

SUMMURY of PRODUCT CHARACTERISTICS

1. **Name of medicinal product:** Ringer`s injection

INN: Sodium chloride, Potassium chloride, Calcium chloride

2. Qualitative and quantitative composition

| | |
|------------------------------------|----------|
| Sodium chloride | - 8,6 g |
| (Eur. Ph., Monograph 0193) | |
| Potassium chloride | - 0,3 g |
| (Eur. Ph., Monograph 0185) | |
| Calcium chloride 6H ₂ O | - 0,49 g |
| (Eur. Ph., Monograph 0707) | |
| Water for injection | - до 1 L |
| (Eur. Ph., Monograph 0169) | |

Description: Clear colorless solution.

3. **Pharmaceutical form:** solution for infusion

4. Clinical particulars

4.1 Indications for use

Dehydration of different genesis, hyponatremia, during and after operations to maintain the volume of plasma, in acute circulatory disorders, accompanied by dehydration.

4.2 Dosage and Administration

Ringer`s injection must be administrated by intravenous at a rate infusion at a rate of 4 - 10 ml / kg / hour (up to 3 liters per day).

The dosage is individual, depending on the deficiency of water and electrolytes.

Prolonged administration of large doses of the drug is preferably to conduct under the control of laboratory tests.

4.3 Contraindications

Hypersensitivity to the drug components, decompensated heart failure, pulmonary edema, brain edema, oliguria, anuria, acidosis, hypervolemia, hyperchloremia,

hypercalcemia, hypernatremia, concomitant therapy with corticosteroids.

With caution - heart failure, hypertension, hepatic or renal dysfunction.

4.4 Special Warning

At a long-term treatment it is necessary to control the plasma electrolytes and water balance.

Due to high levels of chloride ions do not recommend the long-term use of the drug.

4.5 Drug interaction

It is possible the increasing of the sodium retention in the organism at simultaneous use of the following drugs: non-steroidal anti-inflammatory drugs, androgens, anabolic hormones, estrogens, corticotropin, mineralocorticoids, vasodilators or ganglionic blockers.

The simultaneous use with potassium-sparing diuretics, ACE inhibitors and potassium therapy increases the risk of hyperkalemia.

The combination with cardiac glycosides increases the probability of their toxic effects.

4.6 Administration during pregnancy and lactation

According to the indications.

4.7 Side effects

The Introduction in high volumes may cause acidosis. Inadequately high dose may impair water-electrolyte balance, including hypovolemia, hypernatremia, hyperkalemia, hypercalcemia, hyperchloremia.

4.8 Overdose

Severe symptoms of side effects.

5. Pharmacotherapeutical group: rehydratation agent

Code ATC: B05BB01

5.1 Pharmacodynamics

Ringer's solution restores the water-salt and acid-base balance and fills the fluid deficit in the human organism which occurs due to dehydration, accumulation of extracellular fluid in the focus of extensive burns and traumas, during abdominal

operations, peritonitis. The drug increases the alkaline reserve of the blood. Along with this, Ringer's solution improves the rheological properties of blood and tissue perfusion, increasing the effectiveness of blood transfusion actions upon massive blood loss and severe forms of shock.

5.2 Pharmacokinetics

Ringer's solution containing crystalloids of low molecular weight, easily penetrates through the capillary walls and rapidly excreted from the bloodstream into the interstitial space. Thus, Ringer's solution only briefly increases the amount of fluid circulating in the vessel.

During hypovolemia Ringer's solution is used not only to replenish (albeit briefly) the circulating blood volume, but also to compensate the deficit of extracellular fluid in the interstitial space.

5.3 Preclinical Safety Data

One of the first drugs applied for infusion therapy.

6. Pharmaceutical particulars

6.1 List of ingredients: active ingredients: sodium chloride - 8.6 g; potassium chloride - 0.3 g; calcium chloride 6H₂O - 0.49 g; water for injection - up to 1 l.

6.2 Shelf life

2 years. Do not use after expiry date indicated on the packing.

6.3 Storage conditions

Store at room temperature in a place protected from light and out of reach of children.

6.4 Dosage form

Primary packaging.

250 mL, 500 mL and 1000 mL PVC bags.

Secondary packaging.

The drug in a plastic bag from PVC (EP), Packed in a plastic bag.

6.5 Delivery terms

Prescription medicine.

MANUFACTURER



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