Compound Sodium Lactate Infusion BP (Ringer Lactate Solution for Injection BP)

Composition: Each 100ml contains: Sodium Lactate 0.320g, Potassium Chloride BP 0.04g, Sodium Chloride BP 0.6g, Calcium Chloride Dihydrate BP 0.027g, Water for Injections BP q.s. in water of 279mOsm/L. Excipients: Lactic acid BP, Sodium Hydroxide BP, Hydrochloric acid BP.

Pharmacological category: A sterile, non-pyrogenic solution which improves in blood volume and electrolyte changes.

Pharmacological action: Compound Sodium Lactate solution (Ringer Lactate solution) is an isotonic solution of electrolytes. The constituents of Ringer lactate and their concentrations are designed to match those of plasma. The Ringer Lactate solution has an osmolality of 291 mOsm/kg and an osmolality of 279mOsm/kg. The Ringer lactate solution is one of its components (sodium, potassium, calcium, chloride, and lactate). The main effect of Ringer lactate is the expansion of the extracellular compartment including both the interstitial fluid and the intravascular fluid. The lactate is metabolized into bicarbonate, primarily in the liver, and produces an alkalizing effect on the plasma. Ringer lactate decreased serum osmolality, increased blood pH, and the time until first urination was shorter than that with normal saline. There are no significant changes in gluconeogenesis, noradrenaline, epinephrine, blood glucose and insulin levels in aortic surgery patients receiving Ringer lactate. When medication is added to Ringer lactate, the overall pharmacodynamics of the solution will depend on the nature of the drug used.

Pharmacokinetics: The pharmacokinetic properties of the Ringer lactate solution are those of the ions its composition includes (sodium, potassium, calcium, and chloride). The infusion of Ringer lactate in normal hemodynamically stable adults does not increase circulating lactate concentrations. The lactate in Ringer lactate solution is metabolized by both oxidation and gluconeogenesis, predominantly in the liver, and bicarbonate is generated by both processes over 1-2 hours. When medication is added to Ringer lactate, the overall pharmacokinetics of the solution will depend on the nature of the drug used.

Therapeutic indications: Source of water and electrolytes. Regulation or maintenance of metabolic acidosis (except lactic acidosis).

Contraindications: The solution is contra-indicated in patients presenting: extracellular hyperhydration or hypervolemia, severe renal insufficiency (with oliguria/anuria), uncompensated cardiac failure, hyperkalemia, hypernatremia, hypercalcemia, hypercholesterolemia, metabolic alkalosis, severe metabolic acidosis, lactic acidosis, severe hepatocellular insufficiency or impaired lactate metabolism, general oedema and ascitic cirrhosis & concomitant digitalis therapy.

Dosage and directions for use: Adults, the Elderly and Children: The dosage depends on the age, weight, clinical and biological (acid-base balance) conditions of the patient, and concomitant therapy. Recommended dosage: The amount of Ringer lactate solution needed to restore normal blood volume is 3 to 5 times the volume of lost blood. The recommended dosage for adults: 500ml to 3 liters / 24h & for babies and children: 20 to 100ml/kg / 24h. Administration rate: The infusion rate is usually 40ml/kg/24h in adults. In pediatric patients the infusion rate is 5ml/kg/h in average but the value varies with age: 6-8ml/kg/h for infants, 4-6ml/kg/h for toddlers, and 2-4ml/kg/h for schoolchildren. In children with burns, the dose on average 3.4ml/kg/100ml/kg per cent burn at 24h post-burn and 6.3ml/kg/100ml/kg per cent burn at 48h. In severely head-injured children the dose is on average 2850ml/m². Infusion rate and total volume can be higher in surgery or in case of need. Note: Infants and toddlers: age ranges from about 28 days to 23 months (a toddler is an infant who can walk) & Children and Schoolchildren: age ranges from about 2 years to 11 years. Administration: The administration is performed by intravenous route using sterile and non-pyrogenic equipment.

Adverse reactions: Very common: Allergic reactions or anaphylactic/anaphylactoid symptoms such as localized or generalized urticaria, skin rash & erythema and itching/pruritus; skin swelling, periorbital facial and/or laryngeal edema (Quincke’s edema). Nasal congestion, coughing, sneezing, bronchospasm and/or difficulty breathing. Common: Chest tightness, chest pain, with tachycardia or bradycardia. Pruritus has been reported to occur in about 10% of patients receiving Ringer lactate. Hyperhydration and heart failure are very common in patient with cardiac disorder or pulmonary oedema. Electrolyte disturbances have been very commonly reported too. Lactate infusions commonly induce feeling of anxiety, and few cases of panic attack have been reported. Seizure may be precipitated by the alkalosis induced by lactate but this is uncommon. Adverse reactions may be associated with the technique of administration including febrile response, infection at the site of injection, local pain or reaction, vein irritation, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia. Adverse reactions may be associated to the medications added to the solution; the nature of the additive will determine the likelihood of any other undesirable effects. In case of undesirable effect(s), the infusion must be discontinued.

Warnings & precautions for use in special populations: This solution should not be given by intramuscular injection. High volume infusion must be used under specific monitoring in patients with cardiac or pulmonary failure. The patient’s clinical status and laboratory parameters (blood and urine electrolytes as well as acid-base balance) must be monitored during use of this solution. The plasma potassium level of the patient must be particularly closely monitored in patients at risk of hyperkalaemia. Solutions containing sodium chloride should be carefully administered to patients with hypertension, heart failure, peripheral or pulmonary edema, impaired renal function, preeclampsia, alosteronism, or other conditions associated with sodium retention. Solutions containing potassium salts should be administered with caution to patients with cardiac disease or conditions predisposing to hyperkalaemia such as renal or adenocortical insufficiency, acute dehydration, or extensive tissue destruction as occurs with severe burns. Although Ringer lactate solution has a potassium concentration similar to the concentration in plasma, it is insufficient to produce a useful effect in case of severe potassium insufficiency and therefore it should not be used for this purpose. Solutions containing calcium salts should be given cautiously to patients with impaired renal function, or disease associated with elevated vitamin D concentrations such as sarcoidosis. They should be avoided in patients with calcium renal calculi, or a history of renal calculi. In case of concomitant blood transfusion and because of the presence of calcium, Ringer lactate solution must not be administered via the same infusion system because of the risk of coagulation. Infusion of Ringer lactate solution may cause metabolic alkalosis because of the presence of lactate ions. Ringer lactate solution may not produce its alkalizing action in patients with liver insufficiency since lactate metabolism may be impaired. The solution containing lactate should be administered with particular care to neonates less than 3 months old. During long term parenteral treatment, a convenient nutrient supply must be given to the patient. Pregnancy & Lactation: Ringer lactate solution for infusion can be used safely during pregnancy and lactation as long as the electrolyte and fluid balance is controlled. It is reminded that calcium crosses the placenta and is distributed into breast milk. When a medication is added, the nature of the drug and its use during pregnancy and lactation has to be considered separately.

Drug interactions & other form of interactions: Interaction related to the presence of sodium: Corticoids/Steroids and carbamoxolone which are associated with the retention of sodium and water (with oedema and hypertension). Interaction related to the presence of potassium: Potassium-sparring diuretics (amiloride, spironolactone, triamterene, alone or in association), angiotensin converting enzyme inhibitors (acei) and, by extrapolation, angiotensin ii receptor antagonists, and tacrolimus, cyclosporine which increase concentration of potassium in the plasma and may lead to potentially fatal hyperkalemia notably in case of a renal failure increasing the hyperkalemia. Interaction related to the presence of calcium: Digitalis glycosides (digitalis cardiotonic) whose effects are enhanced by the presence of calcium and may lead to serious or fatal cardiac arhythmia, thiazide diuretics or vitamin d which can lead to hypercalcaemia when co-administered with calcium, and bisphosphonates, fluoride, some fluoroquinolones and tetracyclines which are less absorbed (lower availability) when administered with calcium. Interaction related to the presence of lactate (which is metabolized into bicarbonate): Acidic drugs such as salicylates, barbiturates and lithium whose renal clearance is increased because of the alkalisation of urine by the bicarbonate resulting from lactate metabolism & alkaline drugs, notably sympathomimetics (e.g. ephedrine, pseudoephedrine) and stimulants (e.g. dexamethasone sulphate, phenfuramide hydrochloride) whose half-life is prolonged (slowest elimination).

Symptoms of overdose & its treatment: Overuse or too fast administration may lead to water and sodium overload with a risk of oedema, particularly when there is a defective renal sodium excretion. In this case extra renal dialysis may be necessary. Excessive administration of potassium may lead to the development of hyperkalemia, especially in patients with renal impairment. Symptoms include paresthesia of the extremities, muscle weakness, paralysis, cardiac arrhythmias, heart block, cardiac arrest, and mental confusion. Excessive administration of calcium salts may lead to hypercalcemia. Symptoms of hypercalcemia may include anorexia, nausea, vomiting, constipation, abdominal pain, muscle weakness, mental disturbances, polydipsia, polyuria, nephrocalcinosis, renal calculi, and, in severe cases, cardiac arrhythmias and coma. Too rapid intravenous injection of calcium salts may also lead to many of the symptoms of hypercalcemia as well as to chalky taste, hot flushes, and peripheral vasodilatation. Mild asymptomatic hypercalcemia will usually resolve on stopping administration of calcium and other contributory drugs such as vitamin D. If hypercalcemia is severe, urgent treatment (such as loop diuretics, hemodialysis, calcitonin, bisphosphonates, trisodium edetate) is required. Excessive administration of sodium lactate may lead to hypokalemia and metabolic alkalosis, especially in patients with impaired renal function. Symptoms may include mood changes, tiredness, shortness of breath, muscle weakness, and irregular heartbeat. Muscle hypertonicity, twitching, and tetany may develop especially in hypocalcemic patients. Treatment of metabolic alkalosis associated with bicarbonate overdose consists mainly of appropriate correction of fluid and electrolyte balance. Replacement of calcium, chloride, and potassium may be of particular importance. When overdose is related to the medications added to the solution infused, the signs and symptoms of over infusion will be related to the nature of the additive being used. In the event of accidental over infusion, treatment should be discontinued and the patient should be observed for the appropriate signs and symptoms related to the drug administered. The relevant symptomatic and supportive measures should be provided as necessary.

Storage condition: Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

Presentation: Pack of 500ml.