INDICATIONS AND USAGE

CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections are indicated as a caloric component in a parenteral nutrition regimen and as the protein (nitrogen) source for offsetting nitrogen loss or for the treatment of negative nitrogen balance in patients where

(1) the alimentary tract cannot or should not be used,
(2) gastrointestinal absorption of protein is impaired, or
(3) metabolic requirements for protein are substantially increased, as with extensive burns.

Please see inside fold for Indications and Important risk information.
Please see accompanying Package Inserts for Full Prescribing Information.
Electrolyte profile is consistent with A.S.P.E.N. guidelines
Can be used to treat most parenteral nutrition patients
May reduce risk of medication errors related to compounding
Available in 1 and 2-liter volumes
Central and peripheral formulations
Terminally sterilized, nonpyrogenic, hypertonic solution manufactured in a CLARITY dual-chamber container
- Non-DEHP/Non-PVC
- Non-latex
Extended shelf life
- 2 years room temperature (inactivated and in overwrap)
- 9 days under refrigeration (activated, no additives)
Multiple ports provide flexibility to include additives such as IV fat emulsion, vitamins or trace elements
- Additives may be incompatible; consult with pharmacist, if available

**Good Manufacturing Practices (cGMP) Process**

- Regulations enforced by the FDA that assures products are manufactured according to requirements.¹
  The cGMPs are in place to prevent:
  - Sub-potency or super-potency
  - Contamination
  - Unpredictable safety or efficacy
  - Misbranding

---

¹ http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing.ucm169105.htm
² Tinumalai Rand Porter DAPR. 2005, Vol B.
Electrolyte errors can be a significant problem

According to an A.S.P.E.N. survey, parenteral nutrition related practices can be inconsistent and lead to error.\(^3\) Contributing to some of these inconsistencies are the different conventions used to order electrolytes.

**Considerations for Electrolyte Management**\(^6,7\)

- Electrolytes are tightly regulated by the kidneys
- Electrolyte levels can fluctuate over time
- Micromanaging electrolyte intake may not be necessary in most patients with normal renal function
- Interventions should be made based on trends over time for mild to moderate imbalances
- **It is essential that** a carefully prepared protocol based on current medical practices be followed, preferably by an experienced team. Frequent clinical evaluation and laboratory determinations are necessary for proper monitoring during administration

---

A.S.P.E.N. suggests managing short-term electrolyte abnormalities with parenteral nutrition is inappropriate.
- Managing additional electrolyte needs outside of the parenteral nutrition bag is recommended.

### Nutrient

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>A.S.P.E.N. Daily Electrolyte Guidelines for Adult Parenteral Nutrition*</th>
<th>CLINIMIX E Injections 2 Liter Bag Contains</th>
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<tr>
<td>Calcium</td>
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<td>Magnesium</td>
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<tr>
<td>Potassium</td>
<td>1–2 mEq/kg</td>
<td>60 mEq</td>
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</tbody>
</table>

* Individual dosing needs vary.

### IMPORTANT RISK INFORMATION

- Use with caution when administering to patients with anuria or renal insufficiency, pulmonary insufficiency, or heart disease. The intravenous administration of these solutions can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema.
- Metabolic complications have been reported, such as acid-base, electrolyte, and blood glucose imbalances, elevated liver enzymes, and osmotic diuresis and dehydration.

Please refer to the Indications and detailed Important Risk Information on reverse side. Please refer to the enclosed Full Prescribing Information.
Indications and Usage

CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections are indicated as a caloric component in a parenteral nutrition regimen and as the protein (nitrogen) source for offsetting nitrogen loss or for the treatment of negative nitrogen balance in patients where (1) the alimentary tract cannot or should not be used, (2) gastrointestinal absorption of protein is impaired, or (3) metabolic requirements for protein are substantially increased, as with extensive burns.

Important Risk Information

- It is essential that a carefully prepared protocol based on current medical practices be followed, preferably by an experienced team. Frequent clinical evaluation and laboratory determinations are necessary for proper monitoring during administration.

- CLINIMIX E Injections are contraindicated in patients having intracranial or intraspinal hemorrhage, in patients who are severely dehydrated, in patients hypersensitive to one or more amino acids and in patients with severe liver disease or hepatic coma. Solutions containing corn-derived dextrose may be contraindicated in patients with known allergy to corn or corn products.

- Because of the potential for life-threatening events, caution should be taken to ensure that precipitates have not formed in any parenteral nutrient admixture.

- Use with caution when administering to patients with anuria or renal insufficiency, pulmonary insufficiency, or heart disease. The intravenous administration of these solutions can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema.

- Metabolic complications have been reported, such as acid-base, electrolyte, and blood glucose imbalances, elevated liver enzymes, and osmotic diuresis and dehydration.

- Other adverse reactions that may occur include febrile response, infection at the site of injection, extravasation, and hypervolemia. The infusion of hypertonic nutrient injections into a peripheral vein may result in vein irritation, vein damage, and thrombosis.

- This product contains aluminum that may be toxic with prolonged parenteral administration if kidney function is impaired.

- CLINIMIX E Injections must be admixed prior to infusion.

Please refer to the enclosed full Prescribing Information.
From the minute you place a product order, to the moment it arrives on your loading dock. From the technology designed to help improve dose management and IV efficiency, to drug delivery and nutrition options that let you hang it, mix it or make it. From infusion systems that offer safety features, to IV access products that provide a wide range of choices. From ongoing clinical support and product training, to implementation, analysis and optimization of the system. You decide which products and services work best for you and your patients. And we’ll be there, on the continuum of care. Throughout your institution. Or on one floor. Yet always in your corner.

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pharmacy workflow | drug delivery | nutrition | iv access | infusion systems | support & service

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Visit www.medicationdeliveryproducts.com

Please see inside fold for Indications and Important risk information.
Please see accompanying Package Inserts for Full Prescribing Information.
<table>
<thead>
<tr>
<th>Product Code</th>
<th>2 L Code</th>
<th>1 L Code</th>
<th>Amino Acid Concentration</th>
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<th>g Dextrose/L</th>
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<th>K⁺ (mEq/L)</th>
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<th>Cl⁻ (mEq/L)</th>
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*pH range = 4.5 - 7.0
## CLINIMIX E Injections Product Listing

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Please refer to the enclosed full Prescribing Information.

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Baxter Healthcare Corporation
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Round Lake, IL 60073

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Baxter, Clinimix E and Clinimix Logo are trademarks of Baxter International Inc.
Pediatric Use: Use of CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections for pediatric use has not been thoroughly evaluated. Dosage and administration should be proportionate to the patient's tolerance to dextrose, as indicated by frequent determinations of urine ketones and blood glucose levels. The rate of administration should not exceed two times normal serum osmolarity (718 mOsmol/L), and administration should be under close medical supervision. Pediatric patients should be monitored at all times.

Central Vein Administration: CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections may be administered safely by continuous infusion through a central venous catheter with the tip located in the vena cava. In addition to meeting nitrogen requirements, administration by peripheral vein should not exceed twice normal serum osmolarity (718 mOsmol/L). CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections are also suitable for use in large-volume admixtures with blood and cell components.

Conservative: Conservative doses of these admixed amino acid with electrolytes/dextrose with calcium injections should be given to patients with hoarse or suppressed hepatic dysfunction. Should symptoms of hypermetabolic stress develop, administration should be discontinued and the patient's condition reevaluated. Administration of any amino acid solutions in the presence of impaired renal function presents special issues associated with monitoring of electrolytes. These admixed solutions should not be administered simultaneously with blood through the same intravenous line because of the possibility of protein precipitation. In very low birth weight infants, occasional or rapid administration of dextrose injection may result in increased serum osmolality and possible intravascular hemolysis.

Warnings: Use caution when administering to patients with renal failure. These admixed solutions contain sufficient electrolytes to provide for most permitted nutritional needs with the possible exception of potassium, where supplementation may be required. Intravenous administration of electrolyte solutions over a long period of time may result in dilution of serum electrolyte concentrations, overhydration, congested states, and rarely, hyperkalemia or hypokalemia, which may result in cardiac arrest. Potassium should be used with caution, particularly in the presence of renal disease, diabetes mellitus, hypocalcemia, tetany, or acute or chronic metabolic acidosis. The intravenous administration of these solutions can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema, particularly in patients with renal disease, pulmonary insufficiency, or heart disease.

The intravenous administration of these solutions can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema, particularly in patients with renal disease, pulmonary insufficiency, or heart disease.

Precautions: With the administration of CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections, the intravascular volume and electrolyte concentrations should be monitored. The central nervous system and bone toxicity.

This artwork requires that the supplier insert a code 39 bar code master in the position indicated. Bar code must be readable at the position indicated.

**BAR CODE POSITION ONLY**
sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections have been studied with CLINIMIX E. Carcinogenesis, Mutagenesis, Impairment of Fertility: 

subclinical diabetes mellitus. Caution must be exercised in the administration of these admixed amino acid with electrolytes/dextrose must be selected with caution in pediatric patients. A slight yellow color does not alter the quality and efficacy of this product.

Parenteral drug products should be inspected visually for particulate matter and solution is clear and thoroughly mixed. Potassium should be used promptly after mixing. Any storage with additives should be avoided. 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 judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Do not store solutions containing additives. These vials and vials/electrolyte/dextrose solutions should be used in accordance with the Food and Nutrition Board National Academy of Sciences – National Research Council (Revised 1989).

Table 1

Contents of Admixed Product

Dosage and Administration

1. CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections should be given to a pregnant woman only if strictly needed. Nursing Mothers: Caution should be exercised when CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections are administered to a nursing woman.

Pediatric Dose: Dosages to be safe and effective for the stated indications in pediatric patients (see Indications and Usage). Administration should be aseptic technique. Mix thoroughly when additives have been introduced. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Do not store solutions containing additives. These vials and vials/electrolyte/dextrose solutions should be used in accordance with the Food and Nutrition Board National Academy of Sciences – National Research Council (Revised 1989).
**Figure 2**

**Central Vein Administration:** Hyperosmolar mixtures of amino acid/dextrose injections may be administered safely through a central venous catheter with the tip located in the supraclavicular area. In addition to meeting nutrient needs, the administration rate is governed, especially during the first few days of therapy, by the patient’s tolerance to dilution, as indicated by frequent determinations of urine and blood urea nitrogen. Daily intake of amino acids in dextrose should be increased in order to diminish gradually.

**To Add Fat Emulsion for 3-in-1 admixture:**

See Warnings section regarding incompatible additives including fat emulsions.

1. Prior to adding fat emulsion, mix amino acid and dextrose injection as shown in Figure 2.
2. Prepare full emulsion by referring to instructions provided.
3. Attach transfer set to fat emulsion bottle, using syringe technique.
4. Twist off protector on the additive port of the CLARITY container.
5. Attach the transfer set to the exposed additive port.
6. Open clamp on transfer set.
7. After completing transfer, use appropriate plastic clamp or needle/tube to seal off small port tube.
8. Transfer removed.

**Storage:** Storage of the 3-in-1 admixture may be refrigerated and should be used within 24 hours. See Warnings section regarding incompatible additives.

**To Add Medication:**

**Additives may be incompatible.**

Supplemental replacement may be added with a 19 to 22 gauge needle through the emulsion port.
1. Prepare medication port.
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.
4. Check for leaks.

**Preparations for Administration:**

1. Suspending container from eyelet support.
2. Twist off protector from outlet port of container.
3. Attach administration set. Refer to complete directions accompanying set.

**How Supplied:**

See Table 1.

**Exposure of pharmaceutical products to light should be minimized.**

Because of the potential for the irritating nature, solution should be taken to ensure that propellants have not frozen in any parenteral administration apparatus.

**Contraindications:**

**CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections are contraindicated in patients hypersensitive to any component in these solutions, in patients with renal failure, in patients who have been administered solutions containing alginates, in patients with severe liver disease, and in those with severe heart disease.**

**Warnings:**

**Additives may be incompatible including fat emulsions. Consult with pharmacist, if available. When introducing additives, use syringe technique.**

*This artwork requests that the supplier insert a code 30 bar code marker in the positive indicated bar code marker. Bar code must be black. Make readable on art and at open. Bar code must conform to all applicable Baxter specifications.*
Metabolism: The following metabolic complications have been reported: metabolic acidosis, hyperglycemia, lactic acidosis, hypoglycemia, and hypokalemia. In the absence of fluid and electrolyte imbalances, frequent clinical evaluation and laboratory determinations are necessary, especially during the first few days of therapy to prevent or minimize these complications. Caution must be exercised in the administration of these admixed amino acid/dextrose injections to patients showing cardiovascular or pulmonary insufficiency. These admixed injections should be used with caution in patients with overt or known alcoholism and diabetes mellitus.

Drug product contains no more than 25 mcg of alcohol.

Carcogenesis, Mutagenesis, Impairment of Fertility:

Clinical studies of CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy:

These admixed injections should be used with caution in patients with overt or known hypothyroidism, hyperthyroidism, or diabetes mellitus. Pregnancy should not be attempted until the patient has been under medical supervision for adequate control of these conditions. CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections should be given to a pregnant woman only if clearly needed.

Harm when administered to a pregnant woman or can affect reproduction capacity.

Carcinogenic potential, mutagenic potential, or effects on fertility.

Geriatric Use:

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.

Adverse Reactions

See Warnings and Precautions

The rapid infusion of these CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections may result in diabetes mellitus in neonates, hypoglycemia, and hypomagnesemia. Continued clinical monitoring of the patient is necessary in order to determine the total daily dose of CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections without any major adverse reaction.

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. With thrombophlebitis, large-diameter (12 gauge) intravenous lines have been used. A slight yellow color does not alter the quality and efficacy of this product.

Table 1

<table>
<thead>
<tr>
<th>Amino Acid</th>
<th>mg/100 mL</th>
<th>pH</th>
<th>Osmol/L</th>
<th>kcal/L</th>
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<tr>
<td>Valine</td>
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<td>340</td>
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<td>Isoleucine</td>
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<td>Glycine</td>
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<td>370</td>
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</table>

Dosage and Administration

The following schedule of CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections are administered to a nursing woman.

In neonates, hypoglycemia and glycosuria.

The total daily dose of CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections depends on the patient's metabolic requirement and clinical response. The administration of nitrogen balance and accurately body weight, corrected for fluid balance, are probably the best means of assessing individual nitrogen requirements.

Recommended Dietary Allowances of protein range approximately 0.75 g/kg body weight for adults to 1.8 g/kg for infants up to three months of age. It must be recognized, however, that protein as well as caloric requirements in traumatized or nonreconstituted patients may be increased significantly. Daily amino acid doses of approximately 1.0 to 1.5 g/kg body weight for adults with adequate caloric intake are generally sufficient to satisfy protein needs and promote positive nitrogen balance.

For the initial treatment of trauma or protein calorie malnutrition, higher doses of protein with corresponding quantities of carbohydrate will be necessary to promote adequate protein synthesis and increase nitrogen balance. Protein intake (on the order of 1.5 g/kg) is often necessary to achieve nitrogen balance. In general, doses selected 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.

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Too rapid infusion of these CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from other younger subjects. Other reported clinical experience has not identified responses in elderly patients to be qualitatively different from those of younger patients.

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