


ABACUS PARENTERAL DRUGS LTD.

SUMMARY OF PRODUCT CHARACTERISTICS

DEPARTMENT : QUALITY ASSURANCE		DOCUMENT No.: SPC/QA/004
	TITLE : COMPOUND SODIUM LACTATE INTRAVENOUS INFUSION B.P (RL)	REVISION STATUS: 02
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1. Name of the medicinal product

Compound Sodium Lactate intravenous infusion BP

2. Qualitative and quantitative composition

Each 1ml contains;

- Sodium lactate: 3.2 mg
- Sodium chloride: 6.0 mg
- Potassium chloride: 0.4 mg
- Calcium lactate dihydrate: 0.27 mg

3. Pharmaceutical form

Solution for infusion.

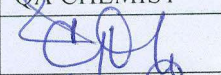
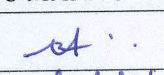


Clear, colourless solution for infusion

4. Clinical particulars


4.1 Therapeutic indications

Compound Sodium Lactate intravenous infusion (Ringer Lactate solution) is used in the following indications:

- ❖ Restoration of extracellular fluid and electrolyte balances or replacement of extracellular fluid loss where isotonic concentrations of electrolytes are sufficient.
- ❖ Short term volume replacement (alone or in association with colloid) in case of hypovolemia or hypotension.
- ❖ Regulation or maintenance of metabolic acidosis balance and/or treatment of mild to moderate metabolic acidosis (except lactic acidosis)
- ❖ As a vehicle for intravenous drug delivery, if the drugs are compatible with the solutions

	PREPARED BY	REVIEWED BY	APPROVED BY	AUTHORISED BY
NAME	RICHARD.A	MARGARET.B	Mr P. K. JOSHI	ZAM.N
DESIGNATION	QA CHEMIST	Q.C MANAGER	QA MANAGER	COMPANY PHARMACIST
SIGNATURE				
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4.2 Posology and method of administration

Adults, the Elderly and Children:

Dosage, rate, and duration of administration are to be individualized and depend upon the indication for use, the patient's age, weight, clinical condition, and concomitant treatment, and on the patient's clinical and laboratory response to treatment.

Recommended dosage:

The amount of Compound Sodium Lactate solution needed to restore normal blood volume is 3 to 5 times the volume of lost blood.

The recommended dosage is:

- For adults : 500 ml to 3Liters /24h
- For infants, toddlers and children : 20 ml to 100 ml / kg / 24 h

Administration rate:

The infusion rate is usually 40 mL/kg/24h in adults.

Use in pediatric patients

The safety and efficacy of Compound Sodium Lactate solution in children has not been established by adequate and well-controlled trials; however, the use of electrolyte solutions in the pediatric population is referenced in the medical literature. Lactate-containing solutions should be administered with particular caution to neonates and infants less than 6 months of age.


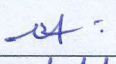


Pediatric infusion rates are 5 ml/kg/h in average but the value varies with age:

- infants: 6-8 mL/kg/h,
- toddlers: 4-6 mL/kg/h
- children: 2-4 mL/kg/h .


In children with burns, the dose is on average 3.4 mL/kg/per cent burn at 24 h post-burn and 6.3 mL/kg/per cent burn at 48 h.

In severely head-injured children the dose is on average 2850 mL/m².

Infusion rate and total volume can be higher in surgery or in case of need.

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Note:

- infants and toddlers: aged from 28 days to 23 months (a toddler is an infant who can walk)
- children: age from 2 to 11 years

Use in geriatric patients

When selecting the type of infusion solution and the volume/rate of infusion for a geriatric patient, consider that geriatric patients are generally more likely to have cardiac, renal, hepatic, and other diseases or concomitant drug therapy.

Method of administration:

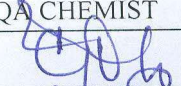
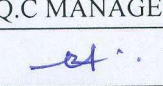

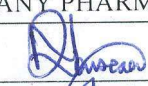
The solution is for intravenous administration through a sterile and non-pyrogenic administration set using aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.

The solution should be inspected visually for particulate matter and discoloration prior to administration. Do not administer unless the solution is clear, free from visible particles and the seal is intact. Do not remove unit from overwrap until ready for use. The inner bag maintains the sterility of the solution. Administer immediately following the insertion of infusion set.

Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container. Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration. Use of a vented intravenous administration set with the vent in the open position could result in air embolism.


Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Additives may be introduced before infusion or during infusion through the injection site.

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When making additions to Compound Sodium Lactate solution, aseptic technique must be used. Mix the solution thoroughly when additives have been introduced. Do not store solutions containing additives.

4.3 Contraindications

As for other calcium-containing infusion solutions, concomitant administration of ceftriaxone and Compound Sodium Lactate solution is contraindicated in newborns (≤ 28 days of age), even if separate infusion lines are used (risk of fatal ceftriaxone-calcium salt precipitation in the neonate's bloodstream).


Compound Sodium Lactate solution is also contraindicated in patients with

- ❖ A known hypersensitivity to sodium lactate.
- ❖ Extracellular hyperhydration or hypervolemia
- ❖ Severe renal insufficiency (with oliguria/anuria)
- ❖ Uncompensated cardiac failure
- ❖ Hyperkalemia
- ❖ Hypercalcaemia
- ❖ Metabolic alkalosis
- ❖ Ascitic cirrhosis
- ❖ Severe metabolic acidosis
- ❖ Conditions associated with increased lactate levels (hyperlactatemia) including lactic acidosis, or impaired lactate utilization, such as severe hepatic insufficiency.
- ❖ Concomitant digitalis therapy

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4.4 Special warnings and precautions for use

Hypersensitivity reactions

The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

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 oedema, impaired renal function, pre-eclampsia, aldosteronism, 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 hyperkalemia such as renal or adrenocortical 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.

Calcium chloride is irritant, therefore care should be taken to prevent extravasation during intravenous injection and intramuscular injection must be avoided. 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.

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Ringer lactate solution may cause metabolic alkalosis because of the presence of lactate ions.
Ringer lactate solution may not produce its alkalinizing 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 nutritive supply must be given to the patient.

4.5 Pregnancy and lactation

Ringer Lactate solution 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 have to be considered separately

4.6 Interaction with Other Medicinal Products And Other Forms Of Interaction

Interaction associated with sodium:



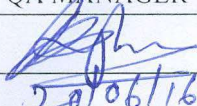
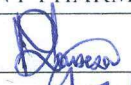
- ❖ Corticoids/Steroids and carbenoxolone which are associated with the retention of sodium and water (with oedema and hypertension).

Interactions associated with calcium:

- ❖ Infusion in association with digitalis cardiac glycosides is contra-indicated because of the risk of severe to fatal cardiac arrhythmia particularly in the case of hypokalaemia
- ❖ Care should be taken in the concurrent use of thiazide diuretics or vitamin D because of the risk of hypercalcaemia resulting from reduced urinary clearance of calcium.
- ❖ Bisphosphonates, fluoride, some fluoroquinolones and tetracyclines which are less absorbed (lower availability) when administered with calcium.


Interactions associated with potassium:

- ❖ Care should be taken in concurrent use of drugs containing potassium and drugs which have the potential for inducing hyperkalaemia, such as potassium-sparing diuretics given alone or

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in combination (such as spironolactone, triamterene, amiloride, potassium canrenoate), ACE inhibitors, angiotensin-II receptor antagonists, tacrolimus and ciclosporin.

Interaction associated with lactate (which is metabolized into bicarbonate):

- ❖ Acidic drugs such as salicylates, barbiturates and lithium whose renal clearance is increased because of the alkalinisation of urine by the bicarbonate resulting from lactate metabolism.
- ❖ Alkaline drugs, notably sympathomimetics (e.g. ephedrine, pseudoephedrine) and stimulants (e.g. dexamphetamine sulphate, phenfluramine hydrochloride) whose halflife is prolonged (slowest elimination).

4.7 Effects on ability to drive and use machines

None

4.8 Side effects

During administration of Compound Sodium Lactate intravenous infusion, the following undesirable effects have been reported as:

➤ very common:

Allergic reactions or anaphylactic/anaphylactoid symptoms such as localized or generalized urticaria, skin rash & erythema and itching/pruritus; skin swelling, periobial facial and/or laryngeal oedema (Quincke's oedema).

Nasal congestion, coughing, sneezing, bronchospasm and/or difficulty breathing

➤ common:

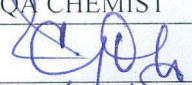



Chest tightness, chest pain, with tachycardia or bradycardia

Pruritus has been reported to occur in about 10% of patients receiving Ringer Lactate.

Hyperhydration and heart failure are very common in patients with cardiac disorder or pulmonary oedema


Electrolytes disturbances have been very commonly reported too.

Lactate infusions commonly induce feelings of anxiety, and a few cases of panic attack have been reported

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DESIGNATION	QA CHEMIST	Q.C MANAGER	QA MANAGER	COMPANY PHARMACIST
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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

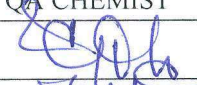
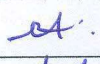

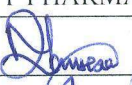
4.9 Overdose

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,

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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 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.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group – Plasma substitutes and infusion solutions / electrolytes

ATC Code: B05BB01

Compound sodium lactate intravenous infusion is an isotonic solution of electrolytes. The constituents of Compound sodium lactate intravenous infusion and their concentrations are designed to match those of plasma.

The pharmacokinetic properties of the solution are those of its constituents (sodium, potassium, calcium and chloride).

The main effect of Compound sodium lactate intravenous infusion is the expansion of the extracellular compartment including both the interstitial fluid and the intravascular fluid.


The lactate is metabolized into bicarbonate, mainly in the liver, and produces an alkalinising effect on the plasma.

In healthy volunteers receiving Compound sodium lactate intravenous infusion, central venous pressure changes were associated with a secretion of atrial natriuretic peptide.

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In healthy volunteers, Compound sodium lactate intravenous infusion decreased serum osmolality, increased blood pH, and the time until first urination was shorter than that with normal saline.

There is no significant change in glucagon, norepinephrine, epinephrine, blood glucose and insulin levels in aortic surgery patients receiving Ringer Lactate.

When medication is added to Compound sodium lactate intravenous infusion, the overall pharmacodynamics of the solution will depend on the nature of the drug used.

5.2 Pharmacokinetic properties

The pharmacokinetic properties of the Compound sodium lactate intravenous infusion are those of the ions its composition includes (sodium, potassium, calcium and chloride).

Infusion of Compound sodium lactate intravenous infusion in normal hemodynamically stable adults does not increase circulating lactate concentrations.

The lactate in Compound sodium lactate intravenous infusion is metabolized by both oxidation and gluconeogenesis, predominantly in the liver, and bicarbonate is generated by both processes over 1-2 h.

When medication is added to Compound sodium lactate intravenous infusion, the overall pharmacokinetics of the solution will depend on the nature of the drug used.

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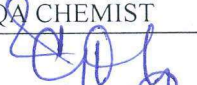
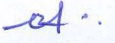

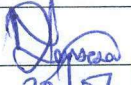
6.1 List of excipients

- Water For Injections BP.

6.2 Incompatibilities

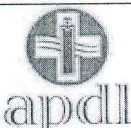
Ceftriaxone must not be mixed with calcium-containing solutions including Compound Sodium Lactate solution.

As with all parenteral solutions additives may be incompatible. Compatibility of the additives with the Compound Sodium Lactate solution and Vial container must be assessed before

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addition. After addition of the additive, incompatibility may become visible by a possible colour change and/or the appearance of precipitates, insoluble complexes or crystals.

The Instructions for Use of the medication to be added and other relevant literature must be consulted.

Before adding a substance or medication, verify that it is soluble and/or stable in water and that the pH range of Compound Sodium Lactate solution is appropriate (pH 5.0 to 7.0).

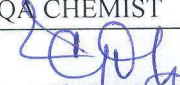



When making additions to Compound Sodium Lactate solution, aseptic technique must be used. Mix the solution thoroughly when additives have been introduced. Do not store solutions containing additives.

As guidance, the following medications are incompatible with the Compound Sodium Lactate solution (*non-exhaustive listing*):

Medications incompatible with Compound Sodium Lactate Solution;


- Aminocaproic acid
- Amphotericin B
- Metaraminol tartrate
- Cefamandole
- Ceftriaxone
- Cortisone acetate
- Diethylstilbestrol
- Etamivan
- Ethyl alcohol
- Phosphate and carbonate solutions
- Oxytetracycline
- Thiopental sodium
- Versenate disodium

Medications with partial incompatibility with Compound Sodium Lactate Solution:

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Tetracycline stable for 12 hours

Ampicillin sodium

concentration of 2%-3% stable for 4 hours

concentration >3% must be given within 1 hour

Minocycline stable for 12 hours

Doxycycline stable for 6 hours Additives known or determined to be incompatible should not be used.

6.3 Shelf life

36 months when unopened

Use immediately on removal from overwrap.

6.4 Special precautions for storage

Do not store above 30⁰C and do not freeze.

6.5 Nature and contents of container

Pack sizes: 500 mL/250mL.

The bottles are made from Low Density Polyethylene plastic; the bottles are then overwrapped with a protective plastic pouch.

6.6 Special precautions for disposal and other handling

For single use only

Solution containing visible solid particles should not be used.


Do not use unless the solution is clear and the container undamaged

Do not connect in series and purge the infusion system to remove all air because of the risk of air embolism.

Discard any unused solution.

Verify the integrity of the container and the site for attachment.

For slow infusion only

	PREPARED BY	REVIEWED BY	APPROVED BY	AUTHORISED BY
NAME	RICHARD.A	MARGARET.B	Mr P. K. JOSHI	ZAM.N
DESIGNATION	QA CHEMIST	Q.C MANAGER	QA MANAGER	COMPANY PHARMACIST
SIGNATURE				
DATE	20/06/16	20/06/16	20/06/16	20/06/16