Lavoisier Ringer Lactate, solution for infusion

Qualitative and quantitative composition

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Chloride</td>
<td>0.60000 g</td>
</tr>
<tr>
<td>Potassium Chloride</td>
<td>0.04000 g</td>
</tr>
<tr>
<td>Calcium Chloride</td>
<td>0.02684 g</td>
</tr>
<tr>
<td>Sodium Lactate solution at 50 percent</td>
<td>0.62000 g</td>
</tr>
</tbody>
</table>

(corresponding quantity of sodium lactate: 0.31000 g)

Water for injectable preparations: 100 ml

Na⁺ .............................................. 130 mmol/l
K⁺ ................................................. 5.4 mmol/l
Ca²⁺ .............................................. 1.8 mmol/l
Cl⁻ ................................................ 111 mmol/l
Lactates ..................................... 27.7 mmol/l
Osmolarity .................................. 276.8 mOsm/l
pH ranging from 6.0 to 7.5

Pharmaceutical form
Solution for infusion

Therapeutic indications
- Dehydration predominantly extracellular regardless the cause (vomiting, diarrhea, fistula, etc.).
- Hypovolemia whatever the cause: hemorrhagic shocks, burns, periopeative electrolyte losses.
- Metabolic acidosis except lactic acidosis.

Posology and administration

Posology:
The physician will determine the posology according to patient’s clinical state, age, weight and results of laboratory determinations.

Administration route
This solution is administered in slow intravenous infusion, with strict asepsis.

Contra-indications
- Congestive cardiac insufficiency.
- Hyperhydration predominantly extracellular.
- Hyperkalaemia, hypercalcemia.
- Metabolic alkalosis.
- In association with digitalis and hyperkalemiant diuretics (see Interactions with other drugs other forms of interactions).

This drug is contraindicated for use in patients with:

Contraindicated interactions:
- Digitalis: severe, even life-threatening arrhythmias.

Association requiring extreme caution:
- Thiazidic diuretics: risk of hypercalcemia due to decreased calcium excretion in urine.

Warnings and precautions for use

Warnings
This solution should not be given by I.M. route.
- Complications may occur due to the volume of the solution and amount of electrolyte administered.
- Risk of overload on the cardiovascular system with pulmonary oedema especially among predisposed subjects.
- Infusion of Ringer Lactate solution may lead to metabolic alkalosis because of the presence of lactate ions.
- In patients with hepatic insufficiency, Lactated Ringer’s solution may not produce its alkalizing action, lactate metabolism being likely to change.
- In concomitant blood transfusion and because of the presence of calcium, Ringer Lactate solution should not be administered in the same intravenous set because of the risk of coagulation (Refer to section Pharmacodynamics and Pharmacokinetics.

Precautions for use
Use of this solution requires patient’s clinical monitoring and laboratory determinations especially in case of:
- Severe renal failure
- Oedemas with sodium retention
- Treatment by corticosteroids and their derivatives.
Since this solution is content-potassium, kalaemia should be closely monitored in patients who may develop hyperkalaemia, for example those with chronic renal impairment.

Safety and handling of bottles
- Prior to use, inspect for limpidity and minute cracks on bottle.
- Cleanse stopper.
- Discard any vial after initial puncture of the stopper and any unused portion.

Physico-chemical incompatibilities
The physician will decide of the incompatibilities of an additive drug with Lactated Ringer’s solution, inspecting for possible discoloration and/or formation of precipitate, insoluble complex or crystals. Refer also to package insert of additive drug.
Prior to any drug admixture, check whether its pH efficacy space matches that of Ringer Lactate solution.
When a drug is added to Ringer Lactate solution, admixture must be administered instantly.

Interactions with other drugs and other forms of interactions

Interactions with calcium
Contraindicated interactions:
- Digitalis: severe, even life-threatening arrhythmias.

Association requiring extreme caution:
- Thiazidic diuretics: risk of hypercalcemia due to decreased calcium excretion in urine.
Interactions with potassium

Contraindicated interactions:

♣ Hyperkalemiant diuretics (amiloride, canrenoate of potassium, spironolactone, triamterene (isolated use or combined therapy): Potentially life-threatening hyperkalaemia, especially in patients with renal insufficiency (additive potassium-sparing effects).

Unsuitable interactions

♣ Angiotensin converting enzyme (ACE) inhibitors: potentially life-threatening hyperkalaemia, especially among patients with renal insufficiency (additive effects of potassium-sparing diuretics).

♣ Tacrolimus: potentially life-threatening hyperkalaemia, especially in patients with renal insufficiency (additive potassium-sparing effects).

ADVERSE REACTION

Interactions with lactates

♣ Risk of metabolic alkalosis, if supplementation in excess or change in lactates metabolism.

CLINICAL PHARMACOLOGY

Pharmacodynamics

BALANCED ELECTROLYTE SOLUTIONS (B: hematopoietic stem cells blood and lymphoid organs)

- Crystalloidal isotonic solution for vascular filling and electrolyte rebalance, with ionic compounds very similar to extracellular liquid.
- Extracellular dehydration and/or volemic deficiency rebalance is associated with hemodilution.
- Pharmacological properties are those of its constituents (sodium, potassium, calcium and chlorides).
- Lactate ion is a buffer anion, precursor of bicarbonate, thus involved in the regulation of acid-basic balance. This transformation may be modified in patients with hepatocellular insufficiency.
- Lactate ions supplementation in excess may result in metabolic alkalosis.
- In lactate metabolism block (lactic acidosis of B type), lactate supplementation leads to accumulation of this anion in blood.
- The improvement of circulation, and thus of hepatic perfusion, helps restore a normal lactate metabolism and corrects the process of an hypovolemic shock (associated with lactic acidosis of A type)

Pharmacokinetics

This solution diffuses out in extracellular space, thus enhancing the volume accordingly.
Lactate ion is rapidly metabolized in liver, converted there to pyruvate, which is utilized in Krebs's cycle in the production of bicarbonate.

PHARMACEUTICAL DATA

Incompatibilities

- Inspect for possible discoloration and/or formation of precipitate, insoluble complex or crystals.
- Prior to drug admixture, check whether its pH efficacy space matches that of Ringer Lactate solution.