

LAVOISIER RINGER LACTATE, solution for infusion

QUALITATIVE AND QUANTITATIVE COMPOSITION

SODIUM CHLORIDE	0.60000 g
POTASSIUM CHLORIDE	0.04000 g
CALCIUM CHLORIDE	0.02684 g
SODIUM LACTATE SOLUTION AT 50 PERCENT	0.62000 g
(corresponding quantity of sodium lactate.....)	0.31000 g)
Water for injectable preparations	s.q..... 100 ml
Na ⁺	130 mmol/l
K ⁺	5.4 mmol/l
Ca ²⁺	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
 - . perioperative 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

This drug is contraindicated for use in patients with:

- congestive cardiac insufficiency.
- Hyperehydration 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 not recommended for use in association with (see Interactions with other drugs and other forms of interactions):

- Angiotensin converting enzyme (ACE) inhibitors
- Tacrolimus.

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 limpity 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:

- ◆ **Hyperkalemiatic 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)

- Crystalloid 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.

Shelf life

5 years

Storage special precautions

Not applicable.

Nature and contents of container

250 ml, 500 ml or 1000 ml bottle, colorless glass (type II), rubber stoppered with a chlorobutyl seal.

PACKAGING AND PRODUCT LICENSE NUMBER

Pharmacy Packaging:

MA 321 622-6: 250 ml bottle (glass) - 1 unit pack - Not reimbursed by French Health Care Security Approved for institutions

MA 320 586-6: 500 ml bottle (glass) - 1 unit pack - Not reimbursed by French Health Care Security Approved for institutions

MA 321 623-2: 1000 ml bottle (glass) - 1 unit pack - Not reimbursed by French Health Care Security Approved for institutions

Hospital Packaging:

MA 553 557-9: 250 ml bottle (glass) - 12 units pack - Approved for institutions

MA 553 556-2: 500 ml bottle (glass) - 12 units pack - Approved for institutions

MA 553 555-6: 1000 ml bottle (glass) - 6 units pack - Approved for institutions

HOW SUPPLIED

Not applicable.

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CDM LAVOISIER

Laboratoires Chaix et Du Marais - 7, rue Labie - 75017 PARIS - FRANCE

Tel: +33 1 55 37 83 83

E-mail: contact@lavoisier.com

Fax: +33 1 55 37 83 84