

## Drug Description

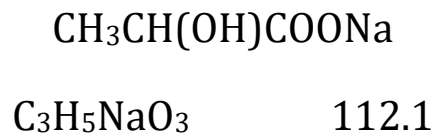
### SODIUM LACTATE

(sodium lactate (sodium lactate injection in aviva) injection in aviva) Injection USP

### DESCRIPTION

Sodium Lactate Injection, USP, 50 mEq (5 mEq/mL) is a sterile, nonpyrogenic, concentrated solution of sodium lactate (sodium lactate injection in aviva) in Water for Injection for additive use only after dilution by intravenous route as an electrolyte replenisher and systemic alkalizer. It should not be administered undiluted.

Sodium lactate (sodium lactate injection in aviva) is chemically designated as propanoic acid, 2-hydroxy-, monosodium salt and has the following structural formula:



A 60% aqueous solution is miscible in water.

Each mL contains: Sodium lactate (sodium lactate injection in aviva) anhydrous 560 mg (5 mEq each of Na<sup>+</sup> and lactate anion); Water for Injection [q.s.](#) Hydrochloric acid and/ or sodium hydroxide for pH adjustment.

The solution contains no bacteriostat, [antimicrobial agent](#) or added buffer. The [osmolar](#) concentration is 10 mOsmol/mL (calc.). When diluted with Sterile Water for Injection to make a 1/6 [molar](#) solution, the pH of sodium lactate (sodium lactate injection in aviva) solution lies between 6.0 and 7.3.

## Indications & Dosage

## INDICATIONS

Sodium Lactate (sodium lactate injection in aviva) Injection, USP is primarily indicated, after dilution, as a source of [bicarbonate](#) for prevention or control of mild to moderate metabolic acidosis in patients with restricted oral intake whose oxidative processes are not seriously impaired. It is not intended nor effective for correcting severe acidotic states which require immediate restoration of plasma bicarbonate levels. Sodium lactate (sodium lactate injection in aviva) has no advantage over [sodium bicarbonate](#) and may be detrimental in the management of [lactic acidosis](#).

## DOSAGE AND ADMINISTRATION

Sodium Lactate (sodium lactate injection in aviva) Injection, 50 mEq (5 mEq/ mL), is administered intravenously only after addition to a larger volume of fluid. The amount of sodium ion and lactate ion to be added to larger volume intravenous fluids should be determined in accordance with the electrolyte requirements of each individual patient.

All or part of the contents of one (50 mEq in 10 mL) or more vial containers may be added to other intravenous solutions to provide any desired number of milliequivalents of lactate anion (with the same number of milliequivalents of Na<sup>+</sup>). The contents of one container (50 mEq in 10 mL) added to 290 mL of a nonelectrolyte solution or of Sterile Water for Injection will provide 300 mL of an approximately isotonic (1/6 molar) concentration of sodium lactate (sodium lactate injection in aviva) (1.9%), containing 167 mEq/L each of Na<sup>+</sup> and lactate anion.

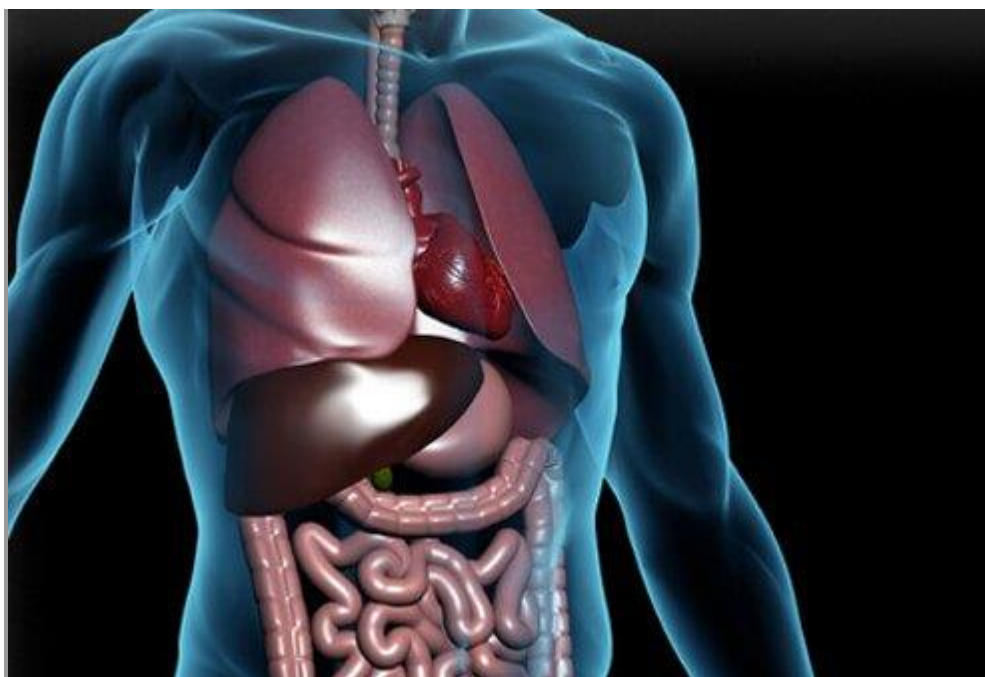
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

## HOW SUPPLIED

Product No.	NDC No.	
7510	63323-375-10	Sodium Lactate Injection, USP, 50 mEq (5 mEq/mL) in mL flip-top single dose vial, in packages of 25.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Abraxis Pharmaceutical Products, Schaumburg, IL 60173. Revised: July 2006. FDA rev date: 8/14/2001



SLIDESHOW

See Slideshow

Side Effects & Drug Interactions

## SIDE EFFECTS

Adverse effects of [sodium](#) lactate are essentially limited to overdosage of either sodium or lactate ions.

See [WARNINGS](#) and [PRECAUTIONS](#).

## DRUG INTERACTIONS

No information provided.

## Warnings

### WARNINGS

WARNING: This product contains [aluminum](#) that may be toxic. Aluminum may reach toxic levels with prolonged [parenteral](#) administration if [kidney](#) function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of [calcium](#) and [phosphate](#) solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with [central nervous system](#) and bone [toxicity](#). Tissue loading may occur at even lower rates of administration.

Solutions containing [sodium](#) ions should be used with great care, if at all, in patients with [congestive heart failure](#), severe [renal](#) insufficiency and in clinical states in which there exists [edema](#) with sodium retention.

In patients with diminished renal function, administration of solutions containing sodium ions may result in sodium retention.

The [intravenous](#) administration of this solution (after appropriate dilution) can cause fluid and/or solute overloading resulting in

dilution of other [serum electrolyte](#) concentrations, overhydration, congested states or [pulmonary edema](#).

Excessive administration of [potassium](#)-free solutions may result in significant [hypokalemia](#).

## Precautions

### PRECAUTIONS

Sodium Lactate (sodium lactate injection in aviva) Injection must be suitably diluted before infusion to avoid a sudden increase in the level of sodium or lactate. Too rapid administration and overdosage should be avoided.

The potentially large loads of sodium given with lactate require that caution be exercised in patients with congestive [heart failure](#) or other edematous or sodium-retaining states, as well as in patients with [oliguria](#) or anuria.

Caution must be exercised in the administration of parenteral fluids especially those containing sodium ions, to patients receiving corticosteroids or corticotropin.

Solutions containing lactate ions should be used with caution as excess administration may result in [metabolic alkalosis](#).

Do not administer unless solution is clear and seal is intact. Discard unused portion.

### Pregnancy Category C

Animal reproduction studies have not been conducted with sodium lactate (sodium lactate injection in aviva) . It is also not known whether sodium lactate (sodium lactate injection in aviva) can cause fetal harm when administered to a pregnant woman or can affect

reproduction capacity. Sodium lactate (sodium lactate injection in aviva) should be given to a pregnant woman only if clearly needed.

## Overdosage & Contraindications

### OVERDOSE

In the event of overdosage, discontinue infusion containing [sodium](#) lactate immediately and institute corrective [therapy](#) as indicated to reduce elevated [serum](#) sodium levels and restore [acid-base balance](#) if necessary. See [WARNINGS](#) and [PRECAUTIONS](#).

### CONTRAINDICATIONS

Sodium Lactate (sodium lactate injection in aviva) Injection is contraindicated in patients suffering from [hypernatremia](#) or fluid retention.

It should not be used in conditions in which lactate levels are increased (e.g., [shock](#), [congestive heart failure](#), [respiratory alkalosis](#)) or in which utilization of lactate is diminished (e.g., [anoxia](#), [beriberi](#)).

NOT FOR USE IN THE TREATMENT OF [LACTIC ACIDOSIS](#).

## Clinical Pharmacology

### CLINICAL PHARMACOLOGY

Lactate [anion](#) ( $\text{CH}_3\text{CH}(\text{OH})\text{COO}^-$ ) serves the important purpose of providing "raw material" for subsequent regeneration of [bicarbonate](#) ( $\text{HCO}_3^-$ ) and thus acts as a source (alternate) of bicarbonate when normal production and utilization of lactic acid is not impaired as a result of disordered lactate [metabolism](#). Lactate anion is usually present in [extracellular](#) fluid at a level of less than 1 mEq/L, but may attain a level of 10 mEq/L during exercise. It is seldom measured as such and thus is one of the "unmeasured

anions" ("anion gap") in determinations of the ionic composition of plasma.

Since metabolic conversion of lactate to bicarbonate is dependent on the integrity of cellular oxidative processes, lactate may be inadequate or ineffective as a source of bicarbonate in patients suffering from acidosis associated with shock or other disorders involving reduced perfusion of body tissues. When oxidative activity is intact, one to two hours time is required for conversion of lactate to bicarbonate.

The lactate anion is in equilibrium with pyruvate and has an alkalizing effect resulting from simultaneous removal by the liver of lactate and hydrogen ions. In the liver, lactate is metabolized to glycogen which is ultimately converted to carbon dioxide and water by oxidative metabolism.

The sodium ( $\text{Na}^+$ ) ion combines with bicarbonate ion produced from carbon dioxide of the body and thus retains bicarbonate to combat metabolic acidosis (bicarbonate deficiency). The normal plasma level of lactate ranges from 0.9 to 1.9 mEq/L.

Sodium is the principal cation of extracellular fluid. It comprises more than 90% of total cations at its normal plasma concentration of approximately 140 mEq/L. The sodium ion exerts a primary role in controlling total body water and its distribution.