, Bicarbonate (as Lactate) 29, pH: 6.5 (6.0 to 7.0), Osmolarity: 280mOsmol/L (calc)

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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, subcutaneously, or intraperitoneally (except in horses) 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: 86043-1001-5

Barcode: 9 317643 192346

Batch Number:

Expiry:

SYKES ELECTROLYTE SOLUTION COMPOUND SODIUM LACTATE HARTMANNS

sodium chloride, potassium chloride, sodium lactate and calcium chloride solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:86043-1001
Route of Administration	INTRAVENOUS, SUBCUTANEOUS, INTRAPERITONEAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	600 mg in 100 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	40 mg in 100 mL
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	28 mg in 100 mL
SODIUM LACTATE (UNII: TU7HW0W0QT) (LACTIC ACID - UNII:33X04XA5AT, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM LACTATE	324 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:86043-1001-1	250 mL in 1 CONTAINER		
2	NDC:86043-1001-2	500 mL in 1 CONTAINER		
3	NDC:86043-1001-3	1000 mL in 1 CONTAINER		
4	NDC:86043-1001-4	3000 mL in 1 CONTAINER		
5	NDC:86043-1001-5	5000 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/20/2015	

Labeler - Sypharma Pty Ltd (753786292)

Registrant - Sypharma Pty Ltd (753786292)

Revised: 12/2017 Sypharma Pty Ltd