



95/12627475/1019

Directions for use

Read carefully!



B. Braun Compound Sodium Lactate Intravenous Infusion B.P.

(Hartmann's Solution)

Full electrolyte solution for replacement of extracellular fluid

Composition

Each 100 ml contains:

Sodium Chloride	0.600 g
Potassium Chloride	0.040 g
Calcium Chloride · 2H ₂ O	0.027 g
Sodium Lactate	0.312 g
Water for Injections to	100 ml
Electrolytes:	mmol/l
Na ⁺	131
K ⁺	5
Ca ⁺⁺	2
Cl ⁻	111
Bicarbonate ⁻ (as lactate ⁻)	29
Osmolarity:	278 mOsm/l

Characteristics

B. Braun Compound Sodium Lactate Intravenous Infusion B.P. has a similar electrolyte composition as the extracellular fluid. The lactate ion is gradually metabolised and converted to bicarbonate in a concentration also resembling that of extracellular fluid. Additionally the lactate ion exerts a slightly alkalinising effect.

Mechanisms of action

Sodium Chloride is the principal salt involved in maintaining the osmotic tension of the blood and tissue. Changes in sodium and chloride levels change this osmotic tension and hence influence the movement of fluids and diffusion of salts in cellular tissue.

Sodium Lactate after absorption, is metabolised in 1 to 2 hours to bicarbonate, it then behaves as endogenous bicarbonate, exerting an alkalinizing effect. In the absence of bicarbonate deficiency, it is excreted by the kidney; urine becomes less acidic with accompanying diuresis.

Potassium Chloride provides potassium ions to the body. Potassium is the principle cation of intracellular fluid and is intimately involved in cell function and metabolism. It is essential for carbohydrate metabolism, glycogen storage and for protein synthesis. Like Sodium it is integral in maintaining transmembrane potential and profoundly affects muscle, including the myocardium.

Similarly, Calcium Chloride provides calcium ions. Calcium is involved in the maintenance of normal muscle and nerve function, normal cardiac function as well as normal blood clotting.

Indications

Replacement of extracellular fluid loss (isotonic dehydration)
Salt depletion
Light metabolic acidosis
Electrolyte substitution in burns

Dosage

Average dose: 2000 ml/day
Drop rate : 120 – 180 drops/min corresponding to 360-540 ml/h

Route of administration I.V.

Contraindications

Hypertonic and hypotonic dehydration
Hyperhydration, oedema
Alkalosis
Hyperkalemia, hypernatremia, hyperlactatemia
Renal insufficiency
Hypertension
Lactic acidosis
Severe liver damage

Side effects/Adverse reactions

In the event the body cannot adequately utilize or excrete any particular ion, it may accumulate to give symptoms characteristic of elevated levels of that particular ion.

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Dokument = 148 x 210 mm
2 Seiten

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Lactate Intravenous Infusion B.P.
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Precautions/Warnings

Use with caution in patients with hypertension. Serum electrolytes and water balance should be monitored regularly.

To be administered with extreme caution, if at all, to patients with an increased level or impaired utilization of lactate, such as in patients suffering from shock, congestive heart failure, hypoxia or beri-beri.

The compatibility of any additives to this solution should be checked before use.

Symptoms and treatment for overdose

Since the concentration of ions in this preparation mimics normal plasma levels, it is unlikely to cause ionic imbalance to any great extent. Any such tendency should be readily detected in the routine serum electrolyte monitoring.

However, the development of any of the following symptoms calls for close scrutiny of blood electrolyte levels and appropriate management:

- Nausea, vomiting, diarrhoea, constipation, anorexia
- Abdominal pain, abdominal cramps
- Listlessness, weakness (general or muscular)
- Restlessness
- Thirst, dry mouth, swollen tongue, polyuria
- Pyrexia
- Paralysis
- Bone pain
- Dizziness, drowsiness, confusion
- Cardiac complications

Usage during pregnancy

No adverse reaction has been reported.

Shelf life

The product must not be used beyond the expiry date stated on the label.

Storage

The product should not be stored above the temperature stated on the label.

Presentation

500 ml, 1000 ml plastic container

Method of administration

In the special case of rapid infusion under external pressure which may be necessary in emergency situations, before starting the infusion, all air must be removed from containers with air space inside, as otherwise there is a risk of producing air embolism during the infusion.

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Product registration
holder and
manufactured by:
**B. Braun Medical
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Penang, Malaysia.

