AUSTRALIAN PRODUCT INFORMATION - COMPOUND SODIUM LACTATE (HARTMANN'S) AND MODIFIED HARTMANN'S SOLUTION FOR INTRAVENOUS INFUSION

1 NAME OF THE MEDICINE

Sodium chloride, sodium lactate, potassium chloride and calcium chloride dihydrate.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Table 1: Hartmann's and Modified Hartmann's IV Infusions

Product*	**Potassium Chloride**	**Sodium Chloride**	**Sodium Lactate**	**Calcium Chloride Dihydrate**	**Osmolarity$^{\alpha}$ mOsmol/L** [Osmolality, mOsmol/kg]
Modified Hartmann's Solution					
Potassium Chloride 0.22%, Sodium Chloride 0.6%, Sodium Lactate 0.322% and Calcium Chloride Dihydrate 0.027% IV Infusion 1000 mL (**AHB2954**)	29.5 mmol/L	102.5 mmol/L	28.75 mmol/L	1.84 mmol/L	329 [304]
Hartmann's Solution					
Potassium Chloride 0.04%, Sodium Chloride 0.6%, Sodium Lactate 0.322% and Calcium Chloride Dihydrate 0.027% IV Infusion 500 mL (**AHB2323**)	2.7 mmol/ 500 mL	51.35 mmol/ 500 mL	14.36 mmol/ 500 mL	0.92 mmol/ 500 mL	280 [254]
Potassium Chloride 0.04%, Sodium Chloride 0.6%, Sodium Lactate 0.322% and Calcium Chloride Dihydrate 0.027% IV Infusion 1000 mL (**AHB2324**)	5.4 mmol/L	102.7 mmol/L	28.72 mmol/L	1.84 mmol/L	280 [254]

Osmolarity$^{\alpha}$ is a calculated figure; whilst the figures in the brackets are Osmolality [mOsmol/kg].

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Solution for intravenous infusion. Hartmann's and Modified Hartmann's Intravenous (IV) Infusion preparations are clear, colourless sterile, non-pyrogenic solutions with pH of 5.0 – 7.0. No antimicrobial agent or buffer is included.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Hartmann's and Modified Hartmann's IV Infusions are indicated as a source of water and electrolytes. They are 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. These solutions are indicated as methods of intravenous drug delivery, if the drugs are compatible with the solutions.

4.2 DOSE AND METHOD OF ADMINISTRATION

To be used as directed by the physician. The dosage of Hartmann's or Modified Hartmann's IV Infusion 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 Hartmann's or Modified Hartmann's IV Infusion 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 Hartmann's or Modified Hartmann's IV Infusion 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 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 below. Do not store solutions containing additives. Do not reconnect any partially used containers.

For Modified Hartmann's IV infusion, slow administration is recommended. The recommended administration rate should not exceed 20 mmol/hour and not exceed 80 mmol for a 24 hour period (= 6 g potassium chloride/24hr).

Direction 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: Hartmann's and Modified Hartmann's IV Infusions 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.

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 medication 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.

4.3 CONTRAINDICATIONS

Hartmann's and Modified Hartmann's IV Infusions are 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 Hartmann's / Modified Hartmann's IV Infusion is contraindicated in neonates (≤ 28 days of age), even if separate infusion lines are used due to risk of fatal ceftriaxone-calcium salt precipitation in the neonate's bloodstream. In patients older than 28 days (including children and adults), ceftriaxone must not be administered simultaneously with IV calcium-containing solutions, including Hartmann's / Modified Hartmann's IV Infusion, through the same infusion line (e.g. via Y-connector).

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Hartmann's and Modified Hartmann's IV Infusions are not for use in the treatment of lactic acidosis, severe metabolic acidosis. Although Hartmann's IV Infusion 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. Modified Hartmann's IV Infusion contains approximately 30 mmol/L potassium and is not for use in patients with hyperkalaemia.

The safety of the VIAFLEX plastic container used in Hartmann's and Modified Hartmann's IV Infusions has been confirmed in tests in animals according to the USP biological tests for plastic container, 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 Dose and method of administration).

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.

Hartmann's IV Infusion is isotonic (254 mOsmol/kg). The addition of potassium chloride (0.18%) to the Hartmann's solution does not result in a hypertonic solution (304 mOsmol/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 Hartmann's or Modified Hartmann's IV 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 Hartmann's or Modified Hartmann's IV Infusion 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

Hartmann's or Modified Hartmann's IV Infusion 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

Hartmann's or Modified Hartmann's IV 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 Hartmann's or Modified Hartmann's IV 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.

Hartmann's and Modified Hartmann's IV Infusions should be used with caution in patients receiving corticosteroids or corticotropin, (i.e. potential sodium retention).

Use in patients with or at risk of alkalosis

Hartmann's or Modified Hartmann's IV Infusion 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 Hartmann's or Modified Hartmann's IV Infusion 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

Hartmann's or Modified Hartmann's IV Infusion 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, Hartmann's or Modified Hartmann's IV Infusion 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 Hartmann's or Modified Hartmann's IV Infusion is used in patients with Type 2 diabetics.

Use in patient with or at risk for hypercalcaemia

Solutions containing calcium salts, including Hartmann's / Modified Hartmann's IV Infusion, 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 Hartmann's and Modified Hartmann's IV Infusions 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 use

Safety and effectiveness of Hartmann's and Modified Hartmann's IV Infusions 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 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Hartmann's or Modified Hartmann's IV Infusion should not be administered simultaneously with blood preparations (e.g. citrate anticoagulated/ preserved blood) through the same administration set, because of a possibility of the likelihood of coagulation.

Concomitant administration with ceftriaxone is not recommended through the same infusion line (see Section 4.3 Contraindications and Section 4.4 Special warnings and precautions for use) due to the risk of fatal ceftriaxone-calcium salt precipitation.

Caution is advised when administering Hartmann's or Modified Hartmann's IV Infusion 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 Section 4.4 Special warnings and precautions for use and Section 4.8 Adverse effects).

- 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 Hartmann's or Modified Hartmann's IV Infusion 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 Hartmann's or Modified Hartmann's IV Infusion to patients treated with thiazide diuretics or vitamin D as these can increase the risk of hypercalcaemia.

Caution is advised when administering Hartmann's or Modified Hartmann's IV Infusion to patients treated with medicines that may increase the risk of sodium and fluid retention such as carbenoxolone and corticosteroids (see Section 4.4 Special warnings and precautions for use).

Caution is advised when administering Hartmann's or Modified Hartmann's IV Infusion to patients treated with drugs for which renal elimination is pH dependent. Due to the alkalinising action of lactate (formation of bicarbonate), Hartmann's or Modified Hartmann's IV Infusion may interfere with the elimination of such drugs:

- Renal clearance of acidic drugs 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.

Modified Hartmann's IV Infusion contains approximately 30 mmol/L potassium and should not be administered concomitantly 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. Hartmann's IV Infusion contains approximately 5 mmol/L potassium and caution is advised when administering Hartmann's IV Infusion to patients treated with these drugs. Simultaneous administration of these drugs can result in severe and potentially fatal hyperkalaemia, particularly in patients with severe renal insufficiency.

See also Section 6.2 Incompatabilities.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy (Category C)

There are no adequate data from the use of Hartmann's or Modified Hartmann's IV Infusion in pregnant women. The potential risks and benefits for each specific patient should be carefully considered before using Hartmann's or Modified Hartmann's IV Infusion in pregnant women.

Use in lactation

There are no adequate data from the use of Hartmann's or Modified Hartmann's IV Infusion in lactating women. The potential risks and benefits for each specific patient should be carefully considered before using Hartmann's or Modified Hartmann's IV Infusion in lactating women.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Allergic reactions or anaphylactic/anaphylactoid symptoms such as localized or generalized urticaria, skin rash & erythema and itching/pruritus; skin swelling, periorbital facial and/or laryngeal edema (Quincke's edema); chest tightness, chest pain, with tachycardia or bradycardia; nasal congestion, coughing, sneezing, bronchospasm and/or difficulty breathing have been reported during administration of Hartmann's or Modified Hartmann's IV 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, dyspnea, cough, urticaria, rash, pruritus, erythema, flushing, throat irritation, paresthesias, 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.

Other adverse reactions (Class reactions)

Other adverse reactions reported with similar products include:

- hyponatraemia
- hyponatraemic encephalopathy
- infusion site anaesthesia (numbness) (reported with Lactated Ringer's and 5% Dextrose Injection).

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

There is no overdose experience with Hartmann's or Modified Hartmann's IV Infusion. No specific antidotes to these preparations 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 information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

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 (160 mEq/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 2.6 mmol 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.

5.2 PHARMACOKINETIC PROPERTIES

Aborption

As Hartmann's or Modified Hartmann's IV Infusion is directly administered to the systemic circulation, the bioavailability (absorption) of the active components is complete (100%).

Excretion

Excess calcium is predominantly excreted by 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

Water for Injections

6.2 INCOMPATIBILITIES

Additives may be incompatible. Those additives known to be incompatible should not be used (see Section 4.2 Dose and method of administration).

Ceftriaxone must not be mixed with calcium-containing solutions including Hartmann's or Modified Hartmann's IV Infusion (see Section 4.3 Contraindications and Section 4.4 Special warnings and precautions for use).

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store 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

Hartmann's and Modified Hartmann's IV Infusions are supplied in VIAFLEX plastic bags as a 500 mL and 100 mL single unit dose and are available in the following pack sizes:

- Baxter 0.22% Potassium Chloride and Hartmann's Solution l000 mL bag (AHB2954), ARTG 19468
- Baxter Compound Sodium Lactate (Hartmann's Solution) 500 mL bag (AHB2323), ARTG 19425

- Baxter Compound Sodium Lactate (Hartmann's Solution) l000 mL bag (AHB2324), ARTG 48510

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

Any unused product or waste material should be disposed of in accordance with local requirements

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure

Sodium lactate

Molecular formula: $C_3H_5O_3Na$
Molecular Weight: 112.06
Appearance: clear, colourless, slightly syrupy liquid
Solubility: miscible with water

Sodium chloride

Molecular formula: NaCl
Molecular Weight: 58.44
Appearance: colourless or white crystal
Solubility: freely soluble in water

Calcium chloride dihydrate

Molecular formula: $CaCl_2.2H_2O$
Molecular Weight: 147.01
Appearance: a white crystalline powder
Solubility: hygroscopic, freely soluble in water

Potassium chloride

Molecular formula: KCl
Molecular Weight: 74.55
Appearance: colourless or white crystal
Solubility: freely soluble in water

CAS number

Sodium lactate
- 72-17-3

Sodium chloride
- 7647-14-5

Calcium chloride dihydrate
- 10035-04-8

Potassium chloride
- 7447-40-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Not scheduled

8 SPONSOR

Baxter Healthcare Pty Ltd
1 Baxter Drive
OLD TOONGABBIE, NSW 2146
AUSTRALIA

9 DATE OF FIRST APPROVAL

30 September 1991

10 DATE OF REVISION

20 May 2019

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
ALL	Reformatting to the latest TGA approved form
3, 4.2, 4.3, 4.4, 4.5, 6.5	Minor editorial changes
4.2, 4.4, 4.5, 4.8, 6.2	Safety related changes