1 COMPOUND SODIUM LACTATE (HARTMANN'S SOLUTION) & 5% GLUCOSE (solution for infusion)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose infusion solution preparation in Water for Injection	
Name of the active components	Quantity (g/L)
Sodium Chloride	6
Sodium Lactate	3.22
Potassium Chloride	0.4
Calcium Chloride Dihydrate	0.27
Glucose	50

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion (intravenous).

Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose infusion solutions are clear liquid, sterile, non-pyrogenic solutions. They are *hypertonic* intravenous solutions (osmolality of 563mOsmol/kg) with pH of 4.0 – 6.5.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose IV 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. 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, rate and duration of administration of **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** infusion solution is to be individualised and depend upon the indication for use, the patient's age, weight, concomitant treatments and clinical condition, as well as laboratory determinations and response.

The infusion rate should not exceed the patient's ability to utilise glucose in order to avoid hyperglycaemia. The infusion rate of intravenous solutions containing glucose should be selected with caution in children (see Section 4.4/*Paediatric use).*

Parenteral medicinal products should be inspected visually for particulate matter and discolouration prior to administration whenever solution and container permit. Sterile and nonpyrogenic equipment must be used for intravenous administration. Do not administer unless the solution is clear and the seal is intact.

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. 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 (Hartmann's Solution) and 5% Glucose** infusion solution is appropriate. After addition, check for a possible colour change and/or the appearance of precipitates, insoluble complexes or crystals.

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 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 below. Solutions containing additives should be used immediately, and not stored. Do not reconnect any partially used containers.

The product should be used for one patient on one occasion only. Any unused portion should be discarded.

Direction for use of Viaflex plastic container
Do not remove unit from over-wrap until ready for use. The inner bag maintains the sterility of the product.

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 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 (Hartmann's Solution) and 5% Glucose infusion solution is a sterile preparation. Thus, aseptic technique must be applied throughout 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
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.

4.3 Contraindications

Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose infusion solution is contraindicated in patients with:

- known hypersensitivity to sodium lactate, or corn/corn products (because corn-starch is used as raw material for glucose production);
- 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 (Hartmann's Solution) and 5% Glucose** infusion solution is contraindicated in newborns (≤ 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 adults), ceftriaxone must not be administered simultaneously with intravenous calcium-containing solutions, including **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** infusion solution, through the same infusion line (e.g. *via* Y-connector).

4.4 Special warnings and precautions for use

Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose infusion solution is not for use in the treatment of lactic acidosis, severe metabolic acidosis or treatment of severe potassium deficiency. Although the solutions have potassium concentrations similar to that of plasma, it is insufficient to produce a useful effect in severe potassium deficiency.

The safety of the Viaflex plastic container used in **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** 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 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.

Due to the risk of coagulation precipitated by its calcium content, **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** infusion solution must not be added to or administered simultaneously through the same tubing with citrate anticoagulated/preserved blood (see section 4.5).

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.

Osmolality
Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose infusion solution is a hypertonic solution (563mOsmol/kg). It is important to bear in mind that an administration of substantially hypertonic solution may cause venous irritation, including phlebitis and may lead to a wide variety of complications, such as crenation (shrinkage) of red blood cells and general cellular dehydration. Hyperosmolar solutions should be administered with caution, if at all, to patients with hyperosmolar states.

Use in patients with renal impairment
In patients with diminished renal function, administration of **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** infusion solution 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.

Use in patients with or at risk of hyperkalaemia
Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose 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 intravenous potassium can rapidly result in severe hyperkalaemia without symptoms, which may lead to fatal adverse reactions.

Use in patients with hypervolaemia or overhydration, or conditions that cause sodium retention and oedema
Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose infusion solution 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 (Hartmann's Solution) and 5% Glucose** infusion solution 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.

Sodium Lactate (Hartmann's Solution) and 5% Glucose infusion solution should be used with caution in patients receiving corticosteroids or corticotropin, i.e. potential sodium retention.

Fluid/solute overload and electrolyte disturbances
Depending on the volume and rate of infusion, intravenous administration of **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** 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 therapy or whenever the condition of the patient or the rate of administration warrants such evaluation.

Use in patients with or at risk of alkalosis
Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose 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 sodium lactate component in **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** infusion on patients with metabolic or respiratory alkalosis should be monitored closely.

Use in patients with or at risk for increased lactate levels or with impaired lactate utilisation
Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose infusion solution be administered with extreme caution, if at all, in patients with conditions associated with increased lactate levels, impaired lactate utilisation such as cardiac disease, shock and severe hepatic insufficiency or otherwise at risk of alkalosis. 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 (Hartmann's Solution) and 5% Glucose** infusion solution may not produce its alkalinising action in patients with severe hepatic insufficiency, since lactate metabolism may be impaired. Seizure may be precipitated by the alkalosis induced by lactate but this is uncommon.

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 or at risk of hyponatraemia
Glucose intravenous infusions are usually isotonic solutions. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolism. Monitoring of serum sodium is particularly important for hypotonic fluids. **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** infusion solution has an osmolality of 563mOsm/kg (see table in section 6.5).

Depending on the tonicity of the solution, the volume and rate of infusion, and depending on a patient's underlying clinical condition and capability to metabolise glucose, intravenous administration of glucose can cause electrolyte disturbances, most importantly hypo- or hyperosmotic hyponatraemia.

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.

Use in patients with or at risk of hyperglycaemia
Solutions containing glucose should be used with caution in patients with impaired glucose tolerance or diabetes mellitus. Lactate is a substrate for gluconeogenesis so caution should be used with **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** infusion solution in Type 2 diabetics. As **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** infusion solution contains glucose and lactate (which is metabolised to glucose), administration that exceeds the metabolic capacity for glucose may lead to hyperglycaemia.

Hyperglycaemia has been implicated in increasing cerebral ischaemic brain damage and impairing recovery after acute ischaemic strokes. Caution is recommended in using glucose-containing solutions in such patients. Early hyperglycaemia has also been associated with poor outcomes in patients with severe traumatic brain injury. Glucose-containing solutions should therefore be used with caution in patients with head injury, in particular during the first 24 hours following the trauma.

If hyperglycaemia occurs, the rate of glucose administration should be reduced and/or insulin administered, or the insulin dose adjusted.

Newborns, especially those born premature and with low birth weight, are at increased risk of developing hypo- or hyperglycaemia and therefore need close monitoring during treatment with intravenous glucose solutions to ensure adequate glycaemic control in order to avoid potential lolong-termdverse effects (see also Paediatric Use below).

Use in patients with or at risk of hypercalcaemia
Solutions containing calcium salts (including **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** infusion solution) should be used with caution in patients with:

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

Geriatric use
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 medicinal therapy.

Paediatric use
Safety and effectiveness of **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** 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. Plasma electrolyte concentrations should be closely monitored in the paediatric population.

Lactate-containing solutions should be administered with particular caution to neonates and infants < 6 months of age.

The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient and concomitant therapy, and should be determined by the consulting physician experienced in paediatric intravenous fluid therapy.

Newborns, especially those born premature and with low birth weight, are at increased risk of developing hypo- or hyperglycaemia and therefore need close monitoring during treatment with intravenous glucose solutions to ensure adequate glycaemic control in order to avoid potential long-term adverse effects. Hypoglycaemia in the newborn can cause prolonged seizures, coma and brain damage. Hyperglycaemia has been associated with intraventricular haemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotising enterocolitis, bronchopulmonary dysplasia, prolonged length of hospital stay, and death.

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 (Hartmann's Solution) and 5% Glucose 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 of the likelihood of coagulation.

Use of intravenous infusions containing glucose may necessitate review of a patient's oral hypoglycaemic or insulin requirements. Close monitoring of serum glucose may be required.

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.

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 (Hartmann's Solution) and 5% Glucose** infusion solution to patients treated with:

- thiazide diuretics or vitamin D as these can increase the risk of hypercalcaemia.
- medicines that may increase the risk of sodium and fluid retention such as carbenoloxone and corticosteroids
- medicines for which renal elimination is pH dependent. Due to the alkalinising action of lactate (formation of bicarbonate), **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** infusion solution may interfere with the elimination of such medicines.
    - 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 (Hartmann's Solution) and 5% Glucose infusion solution should not be administered concomitantly with medication 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) or the immunosuppressants tacrolimus and cyclosporin, or potassium supplement preparations. Simultaneous administration of these medicines can result in severe and potentially fatal hyperkalaemia, particularly in patients with severe renal insufficiency.

Caution is advised when administering **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** infusion solution to patients treated with medicines leading to an increased vasopressin effect. The below listed medications 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).

- Medicines stimulating vasopressin release such as chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors (SSRIs), 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, opioids.
- Medicines 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 (Hartmann's Solution) and 5% Glucose** infusion solution to patients treated with medicines that may increase the risk of hyponatraemia, such as diuretics and antiepileptics (e.g., oxcarbazepine). 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 (Hartmann's Solution) and 5% Glucose** infusion solution in pregnant women. The potential risks and benefits for each specific patient should be carefully considered before using **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** infusion solution in pregnant women.

Breast-feeding

There are no adequate data from the use of **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** infusion solution in lactating women. The potential risks and benefits for each specific patient should be carefully considered before using **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** infusion solution in lactating women.

4.7 Effects on ability to drive and use machines

There is no information on the effects of **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** infusion solution on the ability to operate an automobile or other heavy machinery.

4.8 Undesirable effects

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, bronchospasm, dyspnoea, cough, urticaria, rash, pruritus, erythema, nausea, pyrexia.

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS: Infusion site reactions, including infusion site pruritus, infusion site erythema and infusion site anaesthesia (numbness).

OTHER REACTIONS: Other adverse reactions reported with Lactated Ringer's Injection (without glucose) and Sodium Lactate Injection are:

- other manifestations of hypersensitivity/infusion reactions: decreased heart rate, tachycardia, blood pressure decreased, respiratory distress, flushing, throat irritation, paresthesias, hypoesthesia oral, dysgeusia, anxiety, headache
- hyperkalaemia
- Other infusion site reactions: phlebitis, infusion site inflammation, infusion site swelling, infusion site rash, infusion site pain, infusion site burning.

Other adverse reactions reported with other similar products are:

- hyponatraemia
- hyponatraemic encephalopathy.

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.

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://nzphvc.otago.ac.nz/reporting/

4.9 Overdose

There is no overdose experience with **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** infusion solution. No specific antidotes to this preparation are known. Should overdose occur, immediate medical attention may be required to treat the symptoms and to institute appropriate supportive measures. 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. Excessive administration of glucose may lead to hyperglycaemia, hyperosmolarity, osmotic diuresis, and dehydration.

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

For advice on the management of overdose please contact the National Poisons Centre on phone number: 0800 764 766 [0800 POISON] in New Zealand (or 131126 in Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group

Electrolytes with Carbohydrates.

ATC code

B05BB02.

Mechanism of action

A multiple electrolyte intravenous and glucose solution is intended for restoring the electrolyte balance as well as providing energy 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.

Glucose is readily metabolised into carbon dioxide and water, with a release of energy. As such, an administration of a glucose solution either by oral or parenteral route provides water for body hydration as well as calories. In addition, it may reduce catabolic loss of nitrogen from the body and aids in prevention of depletion of liver glycogen. That is, in the absence of glucose, amino acids undergo deamination. It is followed by oxidation, with a release of energy.

Physicochemical properties

Sodium chloride

Molecular formula	NaCl
Molecular Weight	58.44
CAS number	7647-14-5
Appearance	Colourless or white crystal
Solubility	Freely soluble in water

Sodium lactate

Molecular formula	$C_3H_5NaO_3$
Molecular Weight	112.06
CAS number	867-56-1
Appearance	clear, colourless, slightly syrupy liquid
Solubility	miscible with water

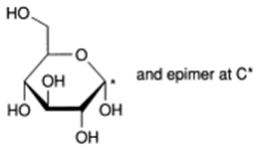
Potassium chloride

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

Calcium chloride dihydrate

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

Glucose (D-(+)glucopyranose)



Molecular formula	$C_6H_{12}O_6$
Molecular Weight	180.2
CAS number	50-99-7
Appearance	a white or almost white, crystalline powder
Solubility	freely soluble in water, sparingly soluble in ethanol (96%)

Clinical trials

No data available.

5.2 Pharmacokinetic properties

As **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** infusion solution is directly administered to the systemic circulation, the bioavailability (absorption) of the active components is complete (100%). 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, potassium chloride, sodium chloride, calcium chloride, sodium lactate and glucose are not mutagenic.

Carcinogenicity

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections, 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 sections 4.2 and 4.5.

Ceftriaxone must not be mixed with calcium-containing solutions including **Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose** infusion solution (see sections 4.3 and 4.4).

6.3 Shelf life

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

6.5 Nature and contents of container

Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose infusion solution is supplied in Viaflex plastic containers as a single unit dose.

Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose IV infusion solution				
Code no.	Name of the active components [Concentrations (%, mmol/1000mL)]	Osmolality (mOsm/kg)	TT50-	Pack size (mL)
AHB2074	Sodium Chloride (0.6%, 102) Sodium Lactate (0.322%, 28.7) Potassium Chloride (0.04%, 5.4) Calcium Chloride dehydrate (0.027%, 2) Glucose (5%, 278)	563	5534	1000

6.6 Special precautions for disposal and other handling

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

7 MEDICINE SCHEDULE

General Sale Medicine.

8 SPONSOR

Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose 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.

Compound Sodium Lactate (Hartmann's Solution) and 5% Glucose infusion solution is distributed in Australia by:

Baxter Healthcare Pty Ltd
1 Baxter Drive
Old Toongabbie, NSW 2146.

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

23 September 2019.

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
All	Document formatting consistent with other data sheets in the Baxter portfolio.
2	Excipient information moved to 6.1. Physiochemical properties moved to 5.1.
4.2	Warning relating to additives included. Warning relating to vented administration sets expanded.
4.4, 4.5, 4.8, 4.9, 6.2	Warnings and precautions information relocated or updated.
5.1	Physiochemical properties tabulated and condensed

Based on Australian PI most recent amendment 8 August 2019; and CCSI 414 2018 0724.

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