Understanding the value of

CLINIMIX
sulfite-free (Amino Acid in Dextrose) Injections

in goal-directed therapy
for patients with parenteral nutritional needs

www.clinimix.com

Baxter
CLINIMIX Injections

a Different Way to Think About PN

- Provide nutritional therapy in innovative multi-chamber bag (MCB) technology.
- Portfolio offers broad clinical flexibility.
- Offer a simple product-prescribing alternative to custom ordering.
- Are a key component of goal-directed nutrition therapy.
- Provide a premix alternative to compounding, which may lower the risk of contamination during the preparation process.

Please see enclosed package insert for complete prescribing information. See back cover for indications and important risk information.
Innovative Multi-chamber Bag

CLINIMIX Injections are a sterile, nonpyrogenic, hypertonic solution manufactured in a CLARITY dual-chamber container.

CLINIMIX and CLINIMIX E Injections with electrolytes are available in:
- 1- and 2-liter volumes
- Central and peripheral formulations

Multiple ports provide flexibility to add IV fat emulsion and other ingredients for total parenteral nutrition.
- Additives may be incompatible. Consult with pharmacist, if available.

CLINIMIX and CLINIMIX E Injections must be admixed prior to infusion.

Because of the potential for life-threatening events, caution should be taken to ensure that precipitates have not formed in any parenteral nutrient admixture.
When PN is indicated consider CLINIMIX and CLINIMIX E Injections for a variety of patient types:

- Malnourished
- Burns
- GI disease/obstruction
- Trauma

Indications and Usage

CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections and 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

CLINIMIX and 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.

Use with caution when administering to patients with anuria or renal insufficiency, pulmonary insufficiency, or heart disease.

Source: CLINIMIX and CLINIMIX E Injections prescribing information.

Please see enclosed package insert for complete prescribing information. See back cover for full Important Risk Information.
Offers a simple product prescribing alternative to custom ordering

CLINIMIX Injections provide adequate protein and dextrose calories. CLINIMIX E Injections is also an adequate source of electrolytes.

**Just check the box**

Maintenance vitamins, additional electrolytes, and trace elements are not included and should be administered as required.

Goal-directed nutrition therapy

Malnutrition can create negative energy balance:

- Energy expenditure exceeds calories consumed.
- Often develops in the first week and is difficult to overcome².
- When GI disease/obstruction occurs.

Energy debt is a marker for nutritional risk².

CLINIMIX and CLINIMIX E Injections are a protein source for offsetting nitrogen loss or for treatment of negative nitrogen balance.

CLINIMIX and CLINIMIX E Injections support goal-directed therapy with safety and confidence.

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.


Please see enclosed package insert for complete prescribing information. See back cover for indications and important risk information.
Reduce sources of contamination

Bloodstream infections (BSIs) are associated with key factors including catheter care and contaminated infusate.

The constant risk of sepsis is present during total parenteral nutrition. Since contaminated solutions and infusion catheters are potential sources of infection, it is imperative that the preparation of PN solution and the placement and care of catheters be accomplished under controlled aseptic conditions:

- Proper catheter care effectively reduces PN-related infections.

CLINIMIX and CLINIMIX E Injections are a sterile infusate:

- Good Manufacturing Practices in a quality-controlled environment
- Terminally sterilized

While the impact of using CLINIMIX and CLINIMIX E Injections on BSI rates has not been adequately studied, the use of manufacturer-prepared products is one alternative method to compounding complex PN solutions to help reduce the potential for touch contamination of infusate solution.

CLINIMIX and CLINIMIX E Injections may also help reduce medication preparation errors by decreasing compounding calculations and minimizing preparation steps.

Potential Sources of Infection

- Contaminated catheter hub
- Contaminated infusate
- Skin organisms
- Hematogenous (from distant infection)


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 and 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 and CLINIMIX E Injections must be admixed prior to infusion.

- Please refer to package insert for full prescribing information.
**Clinical Pharmacology**

CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections provide biologically available source material for protein synthesis and have value as a source of amino acids.

**Indications and Usage**

CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections are indicated as a:  
- Component in parenteral nutrition regimens in which a protein source is required.  
- Treatment of hyperammonemia in children who are deficient in one of the urea cycle enzymes, or in patients with normal urea cycle enzymes who exhibit clinical symptoms related to a deficiency of the urea cycle amino acids of genetic or product origin.  
- Supplemental protein to support a low protein diet in patients with chronic renal disease or uremia.

**Contraindications**

CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections are contraindicated in patients who are:  
- Allergic or hypersensitive to one or more amino acids, and in patients with severe liver disease or hepatic coma.

**Warnings**

Amino acids may be incompatible. Consult with pharmacist, if available.

**Adverse Effects**

The potential for life-threatening events, caution should be taken to ensure that compatible, free from contamination in parenteral nutrition regimens.  
- CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections, must be administered as a complete administration.  
- For complete administration instructions, see Directions for Use of CLARITY Plastic Container, this section.  
- The infusion of hypertonic nutrient injections into a peripheral vein may result in vein damage or thrombosis, and may reduce the protein-sparing effect of infused amino acids.  
- Proper administration of these admixed amino acid/dextrose injections requires knowledge of fluid, electrolyte balance and nutrition as well as administration in recognition and treatment of the complications which may occur.

**Laboratory Tests**

Frequent clinical evaluation and laboratory determinations are necessary for patients receiving this infusion.  
- Serum electrolytes, blood urea nitrogen, creatinine, liver function tests, blood counts, and blood glucose levels are necessary in the management of patients during parenteral hyperalimentation.

Hyponatremia is of special significance in infants. This reaction appears to be more serious in infants, due to excessive rate of osmotic change of the extracellular compartment. It is essential that intravenous fluids be measured carefully in infants.

Administration of amino acid solutions in the presence of impaired renal function presents special issues associated with excess sodium intake. These solutions should be administered with due consideration to excess sodium intake because of the possibility of paroxysmal hypertension.

In very low birth weight infants, acute or rapid administration of hypertonic solutions may result in increased intracranial pressure and decreased intravascular volume.  
- Calculation and delivery systems, in addition to NS infusion.  
- Admixture infusion is contraindicated in patients having intracranial hypertension or intracranial bleeding.  
- Tension headache is not uncommon in patients receiving parenteral nutrition and fluid therapy.  
- Pain and discomfort are common, and may be associated with hypertonic solutions in the central or peripheral veins.

**Precautions**

- If hypoglycemia develops, reduce the rate of NS infusion.  
- Hypertonic solutions may cause tissue damage at the injection site.  
- These adverse reactions are most likely to occur at the injection site when hypertonic solutions are used.  
- Potassium supplements are necessary in patients receiving parenteral nutrition, to maintain adequate serum potassium levels and maintain normal electrolyte balance.

**Pharmacology**

CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections provide biologically available source material for protein synthesis and have value as a source of amino acids.  
- CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections are contraindicated in patients who are allergic or hypersensitive to one or more amino acids, and in patients with severe liver disease or hepatic coma.

**Clinical Pharmacology**

CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections provide biologically available source material for protein synthesis and have value as a source of amino acids.

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CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections are indicated as a:  
- Component in parenteral nutrition regimens in which a protein source is required.  
- Treatment of hyperammonemia in children who are deficient in one of the urea cycle enzymes, or in patients with normal urea cycle enzymes who exhibit clinical symptoms related to a deficiency of the urea cycle amino acids of genetic or product origin.  
- Supplemental protein to support a low protein diet in patients with chronic renal disease or uremia.

**Contraindications**

CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections are contraindicated in patients who are:  
- Allergic or hypersensitive to one or more amino acids, and in patients with severe liver disease or hepatic coma.

**Warnings**

Amino acids may be incompatible. Consult with pharmacist, if available.

**Adverse Effects**

The potential for life-threatening events, caution should be taken to ensure that compatible, free from contamination in parenteral nutrition regimens.  
- CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections, must be administered as a complete administration.  
- For complete administration instructions, see Directions for Use of CLARITY Plastic Container, this section.  
- The infusion of hypertonic nutrient injections into a peripheral vein may result in vein damage or thrombosis, and may reduce the protein-sparing effect of infused amino acids.  
- Proper administration of these admixed amino acid/dextrose injections requires knowledge of fluid, electrolyte balance and nutrition as well as administration in recognition and treatment of the complications which may occur.

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Frequent clinical evaluation and laboratory determinations are necessary for patients receiving this infusion.  
- Serum electrolytes, blood urea nitrogen, creatinine, liver function tests, blood counts, and blood glucose levels are necessary in the management of patients during parenteral hyperalimentation.

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Administration of amino acid solutions in the presence of impaired renal function presents special issues associated with excess sodium intake. These solutions should be administered with due consideration to excess sodium intake because of the possibility of paroxysmal hypertension.

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- Pain and discomfort are common, and may be associated with hypertonic solutions in the central or peripheral veins.

**Precautions**

- If hypoglycemia develops, reduce the rate of NS infusion.  
- Hypertonic solutions may cause tissue damage at the injection site.  
- These adverse reactions are most likely to occur at the injection site when hypertonic solutions are used.  
- Potassium supplements are necessary in patients receiving parenteral nutrition, to maintain adequate serum potassium levels and maintain normal electrolyte balance.
Safety and effectiveness of CLINIMIX sulfite-free (Amino Acids in Dextrose) injections in pediatric patients have not been established by adequate and well-controlled studies. However, the use of other amino acid injections in pediatri patients as an adjunct in the offsetting of nitrogen in an intensive treatment of negative nitrogen balance is referred to in the medical literature. See Dosage and Administration.

Geriatric Use: Clinical studies of CLINIMIX sulfite-free (Amino Acids in Dextrose) injections 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, dosage 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 compositions of these CLINIMIX sulfite-free (Amino Acids in Dextrose) injections may result in diabetics, hyperglycemia, glycosuria, and hyperglycemic coma. Continuous intravenous monitoring of the patient is necessary to identify and initiate measures for these conditions.

Reactions that may occur because of the solution or the technique of administration include intravascular injection, infusion of various substances or phials extending from the site of injection, extravasation, and hyperventilation. Policies and procedures should be established for the recognition and management of such reactions.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and at the reminder of the fluid for examination of arterial necessity.

Dosage and Administration

If the patient is unable to take oral nourishment for a prolonged period of time, institution of total parenteral nutrition should be considered. The factors daily dose of CLINIMIX sulfite-free (Amino Acids in Dextrose) injections depends on the patient's metabolic requirements and clinical response. The determination of nitrogen balance and accurate daily total nitrogen balances are necessary to initiate and monitor appropriate nitrogen intake.

Recommended Dietary Allowance: Administering from approximately 0.75 to 1.0 g/kg of body weight for adult infants up to three months of age. It must be recognized that protein as well as amino acids may be involved in the metabolic stress of the patient. The dosage may be adjusted upward to a maximum of approximately 1.5 to 2.0 g/kg of body weight for adults at adequate levels are employed. For the initial treatment of trauma or protein malnutrition in higher doses of protein with corresponding parenteral fluid volumes will be necessary to provide adequate patient exposure to therapy. The safety of the therapy being related to the primary complication or determining proper dose level. Such higher doses, especially in infants, must be accompanied by more frequent laboratory evaluations.

Care should be exercised to ensure the maintenance of proper levels of serum potassium. Intravenous infusions of 200 to 250 mEq of potassium per litre have been used with adequate clinical effect. It may be necessary to add quantities of this electrolyte to these intravenous admixtures, depending primarily on the amount of carbonate administered to be metabolized by the patient. Presence of CLINIMIX sulfite-free (Amino Acids in Dextrose) injections should not be employed with electrolyte solutions.

Patients receiving CLINIMIX sulfite-free (Amino Acids in Dextrose) injections should be monitored frequently and their electrolyte requirements individualized.

Total daily infusion requirements may be reduced by the addition of electrolyte solutions by supplementing with noncarbohydrate or parenteral electrolyte solutions. Maintenance volumes, additional electrolytes, and trace elements should be administered as required.

In many patients, provision of adequate calories in the form of hyperosmotic dextrose may require the administration of exogenous insulin to prevent hyperglycemia and glucosuria.

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 lipids should be monitored for evidence of EFAD in patients maintained on total parenteral nutrition.

Intravenous fluid infusions should be administered in a single intravenous fluid administration, with or without electrolyte solutions, to be administered at a rate not exceeding 35 to 50 mL per kg per hour. The infusions should be administered at a rate that is calculated to deliver an adequate amount of fluid and electrolytes to the patient to prevent dehydration and electrolyte imbalances. When using CLINIMIX sulfite-free (Amino Acids in Dextrose) injections in combination with other parenteral solutions, the total volume and composition of the final admixture should be calculated to ensure the adequacy of fluid and electrolyte delivery.

Intravenous fluid infusions should be administered in a single intravenous fluid administration, with or without electrolyte solutions, to be administered at a rate that is calculated to deliver an adequate amount of fluid and electrolyte delivery. The rate of infusion should be determined by the patient's metabolic requirement and clinical response. The determination of nitrogen balance and accurate daily total nitrogen balances are necessary to initiate and monitor appropriate nitrogen intake.

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Table 1

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<tr>
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<th>Dosage and Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Liquid, the product (represented)</td>
<td>Code 2B7701 NDC 0338-1089-04</td>
</tr>
<tr>
<td>1) Amino Acids (in mg/100 mL)</td>
<td>2) Electrolytes (in mEq/100 mL)</td>
</tr>
<tr>
<td>Valine</td>
<td>Leucine</td>
</tr>
<tr>
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<td>3) Electrolytes (in mEq/100 mL)</td>
</tr>
<tr>
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<td>Chloride</td>
</tr>
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<tr>
<td>Potassium</td>
<td>Chloride</td>
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</tbody>
</table>

*Food and Nutrition Board/National Academy of Sciences – National Research Council (Revised 1989).*
Pediatric Use: Use of CLINIMIX E sulfite-free with Electrolytes in Dextrose with Calcium injections in pediatric patients is governed by the same considerations that apply to the use of any parenteral solution. The amount administered is based on the weight of the patient and on the body weight of the patient. Two to three times the body weight of the patient should be infused each day to replace protein losses and to provide adequate nitrogen balance. Sodium and potassium levels should be monitored and adjusted as necessary.

Central Vein Administration: Hypersensitivity reactions of an amino acid with electrolytes solution with calcium and/or glucose are not uncommon in patients with continuous intravenous therapy through a central venous catheter. In order to avoid possible fluid overload during central venous administration, the fluid rate should be determined by the patient's fluid balance, and the concentration of the solution to be administered should be adjusted accordingly. If tachycardia occurs, the fluid rate should be reduced. If symptoms of circulatory overload persist, administration should be discontinued until the cause has been determined and corrected.

Contraindications: Hypersensitivity to corn or corn products.

Adverse Reactions: Adverse reactions to those amino acids that are not essential (nonessential amino acids) are generally related to a deficiency of the urea cycle amino acids of genetic or product origin. The most common reaction is transient hyperammonemia, which may result in temporary hypercatabolism and may be related to a deficiency of the urea cycle or to a deficiency of the urea cycle amino acids.

To Add Fat Emulsion to a Brief Period of Time, No Longer Than 24 Hours: See Table 1. For patients requiring prolonged parenteral nutrition, the admixed product should be administered intravenously through a central venous catheter. To avoid air embolism, the needle should be sharply angled to the fluid line at the injection port of the CLARITY container. When adding fat emulsion, the fat emulsion transfer set should be used. To add the fat emulsion to the admixed product, attach the fat emulsion transfer set to the exposed additive port. Open clamp on transfer set. Mix contents of CLARITY container thoroughly. Check for leaks. Storage of the admixed product must be under refrigeration and should be limited to a brief period of time, no longer than 24 hours. See Warnings as regarding incompatible solutions.

To Add Medication: Additives may be incompatible.

Supplemental medication may be added with a 19 to 22 gauge needle through the medication port. Prepare medication port. Using 100 to 120 psi, connect vial and medication port and mix thoroughly for high density medication, such as potassium citrate. Prevent external leaks with appropriate plastic or metal needle to add to additive port. Check for leaks.

To Add Fat Emulsion to a Brief Period of Time, No Longer Than 24 Hours: See Table 1. For patients requiring prolonged parenteral nutrition, the admixed product should be administered intravenously through a central venous catheter. To avoid air embolism, the needle should be sharply angled to the fluid line at the injection port of the CLARITY container. When adding fat emulsion, the fat emulsion transfer set should be used. To add the fat emulsion to the admixed product, attach the fat emulsion transfer set to the exposed additive port. Open clamp on transfer set. Mix contents of CLARITY container thoroughly. Check for leaks. Storage of the admixed product must be under refrigeration and should be limited to a brief period of time, no longer than 24 hours. See Warnings as regarding incompatible solutions.

To Add Medication: Additives may be incompatible. Above 120 psi, connect vial and medication port and mix thoroughly for high density medication, such as potassium citrate. Prevent external leaks with appropriate plastic or metal needle to add to additive port. Check for leaks.
Safety and effectiveness of CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections in pediatric patients have not been established by adequate and well-controlled studies. The use of amino acid injections in pediatric patients as an adjunct in the treatment of nitrogen loss or in the treatment of negative nitrogen balance is referenced in the medical literature. See Design and Administration.

Clinical Use: Clinical studies of CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections did not indicate sufficient numbers of subjects aged 16 and over to determine whether they respond differently from younger subjects, and there are no known differences in safety and effectiveness between younger and older pediatric patients. Caution must be exercised in the administration of these admixed amino acid with electrolytes/dextrose with calcium injections to patients receiving corticosteroids because of the potential for calcium binding with corticosteroids and a reflex increase in serum calcium. These admixed injections should be used with caution in patients with overt or known subclinical diabetes mellitus.

Adverse Reactions

Serious and/or life-threatening reactions that may occur because of the solution or the technique of administration include anaphylactic reaction, infiltration of the site of injection, extravasation or phlebitis extending from the site of injection, extravasation, and hyperventilation. Parenteral administration of calcium should be done only if the serum calcium concentrations are monitored. If an adverse reaction occurs, 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

It is not known whether CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections have been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility. See Pregnancy Category C. Use of this product in pregnancy or lactation should be limited to those situations where, in the opinion of the physician, the possible benefits to the mother outweigh the possible risks to the fetus or infant. See Pregnancy Category C.

Intravenous fat emulsions provide approximately 1.1 kcal per mL (10%), 2.0 kcal per mL from Dextrose and Amino Acids (2.75% Amino Acid with Electrolytes in 5% Dextrose with Calcium) Injection, and 3.5 kcal per mL from Amino Acids (4.25% Amino Acid with Electrolytes in 10% Dextrose with Calcium) Injection. These admixed injections should be used with caution in patients with overt or known subclinical diabetes mellitus.

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 lipids should be monitored for evidence of EFAD in patients maintained on fat-free TPN. Serine, arginine, histidine, and glutamine are essential amino acids in the AMDNFA diet and are generally sufficient to supply protein needs and promote normal protein balance. The total daily dose of CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections should be given to a pregnant woman only if needed.

Table 1

<table>
<thead>
<tr>
<th>Contents of Administered Product</th>
<th>Amino Acids</th>
<th>Electrolytes</th>
<th>Dextrose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caloric Content (kcal)</td>
<td>5.0</td>
<td>4.5</td>
<td>4.0</td>
</tr>
<tr>
<td>Percent Carbohydrate</td>
<td>2.0</td>
<td>1.5</td>
<td>1.0</td>
</tr>
<tr>
<td>Percent Protein</td>
<td>4.0</td>
<td>3.5</td>
<td>3.0</td>
</tr>
<tr>
<td>Percent Fat</td>
<td>1.0</td>
<td>0.5</td>
<td>0.0</td>
</tr>
</tbody>
</table>

For infusion administration should be considered only on prolonged (more than 5 days) parenteral nutrition is required in order to prevent essential fatty acid deficiency (EFAD). Parenteral drug products should be inspected visually for particulate matter and containability prior to administration. See Precautions.

Intravenous fat emulsions provide approximately 1.1 kcal per mL (10%), 2.0 kcal per mL (30%), and 3.5 kcal per mL (50%) and may be admixed along with amino acids with electrolytes/dextrose with calcium injections in the CLINIMIX Container to supplement solute intake.

The maximum volume of intravenous fluids that can be infused in any single administration is 10,000 mL. The maximum duration of infusion is 8 hours for patients weighing more than 100 kg and 24 hours for patients weighing less than 100 kg. See Administration. The maximum individual dose of parenteral nutrition is 3000 mL per day. See Administration. See Administration.

The total daily dose of CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections should be selected with caution in pediatric patients, particularly neonates and low birth weight infants.

The total daily fluid requirements can be met beyond the volume of amino acids solution by supplementing with noncarbohydrate or carbohydrate-containing electrolyte solutions. The total daily dose of CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections is based on the amount of electrolytes administered to a continuously perfused patient. See Administration. See Administration.

Inappropriate diets for patients who are at risk for hyperglycemia or hypoglycemia. Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants.

It is also not known whether CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections have been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility. See Pregnancy Category C. Use of this product in pregnancy or lactation should be limited to those situations where, in the opinion of the physician, the possible benefits to the mother outweigh the possible risks to the fetus or infant. See Pregnancy Category C.

Drug product contains no more than 25 µg/L of aluminum.

Intravenous fat emulsions provide approximately 1.1 kcal per mL (10%), 2.0 kcal per mL from Dextrose and Amino Acids (2.75% Amino Acid with Electrolytes in 5% Dextrose with Calcium) Injection, and 3.5 kcal per mL from Amino Acids (4.25% Amino Acid with Electrolytes in 10% Dextrose with Calcium) Injection. These admixed injections should be used with caution in patients with overt or known subclinical diabetes mellitus.

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 lipids should be monitored for evidence of EFAD in patients maintained on fat-free TPN. See Table 1

* Food and Nutrition Board National Academy of Sciences - National Research Council (Revised 1989).