1 COMPOUND SODIUM LACTATE (HARTMANNS), (solution for infusion)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Compound Sodium Lactate (Hartmanns) infusion solution					
Product	Potassium chloride	Sodium chloride	Sodium lactate	Calcium chloride dihydrate	Osmolarity[α] mOsmol/L [Osmolality, mOsmol/kg]
Compound Sodium Lactate (Hartmanns) IV infusion 500mL (AHB2323)					
Potassium chloride 0.04%, Sodium chloride 0.6%, Sodium lactate 0.322% and Calcium chloride dihydrate 0.027%	2.7mmol/ 500mL	51.35mmol/ 500mL	14.36mmol/ 500mL	0.92mmol/ 500mL	280 [254]
Compound Sodium Lactate (Hartmanns) IV infusion 1000mL (AHB2324)					
Potassium chloride 0.04%, Sodium chloride 0.6%, Sodium lactate 0.322% and Calcium chloride dihydrate 0.027%	5.4mmol/L	102.7mmol/L	28.72mmol/L	1.84mmol/L	280 [254]
Osmolarity[α] is a calculated figure; whilst the figures in the brackets are Osmolality [mOsmol/kg].					

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion.

Appearance

Compound Sodium Lactate (Hartmanns), an intravenous (IV) infusion preparation, is a clear, colourless, sterile, non-pyrogenic solution.

Compound Sodium Lactate (Hartmanns) is an isotonic intravenous solution with pH of 5.0 – 7.0.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Compound Sodium Lactate (Hartmanns) infusion solution is indicated as a source of water and electrolytes. It is also used in patients as a source of bicarbonate in the treatment of mild to moderate metabolic acidosis associated with dehydration or associated with potassium deficiency. This solution is indicated as a method of intravenous drug delivery, if the drugs are compatible with the solution.

4.2 Dose and method of administration

To be used as directed by the physician. The dosage of **Compound Sodium Lactate (Hartmanns)** infusion solution is dependent upon the age, weight, concomitant treatments and clinical condition of the patient, as well as laboratory determinations and response. Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration whenever solution and container permit. Do not administer **Compound Sodium Lactate (Hartmanns)** unless the solution is clear and the seal is intact. Sterile and nonpyrogenic equipment must be used for intravenous administration.

The introduction of additives to any solution, regardless of type of container, requires special attention to assure that no incompatibilities results. While some incompatibilities are readily observed, one must be aware that subtle physical, chemical and pharmacological incompatibilities can occur.

As with all parenteral solutions, compatibility of the additives with the solution must be assessed before addition, by checking for a possible colour change and/or the appearance of precipitates, insoluble complexes or crystals.

Before adding a substance or medication, verify that it is soluble and/or stable in water and that the pH range of **Compound Sodium Lactate (Hartmanns)** infusion solution is appropriate. Complete information is not available. Those additives known to be incompatible should not be used. The medical literature, the package insert and other available sources of information should be reviewed for thorough understanding of possible of incompatibilities. Consult with a pharmacist, if available. If in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Refer to instructions in section 6.6). Do not store solutions containing additives. Do not reconnect any partially used containers.

4.3 Contraindications

Compound Sodium Lactate (Hartmanns) infusion 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;
- as for other calcium-containing infusion solutions, concomitant administration of ceftriaxone and **Compound Sodium Lactate (Hartmanns)** is contraindicated in neonates (≤ 28 days of age) even if separate infusion lines are used due to risk of fatal ceftriazone-calcium salt precipitation in the neonates bloodstream. In patients older than 28 days (including children and adults), ceftriaxone must not be administered simultaneously with IV calcium-containing solutions, including **Compound Sodium Lactate (Hartmanns)** through the same infusion line (e.g. via Y-connector).

4.4 Special warnings and precautions for use

Compound Sodium Lactate (Hartmanns) infusion solution is not for use in the treatment of lactic acidosis or severe metabolic acidosis. Although **Compound Sodium Lactate (Hartmanns)** has a potassium concentration similar to the concentration in plasma, it is insufficient to produce a useful effect in severe potassium deficiency, therefore it should not be used for treatment of severe potassium deficiency.

The safety of the Viaflex plastic container used in **Compound Sodium Lactate (Hartmanns)** infusion solution has been confirmed in tests in animals according to the USP biological tests for plastic containers, as well as by tissue culture toxicity studies. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. Nevertheless, care should be exercised regarding possible incompatibility outcomes resulted either from the interaction between the plastic container or active ingredients and the added therapeutic substances (see section 4.2).

In patients older than 28 days (including adults), ceftriaxone must not be administered simultaneously with intravenous calcium-containing solutions, through the same infusion line. If the same infusion line is used for sequential administration, the line must be thoroughly flushed between infusions with a compatible fluid.

Compound Sodium Lactate (Hartmanns) infusion solution is isotonic (254mOsmol/kg). The addition of potassium chloride (0.18%, 48mOsmol/L) to the **Compound Sodium Lactate (Hartmanns)** solution does not result in a hypertonic solution (304mOsmol/kg). It is important to bear in mind that administration of a substantially hypertonic solution may lead to a wide variety of complications, such as crenation (shrinkage) of red blood cells and general cellular dehydration.

In patients with diminished renal function, administration of **Compound Sodium Lactate (Hartmanns)** infusion may result in sodium, calcium and/or potassium retention. If a patient receives prolonged therapy, or the rate of administration warrants review, clinical evaluation and laboratory monitoring for changes in fluid balance, electrolyte concentration and acid-base balance should be conducted.

Hypersensitivity reactions
The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Hyponatraemia
Monitoring of serum sodium is particularly important for hypotonic fluids. High volume infusion must be used under specific monitoring in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH), due to the risk of hospital-acquired hyponatraemia. Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (brain oedema) characterised by headache, nausea, seizures, lethargy and vomiting. Patients with brain oedema are at particular risk of severe, irreversible and life-threatening brain injury.

Fluid/solute overload and electrolyte disturbances
Depending on the volume and rate of infusion, the intravenous administration of **Compound Sodium Lactate (Hartmanns)** infusion solution can cause fluid and/or solute overloading resulting in dilution of the serum electrolyte concentrations, over-hydration, congested states (including pulmonary congestion and oedema), clinically relevant electrolyte disturbance and acid-base imbalance. The risk of dilution states is inversely proportional to the electrolyte concentrations of the injections. The risk of solute overload causing congested states with peripheral and pulmonary oedema is directly proportional to the electrolyte concentrations of the injections.

Clinical evaluation and periodic laboratory determinations may be necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation.

Use in patient with or at risk for hyperkalaemia
Compound Sodium Lactate (Hartmanns) infusion solution should be administered with particular caution, if at all, to patients with hyperkalaemia or conditions predisposing to hyperkalaemia (e.g. potassium excretion impairment, adrenocortical insufficiency, acute dehydration, severe renal impairment or extensive tissue injury or burns) and in patients with cardiac disease, as administration of IV potassium can rapidly result in severe hyperkalaemia without symptoms, which may lead to fatal adverse reactions.

Use in patients with hypervolaemia, overhydration, or conditions that cause sodium retention and oedema
Compound Sodium Lactate (Hartmanns) infusion should be administered with particular caution, if at all, to patients with conditions that may cause sodium retention, fluid overload and oedema. Consideration should be given to withholding **Compound Sodium Lactate (Hartmanns)** infusion altogether in hypervolaemic or overhydrated patients, including those with severe renal impairment,

primary or secondary hyperaldosteronism or preeclampsia, due to the risk of potassium and/or sodium retention, fluid overload and oedema.

Compound Sodium Lactate (Hartmanns) infusion solution should be used with caution in patients receiving corticosteroids or corticotrophin, i.e., potential sodium retention.

Use in patients with or at risk of alkalosis

Compound Sodium Lactate (Hartmanns) infusion solution should be administered with particular caution, if at all, to patients with alkalosis or at risk of alkalosis, because lactate is metabolised to bicarbonate and administration may result in, or worsen, metabolic alkalosis. The effect of the sodium lactate component in **Compound Sodium Lactate (Hartmanns)** infusion solution, on patients with metabolic or respiratory alkalosis, should be monitored closely.

Use in patients with or at risk of increased lactate levels or with impaired lactate utilisation

Compound Sodium Lactate (Hartmanns) infusion solution should be administered with extreme caution, if at all, in patients with conditions associated with increased lactate levels or impaired lactate utilisation such as cardiac disease, shock and severe hepatic insufficiency. Hyperlactataemia (i.e., high lactate levels) can develop in patients with severe hepatic insufficiency, since lactate metabolism may be impaired. In addition, **Compound Sodium Lactate (Hartmanns)** infusion solution may not produce its alkalinising action in patients with severe hepatic insufficiency, since lactate metabolism may be impaired. Lactate-containing solutions should be administered with particular caution to neonates and infants less than 6 months of age (see also Paediatric use).

Use in patients with Type 2 diabetes

Lactate is a substrate for gluconeogenesis. This should be taken into account when **Compound Sodium Lactate (Hartmanns)** infusion solution is used in patients with Type 2 diabetes.

Use in patient with or at risk for hypercalcaemia

Solutions containing calcium salts, including **Compound Sodium Lactate (Hartmanns)** infusion solution, should be used with caution in patients with:

- hypercalcaemia, or conditions predisposing to hypercalcaemia such as severe renal impairment and granulomatous diseases associated with increased calcitriol synthesis including sarcoidosis
- calcium renal calculi or a history of such calculi.

Use in the elderly

Clinical studies of **Compound Sodium Lactate (Hartmanns)** infusion solution did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

Paediatric population

Safety and effectiveness of **Compound Sodium Lactate (Hartmanns)** infusion solution in paediatric patients have not been established by adequate and well controlled trials; however, the use of electrolyte solutions in the paediatric population is referenced in the medical literature. Lactate-containing solutions should be administered with particular caution to neonates and infants < 6 months of age. The precautions and adverse reactions identified for infants, children and adults should be observed in the paediatric population.

Effects on laboratory tests
The effect of this medicine on laboratory tests has not been established.

4.5 Interaction with other medicines and other forms of interaction

Compound Sodium Lactate (Hartmanns) infusion solution should not be administered simultaneously with blood preparations (e.g. citrate anticoagulated/preserved blood) through the same administration set, because of a possibility or the likelihood of coagulation.

Concomitant administration with ceftriaxone is not recommended through the same infusion line (see sections 4.3 and 4.4) due to the risk of fatal ceftriaxone-calcium salt precipitation.

Caution is advised when administering **Compound Sodium Lactate (Hartmanns)** infusion solution to patients treated with drugs leading to an increased vasopressin effect. The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and may increase the risk of hyponatraemia following treatment with intravenous fluids (see sections 4.4 and 4.8 .

- Drugs stimulating vasopressin release such as chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors (SSRIs), 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, opioids.
- Drugs potentiating vasopressin action such as chlorpropamide, non-steroidal anti-inflammatories (NSAIDS), cyclophosphamide.
- Vasopressin analogues such as desmopressin, oxytocin, vasopressin, terlipressin.

Caution is advised when administering **Compound Sodium Lactate (Hartmanns)** infusion solution to patients treated with drugs that may increase the risk of hyponatraemia, such as diuretics and antiepileptics (e.g., oxcarbazepine).

Administration of calcium may increase the effects of digitalis and lead to serious or fatal cardiac arrhythmias. Therefore, larger volumes or faster infusion rates should be used with caution in patients treated with digitalis glycosides.

Caution is advised when administering **Compound Sodium Lactate (Hartmanns)** infusion solution to patients treated with thiazide diuretics or vitamin D as these can increase the risk of hypercalcaemia.

Caution is advised when administering **Compound Sodium Lactate (Hartmanns)** infusion solution to patients treated with medicines that may increase the risk of sodium and fluid retention such as carbenoxolone and corticosteroids (see section 4.4).

Caution is advised when administering **Compound Sodium Lactate (Hartmanns)** infusion solution to patients treated with drugs for which renal elimination is pH dependent. Due to the alkalinising action of lactate (formation of bicarbonate), **Compound Sodium Lactate (Hartmanns)** infusion solution may interfere with the elimination of such drugs:

- Renal clearance of acidic medicines such as salicylates, barbiturates and lithium may be increased.
- Renal clearance of alkaline medicines such as sympathomimetics (e.g. pseudoephedrine), dexamphetamine sulphate and fenfluramine hydrochloride may be decreased.

Compound Sodium Lactate (Hartmanns) infusion solution contains approximately 5 mmol/L potassium and caution is advised when administering **Compound Sodium Lactate (Hartmanns)** to patients treated with drugs that can cause hyperkalaemia or increase the risk of hyperkalaemia, such as potassium sparing diuretics (amiloride, spironolactone, triamterene), angiotensin converting enzyme (ACE) inhibitors, angiotensin II receptor antagonists (ARAs), the immunosuppressants

tacrolimus and cyclosporin, or potassium supplement preparations. Simultaneous administration of these drugs can result in severe and potentially fatal hyperkalaemia, particularly in patients with severe renal insufficiency (see section 6.2).

4.6 Fertility, pregnancy and lactation

Fertility

No data available.

Pregnancy (Category C)

There are no adequate data from the use of **Compound Sodium Lactate (Hartmanns)** infusion solution in pregnant women. The potential risks and benefits for each specific patient should be carefully considered before using **Compound Sodium Lactate (Hartmanns)** infusion solution in pregnant women.

Breast-feeding

There are no adequate data from the use of **Compound Sodium Lactate (Hartmanns)** infusion solution in lactating women. The potential risks and benefits for each specific patient should be carefully considered before using **Compound Sodium Lactate (Hartmanns)** infusion solution in lactating women.

4.7 Effects on ability to drive and use machines

The effects of **Compound Sodium Lactate (Hartmanns)** infusion solution on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 Undesirable effects

Allergic reactions or anaphylactic/anaphylactoid symptoms such as localised or generalised urticaria, skin rash & erythema and itching/pruritus; skin swelling, periobital facial and/or laryngeal oedema (Quincke's oedema); chest tightness, chest pain, with tachycardia or bradycardia; nasal congestion, coughing, sneezing, bronchospasm and/or difficulty breathing have been reported during administration of **Compound Sodium Lactate (Hartmanns)** infusion.

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

Post-marketing Adverse Reactions

The following adverse reactions have been reported in the post-marketing experience:

IMMUNE SYSTEM DISORDERS: Hypersensitivity/infusion reactions, including Anaphylactic/Anaphylactoid reactions and the following manifestations:
Angioedema, chest pain, chest discomfort, decreased heart rate, tachycardia, blood pressure decreased, respiratory distress, bronchospasm, dyspnoea, cough, urticaria, rash, pruritus, erythema, flushing, throat irritation, paraesthesia's, hypoesthesia oral, dysgeusia, nausea, anxiety, pyrexia, headache.

METABOLISM AND NUTRITION DISORDERS: Hyperkalaemia.

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS: Infusion site reactions, including phlebitis, infusion site inflammation, infusion site swelling, infusion site rash, infusion site pruritus, infusion site erythema, infusion site pain, infusion site burning.

Class Reactions
Other adverse reactions reported with similar products are:
- hyponatraemia
- hyponatraemic encephalopathy
- infusion site anaesthesia (numbness) (reported with Lactated Ringer's and 5% Dextrose Injection).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://pophealth.my.site.com/carmreportnz/s/

4.9 Overdose
There is no overdose experience with **Compound Sodium Lactate (Hartmanns)** infusion solution. No specific antidotes to this preparation are known. Should overdose occur, treat the symptoms and institute appropriate supportive measures as required. The effects of an overdose may require immediate medical attention and treatment.

An excessive volume or too high a rate of administration may lead to fluid and sodium overload with a risk of oedema (peripheral and/or pulmonary), particularly when renal sodium excretion is impaired. Excessive administration of lactate may lead to metabolic alkalosis, which may be accompanied by hypokalaemia. Excessive administration of potassium may lead to the development of hyperkalaemia, especially in patients with severe renal impairment. Excessive administration of calcium salts may lead to hypercalcaemia.

When assessing an overdose, any additives in the solution must also be considered.

For risk assessment and advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800764 766).

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group
Electrolytes.

ATC code
B05BB01.

Mechanism of action
A Multiple electrolyte intravenous solution is intended for restoring the electrolyte balance and water for hydration. A combination of multiple electrolyte and sodium lactate alkalinising agent, will provide electrolyte balance and normalise the pH of the acid-base balance of the physiological system.

Sodium is the major cation of extracellular fluid and functions principally in the control of water distribution, fluid and electrolyte balance and osmotic pressure of body fluids. Chloride, the major extracellular anion, closely follows the physiological disposition of sodium cation in maintenance of acid-base balance, isotonicity and electrodynamic characteristic of the cells.

In contrast to sodium ion, potassium is a major cation of the intracellular fluid (160mEq/litre of intracellular water) and functions principally in the control of body fluid composition and electrolyte

balance. Potassium participates in carbohydrate utilisation, protein synthesis, and is critical in the regulation of nerve conduction and muscle contraction, particularly in the heart.

Calcium is essential for maintenance of the functional integrity of nervous, muscular, and skeletal system and cell membrane and capillary permeability. Calcium is the major component of the body skeleton. The calcium content in bone is continuously undergoing a process of resorption and formation. The normal concentration of calcium in plasma is between 2.2 to 2.6mmol per litre.

Sodium lactate is an alkalising agent. Lactate is slowly metabolised to bicarbonate and water. This reaction depends on the cellular oxidative activity. Under normal physiological conditions conversion of sodium lactate to bicarbonate requires about 1 – 2 hours. The bicarbonate metabolite then has similar actions to those of sodium bicarbonate preparations. That is, bicarbonate metabolites react with acid to produce carbon dioxide and water.

Clinical trials
No data available.

Chemical structure
Sodium lactate

Molecular formula: $C_3H_5O_3Na$
Molecular Weight: 112.06
Appearance: clear, colourless, slightly syrupy liquid
Solubility: miscible with water
CAS number: 72-17-3.

Sodium chloride

Molecular formula: NaCl
Molecular Weight: 58.44
Appearance: colourless or white crystal
Solubility: freely soluble in water
CAS number: 7647-14-5.

Calcium chloride dihydrate

Molecular formula: $CaCl_2.2H_2O$
Molecular Weight: 147.01
Appearance: a white crystalline powder
Solubility: hygroscopic, freely soluble in water
CAS number: 10035-04-8.

Potassium chloride

Molecular formula: KCl
Molecular Weight: 74.55
Appearance: colourless or white crystal
Solubility: freely soluble in water
CAS number: 7447-40-7.

5.2 Pharmacokinetic properties
Absorption
As **Compound Sodium Lactate (Hartmanns)** is directly administered to the systemic circulation, the bioavailability (absorption) of the active components is complete (100%).

Excretion
Excess calcium is predominantly excreted by the renal system, as in the case of potassium and sodium excretion.

5.3 Preclinical safety data
Genotoxicity
The active ingredients: sodium chloride, sodium lactate, potassium chloride and calcium chloride are not mutagenic.

Carcinogenicity
The active ingredients, potassium chloride, sodium chloride, calcium chloride and sodium lactate are not carcinogenic.

6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
The only excipient in this solution is Water for Injection, q.s. to 1000mL.

No antimicrobial agent or buffer is included.

6.2 Incompatibilities
Additives may be incompatible. Those additives known to be incompatible should not be used (see also sections 4.2 and 4.4).

Ceftriaxone must not be mixed with calcium-containing solutions including **Compound Sodium Lactate (Hartmanns)** infusion solution (see sections 4.3 and 4.4).

6.3 Shelf life
Bag, plastic 500mL 18 months from date of manufacture.
Bag, plastic 1000mL 24 months from date of manufacture.

The expiry date can be found on the packaging.

6.4 Special precautions for storage
Store at or below 30°C. Do not freeze.

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat.

6.5 Nature and contents of container
Compound Sodium Lactate (Hartmanns) infusion solution is supplied in Viaflex plastic bags in the following pack sizes:

Code	Size (mL)
AHB2323 **Compound Sodium Lactate (Hartmanns)** infusion solution	500
AHB2324 **Compound Sodium Lactate (Hartmanns)** infusion solution	1000
Note: Not all pack sizes may be marketed.	

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Directions for use of Viaflex plastic container
Do not use plastic containers in series connections. Such use could result in embolism due to residual air being drawn from the primary container before administration of the fluid from the

secondary container is completed. Pressurising intravenous solutions contained in flexible plastic containers to increase flow rate can also result in air embolism if the residual air in the container is not fully evacuated prior to administration. Use of vented intravenous administration sets with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

To open
Tear over wrap down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilisation 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 inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for administration
Compound Sodium Lactate (Hartmanns) infusion solutions are sterile preparations. Thus, aseptic technique must be applied throughout the administration.
1. Suspend container from eyelet support.
2. Remove plastic protector from outlet port at the bottom of container.
3. Attach administration set.

To add medication
WARNING: Additives may be incompatible.

To add medication before solution administration:
Prepare medication site. Using syringe with 19 to 22-gauge needle, puncture resealable medication port and inject. Mix solution and medication thoroughly. For high-density medications, such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration:
Close clamp on the set. Prepare medication site. Using syringe with 19 to 22-gauge needle, puncture resealable medication port and inject. Remove container from IV pole and/or turn to upright position. Evaluate both ports by squeezing them while container is in the upright position. Mix solution and medication thoroughly. Return container to in use position and continue administration.

7 MEDICINE SCHEDULE
General Sale Medicine.

8 SPONSOR
Compound Sodium Lactate (Hartmanns) infusion solution is distributed in New Zealand by:

Baxter Healthcare Ltd
33 Vestey Drive
Mt Wellington
Auckland 1060

Baxter Healthcare Ltd
PO Box 14 062
Panmure
Auckland 1741

Phone (09) 574 2400.

9 DATE OF FIRST APPROVAL
Date of publication in the New Zealand Gazette of consent to distribute the medicine:
22 August 1974.

10 DATE OF REVISION OF THE TEXT

1 December 2025.

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
4.8	Reporting suspected adverse reactions url updated.
4.9	Contact for overdose updated.
6.3	Shelf-life updates.
8	Sponsor details section updated.

Based on Australian PI approved 20 May 2019; and CCSI 41320180621.

Please refer to the Medsafe website (www.medsafe.govt.nz) for most recent data sheet.