

LAVOISIER RINGER, solution for infusion

QUALITATIVE AND QUANTITATIVE COMPOSITION

SODIUM CHLORIDE	0.80000 g
POTASSIUM CHLORIDE	0.02000 g
CALCIUM CHLORIDE	0.01342 g
SODIUM BICARBONATE	0.02000 g
GLUCOSE MONOHYDRATE	0.11000 g
(corresponding quantity in anhydrous glucose	0.10000 g)

Water for injectable preparations s.q. ... 100 ml

Sodium	139.1 mmol/l
Potassium	2.7 mmol/l
Calcium	0.9 mmol/l
Bicarbonates	2.4 mmol/l
Chlorides	141.3 mmol/l
Glucose	5.5 mmol/l
Osmolarity	292 mOsm/l

pH ranging from 6.5 to 7.5

PHARMACEUTICAL FORM

Solution for infusion

THERAPEUTIC INDICATIONS

- States of predominantly extracellular dehydration, regardless of the cause (vomiting, diarrhoea, fistulas...).
- Hypovolemia whatever the cause:
 - . hemorrhagic shock
 - . burns
 - . perioperative electrolyte losses.

POSODOLOGY 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.
- In association with digitalis and hyperkalemiant diuretics
(See section Interactions with other drugs and other forms of interactions).

This drug is not recommended for use in association with:

- (See section on Interactions with other medicaments and other forms of interactions).
- Angiotensin converting enzyme (ACE) inhibitors.
- Tacrolimus.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Warnings

This solution should not be injected by IM 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.
- In concomitant blood transfusion and because of the presence of calcium, Ringer should not be administered in the same intravenous set because of the risk of coagulation (refer to sections Pharmacodynamics and Pharmacokinetics).

PRECAUTIONS FOR USE

Use of this solution requires that patient's clinical state and laboratory tests be monitored as follows:

- 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 bottle 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 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's solution.

When a drug is added to Ringer's 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:**
Decreased calcium excretion in urine.

Interactions with potassium

Contraindicated interactions:

- ◆ **Hyperkalemiat diuretics (amiloride, canrenoate of potassium, spironolactone, triamterene (isolated use or combined therapy):**
Potentially life-threatening hyperkalemia, especially among patients with renal failure (additive potassium-sparing effects).

Unsuitable interactions:

- ◆ **Angiotension converting enzyme (ACE) inhibitors:**
Potentially life-threatening hyperkalemia, especially among patients with renal failure (additive potassium-sparing effects).
- ◆ **Tacrolimus:**
Potentially life-threatening hyperkalemia, especially among patients with renal failure (additive potassium-sparing effects).

CLINICAL PHARMACOLOGY

Pharmacodynamics

BALANCED ELECTROLYTE SOLUTIONS

(B: Hematopoietic stem cells blood and lymphoid organs)

- 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), Ringer's solution is neutral and has a high amount of chloride ions compared to sodium ions, because of the presence of potassium chloride and calcium chloride.

Pharmacokinetics

This solution diffuses out in extracellular space, thus enhancing the volume accordingly.

The metabolism of this solution is similar to the different ions of its composition: sodium, potassium, calcium and chlorides.

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's solution.

Shelf life

5 years

Storage special precautions

Not applicable.

Nature and contents of container

500 ml bottle, colorless glass (type II), closed with a chlorobutyl stopper.

PACKAGING AND PRODUCT LICENSE NUMBER

Pharmacy Packaging:

MA 324 674-7: 500 ml bottle (glass) - 1 unit pack - Not reimbursed by French Health Care Security
- Approved for Institutions

Hospital Packaging:

MA 553 520-8: 500 ml bottle (glass) - 12 units pack - Approved for Institutions

HOW SUPPLIED

Not applicable.

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