A parenteral nutrition solution with electrolytes

CLINIMIX E
sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections

Baxter
CLINIMIX E Injections with Electrolytes

- 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 safety and efficacy of drug products.¹
- The cGMPs are in place to prevent:
  - Sub-potency or super-potency
  - Contamination
  - Unpredictable safety or efficacy
  - Misbranding

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.
Electrolyte errors can be a significant problem

According to an A.S.P.EN. survey, parenteral nutrition related practices can be inconsistent and lead to error. Contributing to some of these inconsistencies are the different conventions used to order electrolytes.

Parenteral nutrition components most often associated with error

- 71% of respondents associated electrolytes with the source of error in parenteral nutrition
- 31% of respondents associated insulin with the source of error in parenteral nutrition
- 31% of respondents associated dextrose with the source of error in parenteral nutrition

Nutrition and Electrolytes

- Patients on parenteral nutrition usually receive maintenance electrolytes
- Electrolytes in parenteral nutrition can be customized or standardized
- Electrolytes are standardized in most EN formulations

Considerations for Electrolyte Management

- 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

Standardized Parenteral Nutrition (PN) with Electrolytes can be an appropriate choice

- 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
- In a 2005 prospective study to evaluate the effect of standardized vs. customized parenteral nutrition, patients receiving standardized formulations were more likely to have electrolyte values within normal limits
- A.S.P.E.N. PN Safety Summit recommends standardization of parenteral nutrition formulation processes to reduce risk of adverse events

<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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<tbody>
<tr>
<td>Calcium</td>
<td>10–15 mEq</td>
<td>9 mEq</td>
</tr>
<tr>
<td>Magnesium</td>
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<td>Sodium</td>
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<tr>
<td>Potassium</td>
<td>1–2 mEq/kg</td>
<td>60 mEq</td>
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</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.

To place an order, contact your Baxter representative or call 888-229-0001
# CLINIMIX E Injections Formulation Profiles

**CLINIMIX E SULFITE-FREE (AMINO ACID WITH ELECTROLYTES IN DEXTROSE WITH CALCIUM) INJECTIONS**

| Product Code | 2 L Code | 1 L Code | Amino Acid Concentration | Dextrose Concentration | g Protein/L | g Dextrose/L | Dextrose (kcal/L) | g N2/L | Na+ (mEq/L) | K+ (mEq/L) | Ca++ (mEq/L) | Mg++ (mEq/L) | Ac- (mEq/L) | Cl- (mEq/L) | HPO4= (mmol/L) | Osmolarity (mOsm/L) | pH |
|--------------|---------|---------|--------------------------|------------------------|-------------|-------------|-----------------|-------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|------------------|-----------------|----|
| CLINIMIX E 2.75/5 | 2B7713  | 2B7735  | 2.75%                    | 5%                     | 27.5        | 50          | 170             | 4.54  | 35          | 30          | 5           | 4.5          | 51          | 39          | 15          | 625              | 6.0             |    |
| CLINIMIX E 2.75/10 | 2B7714 | 2B7736  | 2.75%                    | 10%                    | 27.5        | 100         | 340             | 7.02  | 35          | 30          | 5           | 4.5          | 51          | 39          | 15          | 920              | 6.0             |    |
| CLINIMIX E 4.25/5  | 2B7715  | 2B7737  | 4.25%                    | 5%                     | 42.5        | 50          | 170             | 7.02  | 35          | 30          | 5           | 4.5          | 70          | 39          | 15          | 815              | 6.0             |    |
| CLINIMIX E 4.25/10 | 2B7717  | 2B7738  | 4.25%                    | 10%                    | 42.5        | 100         | 340             | 7.02  | 35          | 30          | 5           | 4.5          | 70          | 39          | 15          | 1070             | 6.0             |    |
| CLINIMIX E 4.25/25 | 2B7719  | 2B7739  | 4.25%                    | 25%                    | 42.5        | 250         | 850             | 7.02  | 35          | 30          | 5           | 4.5          | 70          | 39          | 15          | 1825             | 6.0             |    |
| CLINIMIX E 5/15   | 2B7721  | 2B7740  | 5%                       | 15%                    | 50          | 150         | 510             | 8.26  | 35          | 30          | 5           | 4.5          | 80          | 39          | 15          | 1395             | 6.0             |    |
| CLINIMIX E 5/20   | 2B7722  | 2B7741  | 5%                       | 20%                    | 50          | 200         | 680             | 8.26  | 35          | 30          | 5           | 4.5          | 80          | 39          | 15          | 1650             | 6.0             |    |
| CLINIMIX E 5/25   | 2B7723  | 2B7742  | 5%                       | 25%                    | 50          | 250         | 850             | 8.26  | 35          | 30          | 5           | 4.5          | 80          | 39          | 15          | 1900             | 6.0             |    |

*pH range = 4.5 - 7.0*
## CLINIMIX E Injections Product Listing

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<th>BAXTER CODE</th>
<th>PRODUCT DESCRIPTION</th>
<th>AMERISOURCE BERGEN SAP</th>
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<th>MCKESSON</th>
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Please refer to the enclosed full Prescribing Information.

Medical Products

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Baxter Healthcare Corporation, Route 120 and Wilson Road, Round Lake, IL 60073 www.baxter.com 801496B 5K 5/12
Pediatric Use: Use of CLINIMIX E sulfate-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections in children is not recommended, except under special circumstances where the child's medical condition and hospital practices dictate its use. Use in children is not recommended because the safety and efficacy of CLINIMIX E sulfate-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections in children has not been established. If use in children is deemed necessary, it should be conducted under carefully controlled conditions. See Precautions, Warnings, and Administration.

Central Vein Administration: Use of CLINIMIX E sulfate-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections may be administered safely, by continuous infusion through a central vein catheter with its tip located in the upper vena cava. In addition to measuring intravenous pressure, it is important that the patient's tolerance to dextrose, as indicated by frequent determinations of urine for infants with adequate calories are generally sufficient to satisfy protein needs and protein-sparing effect of infused amino acids. To prevent hypeension, increased osmolarity, and hypernatremia, the final solution should not exceed twice normal serum osmolarity (718 mOsmol/L). Mixtures of amino acids and electrolytes can be infused at the rate of 3 ml/hr per kg of body weight. Thorough mixing ensures complete mixing of amino acids and electrolytes. SEAL BETWEEN CHAMBERS. After opening the seal between chambers, lipids and/or calcium injections should be added to each chamber to maintain a solution osmolarity of 1000-1100 mOsmol/L.

SEVERE CONTRAINDICATIONS: Severe hepatic dysfunction (ascites, hypoproteinemia, poor protein synthesis) or hepatic failure may result. Severe renal dysfunction (creatinine clearance less than 20 ml/min) or tubular dysfunction may result in increased serum osmolarity and possible intracellular hemolysis.

Warning: Administration of amino acid solutions in the presence of impaired renal function presents special issues associated with monitoring of electrolytes.

WARNING: These admixed injections should not be administered simultaneously with blood through the same infusion set because of the possibility of pharmacological interactions.

Peripheral Venous Administration: For the patient requiring parenteral nutrition when the peripheral vein cannot support the required concentration of amino acids and electrolytes with dextrose, CLINIMIX E Injections may be administered by peripheral veins. In pediatric patients, the final solution should not exceed twice normal serum osmolarity (718 mOsmol/L). Additives can be infused at the rate of 3 ml/hr per kg of body weight. Thorough mixing ensures complete mixing of amino acids and electrolytes. SEAL BETWEEN CHAMBERS. After opening the seal between chambers, lipids and/or calcium injections should be added to each chamber to maintain a solution osmolarity of 1000-1100 mOsmol/L. Mixtures of amino acids and electrolytes can be infused at the rate of 3 ml/hr per kg of body weight. Thorough mixing ensures complete mixing of amino acids and electrolytes. SEAL BETWEEN CHAMBERS. After opening the seal between chambers, lipids and/or calcium injections should be added to each chamber to maintain a solution osmolarity of 1000-1100 mOsmol/L.

Intravenous Therapy: Parenteral nutrition mixtures should be warmed to body temperature before administration. Sudden cessation in administration of these admixed injections may result in hypoglycemia. Maximal patient response requires a knowledge of fluid and electrolyte balance and nutrition as well as overall patient status. When introducing additives, use aseptic techniques. Mix thoroughly.

CLINIMIX E Injections containing valtricolen additivions should be used promptly after addition. Any changes should be under refrigeration and limited to a brief period of time, less than 24 hours.

To add Fat Emulsion (2-in-1 solution):

1. Prior to adding valtricolen, the amino acid and dextrose injection is shown in Figure 2.
2. Prepare fat emulsion injection following instructions provided.
3. Attach transfer set to fat emulsion solution using aseptic technique.
4. Two twist off the additive port chloride solution and inject into CLARITY container.
5. After transferring solution to the additive port of the CLARITY container.
6. Open cap on transfer set.
7. After completing transfer, use appropriate plastic clamp on metal female to off-additive port line.
8. Repeat transfer set.

Storage: Storage of the 2-in-1 admixture must be under refrigeration and limited to a brief period of time; no longer than 24 hours. See Warnings section regarding incompatible additives.

DIRECTIONS FOR USE OF PLASTIC CONTAINER

WARNING: Do not use plastic containers in series connections. Such use could result in air embolism due to vacuum being drawn from the primary container before administration of fluid is completed from the secondary container. As SURE THE CONTENTS OF BOTH CHAMBERS ARE MIXED TOGETHER AFTER OPENING by the patient's tolerance to dextrose, as indicated by frequent determinations of urine for infants with adequate calories are generally sufficient to satisfy protein needs and on the basis of grams of amino acids/kg of body weight/day. Two to 3 g/kg of body weight addtives can be introduced to the container. Thorough mixing ensures complete mixing of amino acids and electrolytes. SEAL BETWEEN CHAMBERS. After opening the seal between chambers, lipids and/or calcium injections should be added to each chamber to maintain a solution osmolarity of 1000-1100 mOsmol/L. Mixtures of amino acids and electrolytes can be infused at the rate of 3 ml/hr per kg of body weight. Thorough mixing ensures complete mixing of amino acids and electrolytes. SEAL BETWEEN CHAMBERS. After opening the seal between chambers, lipids and/or calcium injections should be added to each chamber to maintain a solution osmolarity of 1000-1100 mOsmol/L. Mixtures of amino acids and electrolytes can be infused at the rate of 3 ml/hr per kg of body weight. Thorough mixing ensures complete mixing of amino acids and electrolytes.

AUTHOR: Baxter Healthcare Corporation

Print Name: "Ivanova, E. and Clarity of treatment Baxter International Inc.

[Signature]

Date: 07-19-57-385

BAR CODE POSITION ONLY
sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections have a constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients. Dextrose is safe and effective for the stated indications in pediatric patients with Electrolytes in Dextrose with Calcium) Injections are administered to a nursing woman. Caution should be exercised when CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections should be given to a pregnant woman as it is not known whether the drug can affect reproduction capacity. CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections can cause fetal harm when administered to a pregnant woman.

**Teratogenic Effects**

The following metabolic complications have been reported:

- Osmotic diuresis and dehydration
- Rebound hypoglycemia
- Elevated liver enzymes
- Hypokalemia
- Hypocalcemia
- Hyperosmolar coma
- Continual clinical monitoring of the patient is necessary in order to identify and manage any of these clinical conditions.

- Reactions that may occur because of the solution or the technique of administration include hyperosmolality, hypokalemia, hypocalcemia, and hyperglycemia. Care should be exercised to ensure the maintenance of proper levels of serum potassium. Quantities of 60 to 180 mEq of potassium per day have been used with adequate clinical effect. It may be necessary to add potassium to the intravenous electrolyte solution if plasma levels fall below normal. Such higher doses, especially in infants, should be used only under the direct supervision of a physician experienced in the care of intensive care patients.

- Total daily fluid requirements can be met beyond the volume of amino acids solution depending primarily on the amount of carbohydrates administered to the patient. The severity of the illness being treated is the primary consideration in determining proper fluid levels. Such higher doses, especially in infants, should be used only under the direct supervision of a physician experienced in the care of intensive care patients.

- It is not known whether the drug can affect reproduction capacity. CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections can cause fetal harm when administered to a pregnant woman. Teratogenic effects have been reported in animals treated with CLIMINIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections.

**Adverse Reactions**

See *Warnings and Precautions*.

Fat emulsion administration should be considered when prolonged (more than 5 days) parenteral nutrition is required in order to prevent essential fatty acid deficiency (EFAD). Serum fats should be monitored for evidence of EFAD in patients maintained on fat emulsions. Intravenous fat emulsions provide approximately 1,1 kcal per mL (15%), 2 kcal per mL (20%), or 3 kcal per mL (30%) and may be admixed along with amino acid and electrolyte/dextrose/calcium injections in the CLINIMIX Container to supplement caloric intake. Depending upon the clinical condition of the patient, approximately 2-3 liters of solution may be administered per 24 hour period. When small quantities of the total therapy should begin with 1005 mL, the first 24 hour period. Thereafter, the dose may be increased to 3300 mL per day.


**Table 1**

**Contents of Admixed Product**

<table>
<thead>
<tr>
<th>Component</th>
<th>Use</th>
<th>Source</th>
<th>Molecular Mass (Da)</th>
<th>Concentration (mg/mL)</th>
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<tbody>
<tr>
<td>Sodium Chloride</td>
<td>USP</td>
<td>NaCl</td>
<td>58.44</td>
<td>3.50 g/1000 mL</td>
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<tr>
<td>Magnesium Chloride</td>
<td>USP</td>
<td>MgCl2</td>
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<td>0.05 g/1000 mL</td>
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<tr>
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<td>CaCl2</td>
<td>110.98</td>
<td>0.05 g/1000 mL</td>
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<tr>
<td>Potassium Chloride</td>
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<td>KCl</td>
<td>39.10</td>
<td>0.05 g/1000 mL</td>
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<tr>
<td>Glucose (Hydrous)</td>
<td>USP</td>
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<tr>
<td>Amino Acids</td>
<td>USP</td>
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<td></td>
<td>5% w/v</td>
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**Composition**

- **Essential Amino Acids**
  - Methionine - CH3S (CH2)2 CH (NH2) COOH
  - Valine - CH3C (CH2)3 CH (NH2) COOH
  - Isoleucine - CH3C (CH2)3 CH (NH2) COOH
  - Leucine - CH3C (CH2)4 CH (NH2) COOH
  - Threonine - (CH3)2 CHCH (NH2) COOH
  - Serine - CH2OH (CH2)2 CH (NH2) COOH
  - Glycine - H2NCH2 COOH
  - Proline - H2NCH2 COH
  - Histidine - (CH3)2 CHNH C (COOH)
  - Arginine - (CH3)2 CHNH C (COOH)
  - Lysine - (CH3)2 CH2NH C (COOH)
  - Aspartate - CH2NH COOH
  - Glutamate - CH2NH C (COOH)

- **Nonessential Amino Acids**
  - Alanine - H2NCH2 COOH
  - Asparagine - H2NCH2 COOH
  - Glutamine - H2NCH2 COOH
  - Cysteine - H2NCH2 COOH
  - Glutathione - H2NCH2 COOH
  - Tyrosine - H2NCH2 COOH

**Caloric Content (kcal/L)**

- From Dextrose
  - 80 39
  - From Amino Acids
  - 920 200
  - Total kcal/L
  - 1720 580

Fat emulsion administration should be considered when prolonged (more than 5 days) parenteral nutrition is required in order to prevent essential fatty acid deficiency (EFAD). Serum fats should be monitored for evidence of EFAD in patients maintained on fat emulsions. Intravenous fat emulsions provide approximately 1,1 kcal per mL (15%), 2 kcal per mL (20%), or 3 kcal per mL (30%) and may be admixed along with amino acid and electrolyte/dextrose/calcium injections in the CLINIMIX Container to supplement caloric intake. Depending upon the clinical condition of the patient, approximately 2-3 liters of solution may be administered per 24 hour period. When small quantities of the total therapy should begin with 1005 mL, the first 24 hour period. Thereafter, the dose may be increased to 3300 mL per day.