ALFA LABORATORIES S.A.L.

Electrolyte 67 Injection USP

Description:

Electrolyte 67 Injection USP is a sterile, non-pyrogenic aqueous hypertonic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration.

Each 100 mL of Electrolyte #67 Injection USP contains:

Dextrose Monohydrate USP	5.0g
Calcium Gluconate USP	0.1 g
Sodium Chloride USP	0.3 g
Potassium Chloride USP	0.075 g
Water For Injection USP	Q.S.

pH: (4.0–6.5)
Osmolarity: 382 mOsmol/liter

Note: Normal physiologic range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions may cause vein damage.

Clinical Pharmacology:

Electrolyte 67 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.

Calcium Gluconate is used to prevent and to treat calcium deficiencies. Calcium is a mineral that is found naturally in foods. Calcium is necessary for many normal functions of your body, especially bone formation and maintenance. Calcium can also bind to other minerals (such as phosphate) and aid in their removal from the body.

Sodium Chloride is used to treat or prevent sodium loss caused by dehydration, excessive sweating, or other causes. Ions of sodium and chlorine are the major inorganic components of the extracellular fluid, maintaining an appropriate osmotic pressure of blood plasma and extracellular fluid.

Potassium Chloride is used to prevent or to treat low blood levels of potassium (hypokalemia) which may produce weakness, fatigue, disturbances of cardiac rhythm, prominent U-waves in the electrocardiogram, and, in advanced cases, flaccid paralysis and/or impaired ability to concentrate urine).

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Indications and Usage:

Electrolyte 67 Injection USP is indicated as a source of water and electrolytes.

Electrolyte 67 Injection USP is contraindicated in the following conditions:

- Patients with hypersensitive to any ingredient in the formulation or component of the container.
- Concomitant administration of ceftriaxone in newborns (≤ 28 days of age), even if separate infusion lines are used due to risk of fatal ceftriaxone-calcium salt precipitation in the neonate's bloodstream.
- Simultaneous administration of ceftriaxone through the same infusion line (e.g., via Y-port/Y-site) in patients older than 28 days of age. If the same infusion line is used for sequential administration, the line must be thoroughly flushed between infusions with a compatible fluid.

Dosage and Administration:

This solution is for intravenous use only.

Dosage is to be directed by a physician and is dependent upon age, weight, clinical condition of the patient. Frequent laboratory determinations and clinical evaluation are essential to monitor changes in blood glucose and electrolyte concentrations, and fluid and electrolyte balance during prolonged parenteral therapy.

Storage Conditions:

Store in moisture barrier overwrap below 25°C until ready to use.

Packaging and Volumes:

DESCRIPTION			CODE		SHELF LIFE	PACKAGING (Bags)
ELECTROLYTE 67	VIAFLEX BAG	500 mL	20	469-27	2 YEARS	24