# *Baxter*

## Sodium Lactate Injection, USP (M/6 Sodium Lactate)
### in AVIVA Plastic Container

**Description**
Sodium Lactate Injection, USP (M/6 Sodium Lactate) is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. It contains no antimicrobial agents. The pH may have been adjusted with lactic acid. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

**Table 1**

| | Size (mL) | Composition (g/L) | *Osmolarity (mOsmol/L) (calc) | pH | Ionic Concentration (mEq/L) | | Caloric Content (kcal/L) |
|---|---|---|---|---|---|---|---|
| | | Sodium Lactate ($C_3H_5NaO_3$) | | | Sodium | Lactate | |
| Sodium Lactate Injection, USP (M/6 Sodium Lactate) | 500 | 18.7 | 334 | 6.5 (6.0 to 7.3) | 167 | 167 | 54 |
| | 1000 | | | | | | |

*Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.
Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication

(See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

**Clinical Pharmacology**
Sodium Lactate Injection, USP has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Sodium Lactate Injection, USP produces a metabolic alkalinizing effect. Lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

**Indications and Usage**
Sodium Lactate Injection, USP is indicated as a source of water, electrolytes, and calories or as an alkalinizing agent.

**Contraindications**
None known

**Warnings**
Sodium Lactate Injection, USP 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.

Sodium Lactate Injection, USP should be used with great care in patients with metabolic or respiratory alkalosis. The administration of lactate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

The intravenous administration of these injections can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

Excessive administration of Sodium Lactate Injection, USP may result in significant hypokalemia.

In patients with diminished renal function, administration of Sodium Lactate Injection, USP may result in sodium retention.

Sodium Lactate Injection, USP is not for use in the treatment of lactic acidosis.

**Precautions**
**General**

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

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.

**Laboratory Tests**

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

**Drug Interactions**

Caution must be exercised in the administration of Sodium Lactate Injection, USP (M/6 Sodium Lactate) to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Sodium Lactate Injection, USP (M/6 Sodium Lactate).

**Carcinogenesis, mutagenesis, impairment of fertility**

Studies with Sodium Lactate Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

**Pregnancy: Teratogenic Effects**

Pregnancy Category C. Animal reproduction studies have not been conducted with Sodium Lactate Injection, USP. It is also not known whether Sodium Lactate Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Lactate Injection, USP should be given to a pregnant woman only if clearly needed.

**Labor and Delivery**

Studies have not been conducted to evaluate the effects of Sodium Lactate Injection, USP (M/6 Sodium Lactate) on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

**Nursing Mothers**

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Sodium Lactate Injection, USP is administered to a nursing mother.

**Pediatric Use**
Safety and effectiveness of Sodium Lactate Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of sodium lactate solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

**Geriatric Use**
Clinical studies of Sodium Lactate Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

**Adverse Reactions**
Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

**Dosage and Administration**
As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Use of a final filter is recommended during administration of all parenteral solutions, where possible. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

**How Supplied**
Sodium Lactate Injection, USP (M/6 Sodium Lactate) in AVIVA plastic container is available as follows:

| Code | Size (mL) | NDC |
|---|---|---|
| 6E1803 | 500 | 0338-6311-03 |
| 6E1804 | 1000 | 0338-6311-04 |

EXPOSURE OF PHARMACEUTICAL PRODUCTS TO HEAT SHOULD BE MINIMIZED. AVOID EXCESSIVE HEAT. IT IS RECOMMENDED THE PRODUCT BE STORED AT ROOM TEMPERATURE (25°C); BRIEF EXPOSURE UP TO 40°C DOES NOT ADVERSELY AFFECT THE PRODUCT.

**Directions for Use of AVIVA Plastic Container**
**To Open**
Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

**Preparation for Administration**
**Caution:** Do not use plastic containers in series connections.
**Caution:** Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

**To Add Medication**
Additives may be incompatible.

**To add medication before solution administration**
1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

**To add medication during solution administration**
1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.

5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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Printed in USA

* Bar Code Position Only
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Rev. August 2005