

PACKAGE LEAFLET: Information for the patient

RINGER LACTATE

Solution for infusion – (0.135 g + 0.2 g + 3 g + 1.56 g) / 500 ml

(Calcium chloride dihydrate, Potassium chloride, Sodium chloride, Sodium lactate)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Ringer Lactate is and what it is used for
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1. WHAT RINGER LACTATE IS AND WHAT IT IS USED FOR

Ringer Lactate is a pharmaceutical product which contains the active substances calcium chloride dihydrate, sodium chloride, potassium chloride and sodium lactate. These are part of the large group of electrolytes.

Ringer Lactate is used to adjust the acid-base balance of the blood. Electrolytes are taken in order to achieve or maintain a normal osmotic situation in cellular fluids and extracellular ones.

2. BEFORE YOU TAKE RINGER LACTATE

Do not take Ringer Lactate:

- if you are hypersensitive (allergic) to any of the ingredients, since allergic reactions may happen;
- in case of hyperhydration;
- neonates (≤ 28 days), this drug administered concurrently with ceftriaxone, even if separate infusion lines are used, can lead to a fatal risk of precipitation of calcium salts in the neonate's bloodstream;
- in case of concomitant digitalis therapy;
- in case of metabolic alkalosis;
- in case of lactic acidosis.

Take special care with Ringer Lactate

Ask your doctor before taking Ringer Lactate.

The solution of Ringer Lactate should be used with caution, or not at all, in patients with:

- congestive heart failure;
- renal insufficiency;
- hyperkalemia;
- hypercalcemia;
- hyperchloremia;
- hyponatremia;
- hypertension;
- hypervolemia;
- respiratory or metabolic alkalosis;
- ascitic cirrhosis;
- severe metabolic acidosis.

Since it contains sodium salts, it should be used with caution in patients with peripheral or pulmonary edema, impaired pulmonary function, pre-eclampsia, aldosteronism or other conditions associated with sodium retention.

Solutions that contain lactate ions should be used with caution in patients with respiratory or metabolic alkalosis. The administration of lactate ions should be done with caution, especially in cases of hepatic insufficiency, because in these cases there is an increase of the concentration of these ions because of incomplete utilization.

Calcium chloride can be harmful if injected into the body tissues. Therefore, the solution must not be given by injecting it into a muscle (intramuscular injection) and caution must be taken to avoid the extravasation of the solution into the tissues surrounding the vein.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

To minimize the risk of possible incompatibilities that may arise from the mixing of Ringer Lactate with other solutions, the final mixture should be observed carefully before administration and periodically during the use because of the possibility of any turbulence or precipitation.

It is especially important that you be careful because:

- the presence of sodium lactate in Ringer Lactate prevents the precipitation of calcium carbonate because calcium in lactate form is soluble in water;
- drugs containing oxalates, phosphates or carbonates and bicarbonates may cause precipitation when mixed with Ringer Lactate solution for infusion;
- simultaneous administration of Ringer Lactate with ceftriaxone to neonates, even if in separate infusion lines, presents a fatal risk of precipitation of calcium salts with ceftriaxone in the neonate's bloodstream.

Interactions related to the presence of sodium:

- corticosteroids, which are associated with the retention of sodium and water (with edema and hypertension).

Interactions related to the presence of potassium:

- potassium-sparing diuretics (amiloride, spironolactone, triamterene, alone or in association);
- angiotensin converting enzyme inhibitors (ACEi) and angiotensin II receptor antagonists;
- tacrolimus, cyclosporine;

which increase potassium plasma concentration and may lead to potentially fatal hyperkalaemia, notably in case of a renal failure increasing the hyperkalaemic effect.

Interactions related to the presence of calcium:

- digitalis glycosides (digitalis cardiotonics) whose effects are enhanced by the presence of calcium and may lead to serious or fatal cardiac arrhythmia;
- thiazide diuretics or vitamin D.

Interactions related to the presence of lactate (which is metabolized into bicarbonate):

Caution is advised when administering Ringer Lactate to patients treated with drugs for which renal elimination is pH dependent. Due to the alkalinizing action of lactate (formation of bicarbonate), Ringer Lactate may interfere with the elimination of such drugs.

- Renal clearance of acidic drugs such as: salicylates, barbiturates and lithium may be increased because of the alkalisation of urine by the bicarbonate resulting from lactate metabolism.
- Renal clearance of alkaline drugs, such as: sympathomimetics (e.g. ephedrine, pseudoephedrine) and stimulants (e.g. dexamphetamine sulphate, phenfluramine hydrochloride) may be decreased.

Taking Ringer Lactate with food or drinks

It is not affected by the intake of foods and drinks.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before taking this medicine.

Ringer Lactate can be given during pregnancy and breastfeeding, but it should be used with caution due to potential toxicity.

Driving and using machines

This medicine has no influence on the ability to drive and use machines.

3. HOW TO TAKE RINGER LACTATE

Your doctor will inform you about the amount of Ringer Lactate you should take and when to take it. It is important to follow your doctor's instructions strictly.

Ringer Lactate solution for infusion is administered parenterally (intravenous route).

Dosage: 20 - 30 ml / kg weight. For fluid replacement up to 3,000 ml Ringer Lactate solution are administered into the vein.

If you take more Ringer Lactate than you should

This drug will be administered to you at the hospital, therefore there are not many chances that an overdose occurs. However, if you think that you may have taken a higher dose than you should, contact immediately your doctor.

Rare side effects occur from overdoses of Ringer Lactate.

Overdose may lead to: hyperhidration, venous congestion, pulmonary edema and disorders of acid-base balance.

Extended administrations with Ringer Lactate can cause metabolic alkalosis, hypercalcemia, hyperkalemia.

Treatment of overdose: termination of the perfusion, taking diuretics with continuous monitoring of blood electrolytes and acid-basic balance correction.

If you forget to take Ringer Lactate

This drug will be administered to you at the hospital, therefore there are not many chances that a dose will be forgotten. However, a double (or higher) dose should not be taken to make up for the forgotten dose.

If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

During the use of Ringer Lactate hyperchloremia may occur.

The side effects of sodium salts result from electrolytic imbalance that comes from the addition of sodium. This causes the accumulation of extracellular fluid, thus causing pulmonary and peripheral edema. Hyponatremia is commonly accompanied with intracellular water retention. The most serious effect is brain dehydration, which causes somnolence and confusion resulting

in convulsions, coma, respiratory depression and death. Other symptoms include: thirst, reduced salivation and tearing, fever, tachycardia, hypertension or hypotension, weakness, irritability, muscle tremors and rigidity.

Allergic reactions may appear, such as: localized or generalized urticaria, edema of the larynx and facial edema, cough, sneezing and difficulty in breathing. These effects are more common during pregnancy.

Reactions may occur from administration techniques which include: fever, injection site infections, thrombosis or thrombophlebitis, hypervolemia, etc.

5. HOW TO STORE RINGER LACTATE

Keep out of the reach and sight of children!

Do not use Ringer Lactate after the expiry date which is stated on the package!

Store below 25°C!

Store in the original package!

6. FURTHER INFORMATION

What Ringer Lactate solution for infusion contains

The active substances are: calcium chloride dihydrate, potassium chloride, sodium chloride and sodium lactate.

Each 500 ml glass bottle or plastic bag contains: 0.135 g calcium chloride dihydrate, 0.2 g potassium chloride, 3 g sodium chloride and 1.56 g sodium lactate.

The other ingredients are: water for injection.

Contents of the pack

Glass bottles or plastic bags of 500 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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