

## PRODUCT INFORMATION

### NAME OF THE MEDICINE

Compound Sodium Lactate (Hartmann's)  
Solution for Injection

### DESCRIPTION

Molecular formulae. Potassium chloride: KCl; sodium chloride: NaCl; calcium chloride dihydrate: CaCl<sub>2</sub>; sodium S- lactate (chemical name, sodium 2-hydroxypropionate): C<sub>3</sub>H<sub>5</sub>O<sub>3</sub>Na.

Sterile solution intended for intravenous use containing Sodium Lactate (3.17 g/L), Sodium Chloride (6.0 g/L), Potassium Chloride (400 mg/L) and Calcium Chloride Dihydrate (270 mg/L). Sodium Hydroxide and Hydrochloric acid is added for pH adjustment. The total amount of electrolytes per litre are: sodium 131 mmol, potassium 5 mmol, chloride 112 mmol, calcium 2 mmol, bicarbonate (as lactate) 28 mmol. The osmolality is approximately 255 mOsm/kg water. The solutions are isotonic, sterile, non-pyrogenic and do not contain antimicrobial agent or added buffers. The pH range is 5.0 to 7.0. Compound Sodium Lactate (Hartmann's) Solution for Injection is also known as Ringer-Lactate.

### ACTIONS

#### PHARMACOLOGY

A multiple electrolyte intravenous solution is intended for restoring the electrolyte balance and water for hydration. A combination of multiple electrolytes and sodium lactate, an 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 physiologic disposition of the sodium cation in maintenance of the acid-base balance, isotonicity and electrodynamic characteristic of the cells.

In contrast to the sodium ion, potassium is a major cation of the intracellular fluid (160 mEq/L 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 the nervous, muscular, and skeletal systems 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 and 2.6 mmol/L.

Sodium lactate is an alkalinising 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 one to two 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.

### Pharmacokinetics

As Compound Sodium Lactate (Hartmann's) is directly administered to the systemic circulation, the bioavailability (absorption) of the active components is complete (100%). Excess of calcium is predominantly excreted by the renal system, as in the case of potassium and sodium excretion.

### **INDICATIONS**

Compound Sodium Lactate (Hartmann's) is used:

- for intravenous fluid and electrolyte replacement
- as a source of bicarbonate in the treatment of mild to moderate metabolic acidosis associated with dehydration or associated with potassium deficiency
- as a vehicle for intravenous drug delivery, if the drugs are compatible with the solutions.

### **CONTRAINDICATIONS**

Congestive heart failure or severe impairment of renal function.

Clinical states in which the administration of sodium and chloride is detrimental.

Compound Sodium Lactate (Hartmann's) is not for use in the treatment of lactic acidosis.

### **Warnings**

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

Compound Sodium Lactate (Hartmann's) is isotonic.

In patients with diminished renal function, administration of Compound Sodium Lactate (Hartmann's) may result in sodium retention. Prolonged therapy should be monitored for changes in fluid balance, electrolyte concentration and acid/base balance. In patients with potassium excretion impairment, administration of IV potassium can rapidly result in severe hyperkalaemia without symptoms, which may lead to fatal adverse reactions.

Compound Sodium Lactate (Hartmann's) should not be administered simultaneously with blood preparations through the same administration set, because of a possibility of coagulation.

Do not administer Compound Sodium Lactate (Hartmann's) unless the solution is clear and the seals are intact.

### Impaired renal function

See Warnings above.

## **PRECAUTIONS**

### General

The intravenous administration of Compound Sodium Lactate (Hartmann's) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary oedema. 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.

The effect of the sodium lactate component in Compound Sodium Lactate (Hartmann's) on patients with metabolic or respiratory alkalosis should be monitored closely. Compound Sodium Lactate (Hartmann's) should be administered with extreme caution in patients with severe hepatic insufficiency, shock and congestive heart failure.

Compound Sodium Lactate (Hartmann's) should be used with caution in patients receiving corticosteroids or corticotropin, i.e. potential sodium retention. Similarly with a patient receiving a potassium supplement preparation, as it may result in hyperkalaemia.

### Impaired hepatic function:

See Precautions, above

### Use in the elderly:

Clinical studies of Compound Sodium Lactate (Hartmann's) 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.

### Carcinogenesis, mutagenesis, impairment of fertility:

The active ingredients, potassium chloride, sodium chloride, calcium chloride and sodium lactate, are neither carcinogenic nor mutagenic at physiological concentrations.

### Use in pregnancy (Category C):

Animal reproduction studies have not been conducted with the Compound Sodium Lactate (Hartmann's). It is also not known whether this product can cause foetal harm when administered to a pregnant woman or can affect reproductive capacity. These products should only be given to pregnant women if the benefit outweighs the risk.

### Use in lactation:

Safety in lactation has not been established. These products should only be given to breastfeeding women if the benefit outweighs the risk.

### Use in children:

Safety and effectiveness of Compound Sodium Lactate (Hartmann's) 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. The warnings, precautions and adverse reactions identified in the label copy should be observed in the paediatric population.

## **INTERACTIONS**

Compound Sodium Lactate (Hartmann's) should not be administered simultaneously with blood preparations through the same administration set, because of a possibility of coagulation. These products should not be administered concomitantly with potassium sparing diuretics and angiotensin converting enzyme (ACE) inhibitors. Simultaneous administration of these drugs can result in severe hyperkalaemia.

## **ADVERSE REACTIONS**

Allergic reactions or anaphylactic/anaphylactoid symptoms such as localised or generalised urticaria, skin rash and erythema and itching/pruritus; skin swelling, periorbital, 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 Hartmann's Solution.

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 and evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

## **DOSAGE AND ADMINISTRATION**

To be used as directed by the doctor. The dosage of Compound Sodium Lactate (Hartmann's) is dependent upon the age, weight and clinical conditions of the patient as well as laboratory determinations. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

Contains no antimicrobials. For use in one patient on one occasion only. Discard any unused portion. Care should be taken with intravenous administration technique to avoid administration site reactions and infection.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with

Pharmacist, if available. If, in the informed judgment of the doctor, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

### **OVERDOSAGE**

Symptoms of overdosage with intravenous solutions are related to disturbed electrolyte levels and fluid imbalance. Symptoms indicative of overdose include shortness of breath, peripheral oedema, nausea, vomiting and diarrhoea, abdominal cramps, weakness, paraesthesia, paralysis, mental confusion, tachycardia and other cardiac abnormalities.

Overdose requires immediate clinical assessment, cessation or slowing of intravenous fluids, laboratory assessment of electrolyte levels, calculation of fluid balance, ECG monitoring and commencement of appropriate supportive treatment.

### **PRESENTATION AND STORAGE CONDITIONS**

Compound Sodium Lactate (Hartmann's) Solution for Injection in Freeflex bags;

#### FREEFLEX

250mL AUST R 148935

500mL AUST R: 29771

1000mL AUST R: 47410

**Store below 25°C**

### **NAME AND ADDRESS OF THE SPONSOR**

Fresenius Kabi Australia Pty Limited

964 Pacific Highway

Pymble NSW 2073

Australia

Tel: (02) 9391 5555

Fresenius Kabi New Zealand Limited

60 Pavilion Drive

Airport Oaks, Auckland, 2022

New Zealand

Freecall: 0800 144 892

### **POISON SCHEDULE OF THE MEDICINE**

Australia: Nil

New Zealand: General Sales Medicine

**Date of Approval:** 10th May 2006

**Date of Most Recent Amendment:** 06 July 2010