PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

CLINIMIX E

Amino Acids with Electrolytes in Dextrose Injection

5% Amino Acids (Blend B) with Electrolytes in 10% Dextrose Injection

5% Amino Acids (Blend B) with Electrolytes in 16.6% Dextrose Injection

5% Amino Acids (Blend B) with Electrolytes in 20% Dextrose Injection

Solution for Infusion, Intravenous

Intravenous Nutritive Supplements

Baxter Corporation

Mississauga, Ontario

L5N 0C2

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RECENT MAJOR LABEL CHANGES

6 Warnings and Precautions	04/2020
3 Dosage and Administration	08/2020
6 Warnings and Precautions	08/2020

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Sections or subsections that are not applicable at the time of authorization are not listed.

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

CLINIMIX E (Amino Acids with Electrolytes in Dextrose Injection) products are indicated as a source of amino acids and carbohydrate calories in clinical conditions where enteral nutritional supply is or is expected to be insufficient or impossible in order to offset or prevent nitrogen loss or negative nitrogen balance.

1.1 Pediatrics

Pediatrics (<18 years of age): There have been no studies performed by Baxter Corporation in the pediatric population. See 7.1.3 Pediatrics regarding monitoring for hyperammonemia in pediatric patients.

1.2 Geriatrics

Geriatrics (> 65 years of age): In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

2 CONTRAINDICATIONS

The use of all formulations of CLINIMIX E (Amino Acids with Electrolytes in Dextrose Injection) is contraindicated in the following populations / situations:

- Known hypersensitivity to any of the substances or component of the container. For a complete listing, see Table 1 and 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING.
- 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.
- CLINIMIX E must not be administered to patients with pathologically elevated plasma concentrations of sodium, potassium, magnesium, calcium and/or phosphorus.
- Known allergy to corn or corn products since the products contain corn-derived dextrose
- Patients with acute renal failure and without undergoing renal replacement therapy.
- Patients with severe liver failure or hepatic coma
- Congenital abnormality of amino acid metabolism
- Severe hyperglycemia (glucose concentration greater than 180 mg/dL or 10 mmol/L)
- Hyperkalemia (see 7 WARNINGS AND PRECAUTIONS)
- Hypercalcaemia (see 7 WARNINGS AND PRECAUTIONS)
- Hyperphosphatemia (see 7 WARNINGS AND PRECAUTIONS)
- Hypernatremia

- Hypermagnesemia
- Co-administration with calcium-containing intravenous solutions (see 7 WARNINGS AND PRECAUTIONS)

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

- CLINIMIX E products contain dextrose and amino acids (Blend B) (see Table 1). The dextrose solution and the amino acid (with electrolytes) solution are contained in separate chambers in the product package (see 4.4 Administration).
- The solutions in the two chambers must be first mixed together (see 4.4 Administration) prior to use (see Table 1 for the contents of the products in the resulting Admixed solution).
- Do not infuse the solution packaged in a chamber without prior mixing.
- Consult the Additives subsection of 4.4 Administration when including electrolytes and lipid emulsion.
- Do not add any additives including electrolytes and lipid emulsion until the solutions in the two chambers are thoroughly mixed to reduce the risk of instability of the resulting solution and formation of precipitates which may result in serious clinical outcomes (see 2 CONTRAINDICATIONS, Respiratory subsection of 7 WARNINGS AND PRECAUTIONS and 8 ADVERSE REACTIONS). Additives must be added before lipid component to facilitate visual inspection for incompatibility.
- Since CLINIMIX E products contain phosphate ions (Table 1), addition of certain cations, especially calcium ions, into the Admixed solution may result in precipitation of phosphate salts which may result in serious clinical outcomes (see 2 CONTRAINDICATIONS, Respiratory subsection 7 WARNINGS AND PRECAUTIONS and 8 ADVERSE REACTIONS).
- Discard any solution where precipitates, particulate matter, cloudiness, discoloration and/or other unusual appearance are observed.
- CLINIMIX E products should be administrated via a central vein, not a peripheral vein, to reduce the risk of phlebitic complications which can be caused by high osmolarity of the product (see 7 WARNINGS AND PRECAUTIONS and 4.4 Administration).
- During infusion, the infused solution, infusion set and catheter should periodically be checked for precipitates. If precipitates (particulate matter) are observed, the infusion must be stopped immediately and medical evaluation initiated.
- Adequate measures should be taken to prevent hyperkalemia when CLINIMIX E products are used due to the high potassium concentration of the products (30 mmol/L, see Table 1)
- If electrolytes are to be added to CLINIMIX E products, the type and the amount of electrolytes should be dictated by the status of electrolyte balance, disease condition and related vital organ function of the patient.
- For single use only.

- When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure after admixture through administration.

- It is recommended that after opening the bag, the contents should be used immediately, and should not be stored for a subsequent infusion**.**

Table 1 - The Contents of the Admixed Solution* of CLINIMIX E Amino Acids (Blend B) with Electrolytes in Dextrose Injection.

	Admixed solution* of CLINIMIX E (Blend B)		
	5% Amino Acids	**5% Amino Acids**	**5% Amino Acids**
	10% Dextrose	**16.6% Dextrose**	**20% Dextrose**
Total amino acids (g/L)	50	50	50
Nitrogen (g/L)	8.4	8.4	8.4
Dextrose (g/L)	100	166	200
Energy: Total energy from amino acids and dextrose approx. (Kcal/L) Energy from dextrose approx. (Kcal/L)	 540 340	 764 564	 880 680
Electrolytes: Sodium (mmol/L) Potassium (mmol/L) Magnesium (mmol/L) / (mEq/L) Phosphate (mmol/L) / (mEq/L) Chloride (mmol/L) Acetate (mmol/L)	 35 30 2.5 / 5 15 / 30 35 75	 35 30 2.5 / 5 15 / 30 35 75	 35 30 2.5 / 5 15 / 30 35 75
Osmolarity approx. (mOsm/L)	1152	1487	1659

* See 4.4 Administration

4.2 Recommended Dose and Dosage Adjustment

The maximum daily doses of each constituent of CLINIMIX E products (i.e., amino acids and dextrose) should be based on individual nutritional requirements and patient tolerance.

The total daily dose of these solutions depends on the patient's metabolic requirement and clinical response. The determination of nitrogen balance and accurate daily body weights (corrected for fluid balance), are probably the best means of assessing individual nitrogen requirements.

Recommended dietary allowances for protein are from approximately 0.8 g/kg of body weight for adults. It must be recognized, however, that protein as well as caloric requirements in traumatized or

malnourished patients may be increased substantially. Daily amino acid doses of approximately 1.0 to 1.5 g/kg of body weight for adults and 2 to 3 g/kg of body weight for infants with adequate calories 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 patient response to therapy. The severity of the illness being treated is the primary consideration in determining proper dose level. Higher doses, especially in infants, must be accompanied by more frequent laboratory evaluation.

Care should be exercised to ensure the maintenance of proper levels of serum potassium. It may be necessary to add additional quantities of this electrolyte to the solution in order to meet the patient's potassium intake needs. Potassium requirements in a parenteral nutrition (PN) formulation for generally healthy people with normal losses are 1-2 mmol/kg/day, but should be customized to meet individual patient needs. CLINIMIX E product inherently contains potassium 30 mmol/L, and this should be taken into account prior to any supplemental potassium additions.

In fluid restricted patients (e.g. renal failure), acceptable total daily administration volumes are dependent upon the fluid balance requirements of the patient. Extreme care should be given to prevent fluctuations of blood osmolarity and serum electrolyte concentrations. Frequent and careful monitoring is mandatory when fluid restricted patients are receiving intravenous nutrition.

Although CLINIMIX E products contains electrolytes, supplementations may be indicated according to the clinical needs of the patient. Compatibility of the additives with the product must be determined prior to and after the addition (see 4.4 Administration).

As indicated on an individual basis, vitamins and trace elements and other components (including lipids) can be added to the regimen to prevent deficiencies and complications from developing (see 4.4 Administration).

4.4 Administration

Preparation of the Product for Administration:

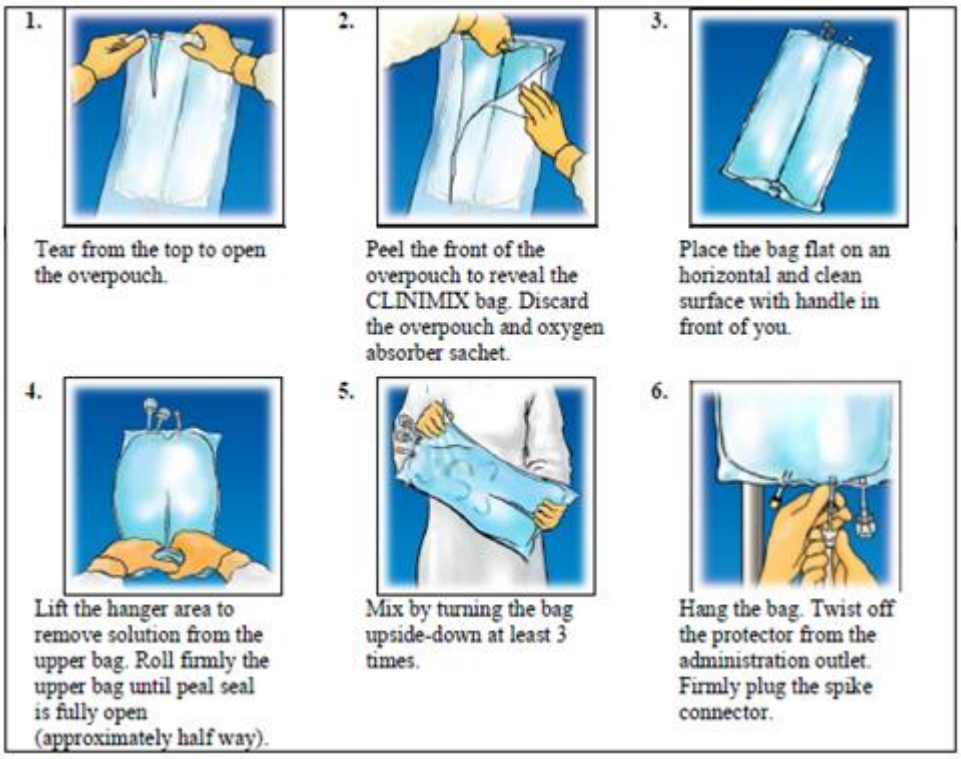
Prior to use, the solutions in the two chambers must be thoroughly mixed following the procedure described below. Any additives including electrolytes and lipid emulsion, if needed, should only be added to the mixed solution of the product. For details on the product packaging, see 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING.

Before Mixing:

- Do not open the overwrap until ready for use. The overwrap is not a sterility barrier. The inner bag maintains the sterility of the product.
- Prior to use, tear the overwrap down side at strip and take out the dual-chamber solution container (see Step 1 and Step 2 in Figure 1).
- Visually inspect the container. If the outlet port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired.
- Confirm that the content of the individual chambers is clear, colorless or slightly yellow. Otherwise, discard the solution and report to Baxter Corporation.
- Confirm that the seal between chambers is intact, i.e. solutions are contained in separate

chambers. Check for minute leaks by separately squeezing each chamber. If external leaks or leakage between the chambers are found, discard the solution.

Figure 1 - Procedure to prepare the Admixed solution of a CLINIMIX E bag.



To Mix Solutions:

As shown in Step 3 and Step 4 in Figure 1, lay the dual chamber bag onto a flat surface. Grasp the container firmly on each side of the top of the bag. Starting from the top squeeze and roll bag to open seal between chambers until the inter-chamber seal is completely broken. If the seal has not been separated completely, flip the bag over and repeat process. Ensure that the seal has been opened and the contents of both chambers are thoroughly mixed. Check for leaks.

The mixed solution should be clear and colorless or slightly yellow. Discard the mixed solution and report to Baxter Corporation when precipitates, particulate matter, cloudiness, discoloration and/or other unusual appearance are observed.

Lipid emulsion or other additives may be added, but ONLY to the mixed solution following the requirements presented under the subheading “Additives” in this section.

Additives:

The plastic chambers of the product package are made of a non-PVC lipid compatible material. If required, a lipid emulsion and/or other additives may be injected to the chamber.

Prior to and after the addition, compatibilities and stability of the resulting solution must be checked prior to the addition and further determined after the addition following the procedure "To perform an addition:" described below.

Ensure that the resulting solution is stable after an IV lipid emulsion is added. The prime destabilizers of lipid emulsions are excessive acidity (low pH) and inappropriate electrolyte concentration, particularly divalent cations (Ca^{++} and Mg^{++}). The concentration of all components should not exceed recommended guidelines. Consult a pharmacist if available.

In any parenteral nutritional regimen, calcium and phosphate ratios must be considered. Excess addition of calcium and phosphate, especially in the form of mineral salts, may result in the formation of calcium phosphate precipitates which may result in serious clinical outcomes (see Respiratory subsection of 7 WARNINGS AND PRECAUTIONS).

CLINIMIX E products contain phosphate ion (Table 1). Caution must be exercised when calcium ion and/or phosphate ion is to be added to the products to ensure the compatibility to prevent formation of calcium phosphate precipitates. The stability of the resulting solution must be checked.

To perform an addition:

1) Aseptic conditions must be observed.
2) Ensure stability and compatibility of additives.
3) Thoroughly mix the solutions in the dual chambers of the product package together (see 4.4 Administration).
4) Prepare the injection site of the bag.
5) Puncture the injection site and inject the additives using an injection needle or a reconstitution device (see step #8 for lipid addition).
6) Mix content of the bag and the additives thoroughly.
7) Inspect final solution for discoloration and particulate matter or other incompatibilities.
8) If a lipid emulsion is needed, it should be the last addition made to allow for visual inspection. Repeat Steps 5 through 7 to add the lipid emulsion and check for incompatibilities.
9) Check bag for leaks.
10) When used in neonates and children below 2 years, protect from light exposure when admixtures include trace elements and/or vitamins, after admixture through administration. Exposure of CLINIMIX E to ambient light after admixture generates peroxides and other degradation products that can be reduced by photoprotection (See 7 WARNINGS AND PRECAUTIONS).
11) Discard the solution whenever discoloration, cloudiness, precipitates, particulate matter and/or leaks are observed.
12) Ensure proper storage requirements of additives are followed.

Method of Administration:

Due to high osmolarity of the mixed solution (from approx. 1152 to 1659 mOsm/L, See Table 1), the products should be infused via central vein to reduce the risk of phlebitic complications (see General in 7 WARNINGS AND PRECAUTIONS).

After appropriate dilution, the products may be infused via peripheral vein if the central venous route is not appropriate (see below for details).

Central Vein Administration: Hypertonic mixtures of amino acids and dextrose may be administered safely by continuous infusion through a central vein catheter with the tip located in the vena cava. In addition to meeting nitrogen needs, the administration rate is governed, especially during the first few days of therapy, by the patient's tolerance to dextrose. Daily intake of amino acids and dextrose should be increased gradually to the maximum required dose as indicated by frequent determinations of urine and blood sugar levels.

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

Parenteral nutrition may be started with infusates containing lower concentrations of dextrose; dextrose content may be gradually increased to estimated caloric needs as the patient's glucose tolerance increases.

Administration by central venous catheter should be used only by those familiar with this technique and its complications.

Peripheral Vein Administration: The osmolarity of a specific infusion solution must be taken into account when peripheral administration is considered. In adult patients, the final solution should be below 900 mOsm/L. The osmolarity of CLINIMIX E products exceed this level (from 1152 to 1659 mOsm/L see Table 1). Therefore, for patients who require parenteral nutrition and in whom the central vein route is not indicated, these solutions should be diluted accordingly and then infused by peripheral vein. Sterile water for injection or sterile dextrose solution for injection with low concentration of dextrose may be used for dilution.

Administration: Depending upon the clinical condition of the patient, approximately 3 litres of parenteral nutrition solution may be administered per 24 hour period. When used postoperatively, the therapy should begin with 1000 mL on the first postoperative day. Thereafter, the dose may be increased to 3000 mL per day.

The rate of administration should be adjusted according to the dosage, the characteristics of the infused solution, the total volume intake per 24 hours and the duration of the infusion. The infusion time should be 12 to 24 hours.

The flow rate should be increased gradually. The flow rate must be adjusted taking into account the dose being administered, the daily volume intake, and the duration of the infusion. To reduce the risk of hypoglycemia after discontinuation, a gradual decrease in flow rate of administration should be considered.

Use of a final filter is recommended during administration of all parenteral nutrition solutions, where possible. For administration of parenteral solutions without lipids, a 0.22 micron filter should be used. If a lipid is also administered, then a 1.2 micron filter should be used.

During infusion, periodically and carefully inspect the infused solution inside the plastic container, the infusion tubing and catheter for precipitates. If precipitates (particulate matter) are observed, immediately stop the infusion, remove the infusion set and catheter, initiate medical evaluation and report to Baxter Corporation.

The prepared product solution is for single use only. Do not reconnect any partially used bag.

Careful attention must be given to the proper care of the intravenous catheter to avoid contamination of the blood and consequent septicemia. If fever develops, consider discontinuing therapy and removing catheter. Blood cultures should be taken and the remainder of the fluid saved for examination when deemed necessary.

It is recommended that all intravenous administration apparatus be replaced at least every 24 hours.

CLINIMIX E (Amino Acids with Electrolytes in Dextrose Injection) must not be infused through the same tubing with blood or blood components unless there is documentation that it is safe.

4.5 Missed Dose

In the event of a missed dose, the infusion should be restarted at the recommended dose and flow rate. Doses should NOT be doubled.

5 OVERDOSAGE

In the event of inappropriate administration (overdose, and/or infusion rate higher than recommended), hyperammonemia, hypervolemia, electrolyte disturbances or acidosis and/or azotemia may occur and result in severe or fatal consequences. In such situations, the infusion must be stopped immediately. If medically appropriate, further intervention may be indicated. See 7 WARNINGS AND PRECAUTIONS.

Hyperglycemia, glucosuria, and hyperosmolar syndrome may develop if dextrose infusion rate exceeds clearance.

There is no specific antidote for overdose. Emergency procedures should include appropriate corrective measures, with particular attention to respiratory and cardiovascular systems.

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table 2 - Dosage Forms, Strengths, Composition and Packaging.

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Intravenous	Solution for Infusion	Amino Acid with electrolytes solution chamber:

	CLINIMIX E 5% Amino Acids (Blend B) with Electrolytes in 10% Dextrose Injection 5% Amino Acids (Blend B) with Electrolytes in 16.6% Dextrose Injection 5% Amino Acids (Blend B) with Electrolytes in 20% Dextrose Injection	Glacial acetic acid for pH adjustment Nitrogen Water for Injection <u>Dextrose solution chamber:</u> Hydrochloric acid for pH adjustment Nitrogen Water for Injection

CLINIMIX E products are solutions for injection packaged in a dual chamber container system. The dual chamber product containers are made of a non-PVC, lipid compatible material. Lipid emulsion may be added to the chamber if required.

The left chamber contains Dextrose Injection, while the right chamber contains Amino Acid Injection with electrolytes. The products are available in amino acid blend B.

The available package sizes of CLINIMIX E products are listed in Table 3. Composition of the admixed solutions of CLINIMIX E products are provided in Table 4.

Table 3 - Package sizes of CLINIMIX E (Amino Acids with Electrolytes in Dextrose Injection) Products.

Product Description	**Volume of Admixed solution***	**Packaged solution volume in a chamber of a CLINIMIX E product**	
		Amino Acids with electrolytes	**Dextrose**
Amino Acids – Blend B			
5% Amino Acids (Blend B) with Electrolytes in 10% Dextrose Injection	1000 mL	500 mL	500 mL
5% Amino Acids (Blend B) with Electrolytes in 16.6% Dextrose Injection	1000 mL	500 mL	500 mL
5% Amino Acids (Blend B) with Electrolytes in 20% Dextrose Injection	1000 mL	500 mL	500 mL

*Package size is based on the amount of the admixed solution from the two chambers.

Table 4 - CLINIMIX E (Amino Acids (Blend B) with Electrolytes in Dextrose Injection) Products - Composition of Admixed Solution.

	CLINIMIX E (Blend B) Products		
	Composition of the admixed solution		
	5% Amino Acids	5% Amino Acids	5% Amino Acids
Contents (g/L)*	**10% Dextrose**	**16.6% Dextrose**	**20% Dextrose**
L-Alanine	10.40	10.40	10.40
L-Arginine	5.20	5.20	5.20
Glycine	10.40	10.40	10.40
L-Histidine	2.20	2.20	2.20
L-Isoleucine	2.40	2.40	2.40
L-Leucine	3.10	3.10	3.10
L-Lysine HCl	2.90	2.90	2.90
L-Methionine	2.90	2.90	2.90
L-Phenylalanine	3.10	3.10	3.10
L-Proline	2.10	2.10	2.10
L-Threonine	2.10	2.10	2.10
L-Tryptophan	0.90	0.90	0.90
L-Tyrosine	0.20	0.20	0.20
L-Valine	2.30	2.30	2.30
Dextrose	100	166	200
Electrolytes:			
Sodium Chloride	0.585	0.585	0.585
Sodium Acetate Trihydrate	3.40	3.40	3.40
equivalent to anhydrous salt	*2.05*	*2.05*	*2.05*
Dibasic Potassium Phosphate	2.61	2.61	2.61

Magnesium Chloride Hexahydrate *equivalent to anhydrous salt*	0.51 *0.24*	0.51 *0.24*	0.51 *0.24*

*Acetic acid glacial is added for pH adjustment

7 WARNINGS AND PRECAUTIONS

General

Proper administration of a CLINIMIX E product requires a knowledge of fluid and electrolyte balance nutritional status, nature of the disease, vital organ function as well as clinical expertise in prescribing parenteral nutritional (PN) regimen and recognition and treatment of the complications which may occur.

Severe water and electrolyte disorders, severe fluid overload states, and severe metabolic disorders should be corrected before starting the infusion.

Infection and sepsis may occur as a result of the use of intravenous catheters to administer parenteral formulations, poor maintenance of catheters or contaminated solutions. Immunosuppression and other factors such as hyperglycemia, malnutrition and/or their underlying disease state may predispose patients to infectious complications.

Refeeding severely undernourished patients may result in the refeeding syndrome that is characterized by the shift of potassium, phosphorus, and magnesium intracellularly as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. Careful monitoring and slowly increasing nutrient intakes while avoiding overfeeding can prevent these complications.

During prolonged parenteral nutrition with concentrated dextrose and amino acid solutions, essential fatty acid deficiency syndrome may develop, but may not be clinically apparent. Early demonstration of this condition can only be accomplished by analysis of plasma lipids. The syndrome may be prevented or corrected by appropriate treatment with intravenous lipid emulsions.

CLINIMIX E products contain high concentration of potassium ion (30 mmol/L, see Table 1. When prescribing these products, such features should be taken into account to prevent hyperkalemia.

Prior to Infusion: Do not administer unless the final prepared solution is clear. A slight yellow color does not alter the quality and activity of the product.

Due to high osmolarity (from approx. 1152 to 1659 mOsm/L, See Table 1), CLINIMIX E products may result in phlebitic complications, such as vein irritation, vein damage, and thrombosis when administrated via peripheral vein. Therefore, these products are generally administrated via central vein through an indwelling central intravenous catheter with the tip located in the superior vena cava (see 4.4 Administration).

Infusion of the preparation of CLINIMIX E products must not be through the same tubing with blood or blood components unless there is documentation that it is safe.

Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

Light exposure of solutions for intravenous parenteral nutrition, after admixture with trace elements and/or vitamins, may have adverse effects on clinical outcome in neonates, due to generation of peroxides and other degradation products. When used in neonates and children below 2 years, CLINIMIX E should be protected from ambient light after admixture until administration is complete.

Additives: Immediately prior to addition of additives or infusion, the solutions in the two chambers of the package of a CLINIMIX E product must be first mixed together. The mixed solution is called admixed solution in this document.

Compatibility of additives including electrolytes and lipid emulsions with the Admixed solution of a CLINIMIX E product must be evaluated before addition to avoid formation of precipitates in the resulting solution. Consult with pharmacist, if available (see 4.1 Dosing Considerations).

If IV lipid emulsion and other additives are to be added to the Admixed solution of a product, the additives must be added before lipid addition to facilitate visual inspection for incompatibility (see 4.4 Administration).

Precipitates in a PN solution may result in life-threatening clinical outcomes (see Respiratory subsection of 7 WARNINGS AND PRECAUTIONS and 8 ADVERSE REACTIONS).

Exercise caution to ensure that precipitates or particulate matter are not formed or present in any solutions before and after preparation of a solution for IV administration. Discard any solution where precipitates, particulate matter, cloudiness, discoloration and/or other unusual appearance are observed.

Due to presence of phosphate in CLINIMIX E product (Table 1), administration of these products may result in precipitation of calcium phosphate in patients with hyperphosphatemia, hypercalcaemia and /or co-administrated with a calcium ion-containing IV solution. Addition of calcium-containing agents to the product may result in precipitation.

If an electrolyte is to be added to a CLINIMIX E product, the type and amount of the electrolyte should be dictated by the status of electrolyte balance, disease condition and related vital organ function of the patient to avoid over-loading the electrolyte and resulting in serious adverse reactions.

Aseptic techniques are required when additives are added as nutrients in the products support growth of microorganisms.

Infusion of the Product: During infusion, the infused solution inside the plastic container, the infusion tubing and catheter should periodically be checked for precipitates and other unusual appearance (see 4 DOSAGE AND ADMINISTRATION**).** If any unusual appearance is observed, immediately stop the infusion, remove the infusion set and catheter and initiate medical evaluation.

During the administration of CLINIMIX E products, serum potassium concentration should be closely monitored to prevent hyperkalemia in case of CLINIMIX E. Administration of CLINIMIX E product must be discontinued if hyperkalemia occurs.

Administration of amino acid solutions and other nutrients via central or peripheral venous catheter may be associated with complications which can be prevented or minimized by careful attention to all aspects of the procedure. This includes attention to solution preparation, administration, and patient monitoring. It is essential that a carefully prepared protocol, based on current medical practices, be followed, preferably by an experienced team.

Careful symptomatic and laboratory monitoring for fever/chills, leukocytosis, technical complications with the access device, and hyperglycemia can help recognize early infections.

The occurrence of septic complications can be decreased with heightened emphasis on aseptic technique in catheter placement, maintenance, as well as aseptic technique in nutritional formula preparation.

Cardiovascular

Use with caution in patients with pulmonary edema or heart failure. Fluid status should be closely monitored.

Endocrine and Metabolism

Metabolic complications may occur if the nutrient intake is not adapted to the patient's requirements, or the metabolic capacity of any given dietary component is not accurately assessed. Adverse metabolic effects may arise from administration of inadequate or excessive nutrients or from inappropriate composition of an admixture for a particular patient's needs.

CLINIMIX E products may contain fructose. Exercise caution when these products are used in patients with hereditary fructose intolerance due to aldolase deficiency.

The following metabolic complications have been reported: metabolic acidosis, hypophosphatemia, alkalosis, hyperglycemia and glycosuria, osmotic diuresis and dehydration, rebound hypoglycemia, elevated liver enzymes, hypo and hypervitaminosis, electrolyte imbalances, and hyperammonemia (see 8.5 Post-Market Adverse Reactions). Frequent clinical evaluation and laboratory determinations are necessary, especially during the first few days of therapy, to prevent or minimize these complications.

Depending on extent and etiology, hyperammonemia may require immediate intervention. Should symptoms of hyperammonemia develop, administration should be discontinued and the patient’s clinical status re-evaluated.

Hyperammonemia is of special significance in newborns and infants. It is essential that blood ammonia be measured frequently in newborns and infants. In some patients this may indicate the presence of a congenital disorder of amino acid metabolism or hepatic insufficiency.

The IV administration of these solutions can lead to fluid or solute overload resulting in hyper or hypoosmolal states. The risk of hypoosmolal states is especially present in conditions associated with Antidiuretic Hormone (ADH) secretion and is proportional to the infusion rate.

Parenteral administration of these products, especially those containing high concentration of dextrose, may result in hyperglycemia, glycosuria, and hyperosmolar syndrome. Blood and urine glucose should be monitored on a routine basis in patients receiving this therapy to adequately control blood glucose level and prevent serious complications associated with hyperglycemia.

Sudden cessation in administration of a concentrated dextrose solution, such as a CLINIMIX E product, may result in rebound hypoglycemia due to continued endogenous insulin production. Parenteral nutrition mixtures should be withdrawn slowly.

Special care must be taken when giving a CLINIMIX E product with high dextrose concentration to patients with impaired glucose tolerance such as diabetics or prediabetics and uremic patients, especially when the latter are receiving peritoneal dialysis. To reduce the risk of hyperglycemia-associated complications, the infusion rate must be adjusted and/or insulin administered if blood glucose levels exceed levels considered acceptable for the individual patient.

Handling of glucose load is also frequently impaired in patients with liver failure.

Hepatic/Biliary/Pancreatic

Administration of amino acid solutions to a patient with hepatic insufficiency may result in serum amino acid imbalances, hyperammonemia, stupor and coma.

Parenteral nutrition in general as well as amino acid solutions should be used with caution in patients with pre-existing liver disease or liver insufficiency. Liver function parameters should be closely monitored in these patients, and they should be monitored for possible symptoms of hyperammonemia (see Endocrine and Metabolism subsection of 7 WARNINGS AND PRECAUTIONS). Should symptoms of hyperammonemia develop, administration should be discontinued and the patient's clinical status should be re-evaluated.

Hepatobiliary disorders including cholestasis, hepatic steatosis, fibrosis and cirrhosis, possibly leading to hepatic failure, as well as cholecystitis and cholelithiasis are known to develop in some patients on parenteral nutrition. The etiology of these disorders is thought to be multifactorial and may differ between patients. Patients developing abnormal laboratory parameters or other signs of hepatobiliary disorders should be assessed early by a clinician knowledgeable in liver diseases in order to identify possible causative and contributory factors, and possible therapeutic and prophylactic interventions.

Immune

Anaphylaxis has been reported with other parenteral nutrition products

Hypersensitivity/infusion reactions have been reported with CLINIMIX E products (see 2 CONTRAINDICATIONS and 8 ADVERSE REACTIONS).

The infusion must be stopped immediately if any signs or symptoms of a hypersensitivity / infusion reaction develop.

Since dextrose in CLINIMIX E products is derived from corn, these products should not be used in patients with known allergy to corn or corn products (see 2 CONTRAINDICATIONS).

Monitoring and Laboratory Tests

CLINIMIX E product contains sufficient electrolytes to provide for most parenteral nutritional needs. However, replacement of exceptional electrolyte loss due to nasogastric suction, fistula drainage, or unusual tissue exudation may be necessary. Particular attention should be given to monitoring serum potassium and phosphate levels.

Monitoring should be appropriate to the patient's clinical situation and condition, and may include determinations of fluid balance, water and electrolyte balance, serum osmolarity, and acid / base balance , blood glucose , serum proteins, blood ammonia levels, kidney and liver function tests, electrolytes, hemogram, arterial blood gases, and blood cultures.

Renal

Use with caution in patients with renal insufficiency. Fluid and electrolyte status should be closely monitored for water and/or electrolyte retention.

Azotemia has been reported with parenteral administration of solutions containing amino acids, and may occur in particular in the presence of renal impairment.

Respiratory

Pulmonary vascular precipitates causing pulmonary vascular emboli and pulmonary distress have been reported in patients receiving parenteral nutrition. In some cases, fatal outcomes have occurred mainly due to pulmonary thromboemboli. Although pulmonary vascular precipitates have been reported even in the absence of phosphate salt in the solution, the risk of such reaction is expected to be much higher for a PN solution containing phosphate ions. Excessive addition of calcium and and/or phosphate ions increases the risk of the formation of calcium phosphate precipitates. Precipitation distal to the in-line filter and suspected in vivo precipitate formation has also been reported.

Pulmonary vascular precipitates have been reported with parenteral nutrition products (see 8 ADVERSE REACTIONS).

If signs of pulmonary distress occur, the infusion must be stopped and medical evaluation initiated.

7.1 Special Populations

7.1.1 Pregnant Women

There are no adequate data on use of CLINIMIX E (Amino Acids with Electrolytes in Dextrose Injection) in pregnant women. Healthcare professionals should carefully consider the potential risks and benefits for each specific patient before prescribing the product.

Animal reproduction studies have not been conducted with amino acid injections. It is also not known whether amino acid injections can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Amino acid injections should be given to a pregnant woman only if clearly needed.

7.1.2 Breast-feeding

There are no adequate data on use of CLINIMIX E (Amino Acids with Electrolytes in Dextrose Injection) in lactating women. Healthcare professionals should carefully consider the potential risks and benefits for each specific patient before prescribing the product.

7.1.3 Pediatrics

There have been no studies performed by Baxter Corporation in the pediatric population. Hyperammonemia is of special significance in newborns and infants. In some patients, this may indicate the presence of a congenital disorder of amino acid metabolism or hepatic insufficiency (see Endocrine and Metabolism subsection of 7 WARNINGS AND PRECAUTIONS). Blood ammonia should be measured frequently in newborns and infants to detect hyperammonemia, should symptoms of hyperammonemia develop, administration should be discontinued and the patient's clinical status should be re-assessed.

7.1.4 Geriatrics

In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

Adverse reaction information is based on post-market experiences.

8.5 Post-Market Adverse Reactions

The following adverse reactions have been reported with CLINIMIX E formulations in the post-marketing experience, listed by MedDRA System Organ Class (SOC), then by Preferred Term in order of severity, where feasible.

Immune System Disorders:
Hypersensitivity/infusion reactions, including the following manifestations: Hypotension, Hypertension, Peripheral cyanosis, Tachycardia, Dyspnea, Vomiting, Nausea, Urticaria, Rash, Pruritus, Erythema, Hyperhidrosis, Pyrexia, Chills

Other adverse reactions reported with parenteral nutrition include:

- Anaphylaxis
- Pulmonary vascular precipitates
- Hyperglycemia; Hyperammonemia, Azotemia
- Hepatic failure, Hepatic cirrhosis, Hepatic fibrosis, Cholestasis, Hepatic steatosis, Blood bilirubin increased, Hepatic enzyme increased
- Cholecystitis, Cholelithiasis
- Infusion site thrombophlebitis, Venous irritation (infusion site phlebitis, pain, erythema, warmth, swelling, induration)
- Anaphylactic/anaphylactoid reactions, including skin, gastrointestinal and severe circulatory (shock) and respiratory manifestations as well as other hypersensitivity/infusion reactions, including arthralgia, myalgia, and headache have been reported with TRAVASOL

9 DRUG INTERACTIONS

9.2 Drug Interactions Overview

No interaction studies have been performed by Baxter Corporation with CLINIMIX E (Amino Acids with Electrolytes in Dextrose Injection).

9.4 Drug-Drug Interactions

Table 5 - Established or Potential Drug-Drug Interactions.

[Proper/Common name]	Source of Evidence	Effect	Clinical comment
ACE inhibitors	T	hyperkalemia or increased risk of hyperkalemia	Because of its high potassium content (30 mmol/L), CLINIMIX E product should be administered with caution in patients treated with agents or products that can cause hyperkalemia or increase the risk of hyperkalemia.
Angiotensin II receptor agonists			
Immunosuppressants tacrolimus and cyclosporine			
Potassium sparing diuretics (amiloride, spironolactone, triamterene)			
Calcium-containing IV products	T	May result in precipitates of calcium phosphate	Co-administration or mixing of calcium-containing IV products with a CLINIMIX E product may result in precipitates of calcium phosphate which may lead to serious adverse reactions. (see 2 CONTRAINDICATIONS, 7 WARNINGS AND PRECAUTIONS and 8 ADVERSE REACTIONS).
Corticosteroids or corticotropin	T	May increase the risk of sodium and fluid retention	Caution must be exercised when administering these injections.

Legend: C = Case Study; CT = Clinical Trial; T = Theoretical

9.5 Drug-Food Interactions

Interactions with food have not been established.

9.7 Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

Scientifically, when CLINIMIX E (Amino Acids with Electrolytes in Dextrose Injection) is administered, nitrogen balance is improved. Maximal nitrogen utilization is promoted by providing adequate calories to meet metabolic needs, usually at least 40 kcal/kg/day (168 kJ/kg/day).

CLINIMIX E products provide essential and nonessential amino acids for protein synthesis and dextrose as a source of calories to improve nitrogen balance in malnutrition or certain disease conditions. In addition, CLINIMIX E products also provide electrolytes including sodium, potassium, phosphate ions to meet individual patient's needs. (See Table 1 for the composition of the products).

10.2 Pharmacodynamics

There have been no pharmacodynamic studies performed by Baxter Corporation.

10.3 Pharmacokinetics

There have been no pharmacokinetic studies performed by Baxter Corporation.

Special Populations and Conditions

There have been no clinical pharmacology studies performed by Baxter Corporation in special populations and conditions.

11 STORAGE, STABILITY AND DISPOSAL

The dosage forms packaged in dual chamber Clarity plastic containers should be stored at temperatures between 15°C and 25°C protected from light and kept from freezing. The prepared amino acids/dextrose admixture should be administered immediately. If not, it should be stored under refrigeration (2° - 8°C) and used within 24 hours.

Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

Mixing calcium-containing IV products with CLINIMIX E products may result in precipitation of calcium phosphate which may lead to serious adverse reactions (see 2 CONTRAINDICATIONS, 7 WARNINGS AND PRECAUTIONS and 8 ADVERSE REACTIONS).

12 SPECIAL HANDLING INSTRUCTIONS

Not applicable.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

CLINIMIX E (Amino Acids with Electrolytes in Dextrose Injection) contains the following drug substances in two chambers.

- Dextrose solution (left chamber)
- Amino acid solution with electrolytes (sodium, potassium, magnesium, phosphate) (right chamber)

Blend B contains the following amino acids:

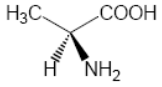
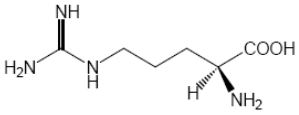
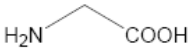
Essential Amino Acids:

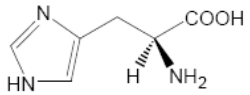
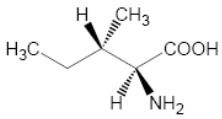
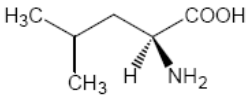
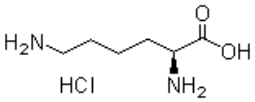
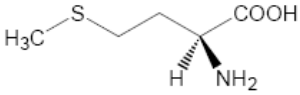
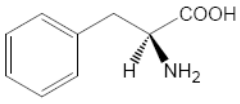
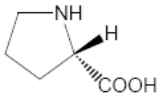
L-Histidine, L-Isoleucine, L-Leucine, L-Lysine HCl, L-Methionine, L-Phenylalanine, L-Threonine, L-Tryptophan, L-Valine

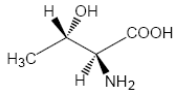
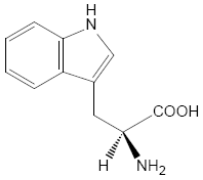
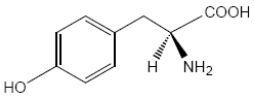
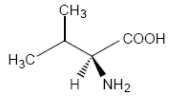
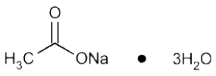
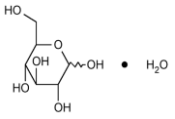
Non-Essential Amino Acids:

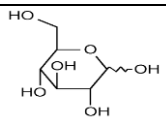
L-Alanine, L-Arginine, Glycine (Aminoacetic Acid), L-Proline, L-Tyrosine

Table 6 - CLINIMIX E (Amino Acids (Blend B) with Electrolytes in Dextrose Injection) Drug Substances.

Proper Name Chemical Name	Molecular Formula and Molecular Mass	Structural Formula	Physicochemical Properties
L-Alanine (S)-2-aminopropionic acid	$C_3H_7NO_2$ 89.09		White or almost white crystalline powder or colourless crystals, freely soluble in water, very slightly soluble in alcohol.
L-Arginine (2S)-2-amino-5-guanidinopentanoic acid	$C_6H_{14}N_4O_2$ 174.20		White or almost white crystalline powder or colourless crystals, freely soluble in water, very slightly soluble in alcohol.
Glycine Aminoacetic acid	$C_2H_5NO_2$ 75.07		White or almost white crystalline powder, freely soluble in water, very slightly soluble in alcohol.

Proper Name Chemical Name	Molecular Formula and Molecular Mass	Structural Formula	Physicochemical Properties
L-Histidine (S)-2-amino-1H-imidazole-4-propionic acid	$C_6H_9N_3O_2$ 155.15		White or almost white crystalline powder or colourless crystals, soluble in water, very slightly soluble in ethanol (96%).
L-Isoleucine (2S, 3S)-2-amino-3-methylpentanoic acid	$C_6H_{13}NO_2$ 131.17		White or almost white crystalline powder or flakes, sparingly soluble in water, slightly soluble in alcohol. It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides.
L-Leucine (2S)-2-amino-4-methylpentanoic acid	$C_6H_{13}NO_2$ 131.17		White or almost white crystalline powder or shiny flakes, sparingly soluble in water, practically insoluble in alcohol. It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides.
L-Lysine Hydrochloride (2S)-2,6 diaminohexanoic acid hydrochloride	$C_6H_{14}N_2O_2{\cdot}HCl$ 182.65		White or almost white crystalline powder or colourless crystals, freely soluble in water, very slightly soluble in ethanol.
L-Methionine (2S)-2-amino-4-(methylsulfanyl) butanoic acid	$C_5H_{11}NO_2S$ 149.21		White or almost white crystalline powder or colourless crystals, soluble in water, very slightly soluble in ethanol.
L-Phenylalanine (2S)-2-amino-3-phenylpropanoic acid	$C_9H_{11}NO_2$ 165.19		White or almost white crystalline powder or shiny, white flakes, sparingly soluble in water, very slightly soluble in alcohol. It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides.
L-Proline (S)-2-pyrrolidinecarboxylic acid	$C_5H_9NO_2$ 115.13		White or almost white crystalline powder or colourless crystals, very soluble in water, freely soluble in alcohol.

Proper Name Chemical Name	Molecular Formula and Molecular Mass	Structural Formula	Physicochemical Properties
L-Threonine (2S, 3R)-2-amino-3-hydroxybutanoic acid	$C_4H_9NO_3$ 119.12		White crystalline powder or colourless crystals, soluble in water, practically insoluble in ethanol.
L-Tryptophan (2S)-2-amino-3-(indol-3-yl)propanoic acid	$C_{11}H_{12}N_2O_2$ 204.23		White or almost white crystalline or amorphous powder, sparingly soluble in water, slightly soluble in alcohol. It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides.
L-Tyrosine (S)-2-amino-3-(4-hydroxyphenyl) propionic acid	$C_9H_{11}NO_3$ 181.19		White crystalline powder or colourless crystals, very slightly soluble in water, practically insoluble in alcohol. It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides.
L-Valine (2S)-2-amino-3-methylbutanoic acid	$C_5H_{11}NO_2$ 117.15		White or almost white crystalline powder or colourless crystals, soluble in water, very slightly soluble in ethanol.
Sodium chloride	NaCl 58.44	not provided	White crystalline powder, hygroscopic, freely soluble in water, soluble in alcohol.
Sodium acetate trihydrate	$C_2H_3NaO_2 \cdot 3H_2O$ 136.08		Colourless crystals, very soluble in water, soluble in alcohol.
Potassium Phosphate Dibasic Anhydrous	K_2HPO_4 174.18	not provided	White or almost white crystalline powder or colourless crystals, freely soluble in water, practically insoluble in anhydrous alcohol.
Magnesium chloride hexahydrate	$MgCl_2 \cdot 6H_2O$ 203.30	not provided	Colourless crystals, hygroscopic, very soluble in water, freely soluble in alcohol.
Dextrose Monohydrate* D-glucose monohydrate	$C_6H_{12}O_6 \cdot H_2O$ 198.17		White crystalline powder with a sweet taste, freely soluble in water.

Proper Name Chemical Name	Molecular Formula and Molecular Mass	Structural Formula	Physicochemical Properties
Dextrose Anhyrous* D-glucose	$C_6H_{12}O_6$ 180.16		White crystalline powder with a sweet taste, freely soluble in water.

*Formulations may contain one of the two types of dextrose

14 CLINICAL TRIALS

There is no clinical trial data available for CLINIMIX E (Blend B). Efficacy and safety have been established by the clinical use of amino acid solutions and dextrose.

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

There have been no pharmacology studies performed by Baxter Corporation.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

CLINIMIX E
(amino acids with electrolytes in dextrose injection) products

Read this carefully before you start taking CLINIMIX E and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about CLINIMIX E.

What is CLINIMIX E used for?

CLINIMIX E is used to provide nutrition to patients who are not receiving enough nutrition by eating food. CLINIMIX E will only be given to you under medical supervision.

How does CLINIMIX E work?

CLINIMIX E provides you with carbohydrates (sugars), amino acids (building blocks of protein) and other nutrients. This helps treat or prevent malnutrition.

What are the ingredients in CLINIMIX E?

Medicinal ingredients:

CLINIMIX E products are solutions for infusion, each supplied in a bag with two chambers:

- one chamber contains a dextrose solution
- one chamber contains a solution of amino acids plus electrolytes:

Amino acid chamber in CLINIMIX E (Blend B) contains: L-alanine, L-arginine, Glycine, L-histidine, L-isoleucine, L-leucine, L-lysine hydrochloride, L-methionine, L-phenylalanine, L-proline, L-threonine, L-tryptophan, L-tyrosine, L-valine plus electrolytes in the form of sodium chloride, sodium acetate trihydrate, dibasic potassium phosphate and magnesium chloride hexahydrate.

Non-medicinal ingredients:

Glacial acetic acid (for pH adjustment)
Hydrochloride acid (for pH adjustment)
Nitrogen
Water for injection

CLINIMIX E comes in the following dosage forms:

CLINIMIX E

5% Amino Acids (Blend B) with Electrolytes in 10% Dextrose Injection

5% Amino Acids (Blend B) with Electrolytes in 16.6% Dextrose Injection

5% Amino Acids (Blend B) with Electrolytes in 20% Dextrose Injection

Do not use CLINIMIX E if:

- You are allergic to any ingredients in CLINIMIX E or components of the container (See "What are the ingredients in CLINIMIX E?", above).
- Your body has problems processing certain amino acids and these amino acids are included in CLINIMIX E.
- You are being administered ceftriaxone.
- You have high plasma concentrations of one of the electrolytes included in CLINIMIX E.
- You have liver failure or coma resulting from liver failure.
- You have kidney failure and are not on dialysis.
- You have hyperglycemia (too much sugar in your blood), which is not controlled.
- You have an allergy to corn or corn products since this product contains dextrose from corn.
- You have a disorder resulting in high blood levels of substances such as potassium (hyperkalemia), calcium (hypercalcemia), phosphorus (hyperphosphatemia), sodium (hypernatremia) and magnesium (hypermagnesemia).
- You are receiving calcium-containing intravenous solutions.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CLINIMIX E. Talk about any health conditions or problems you may have, including if you:

- suffer from metabolic acidosis (when the blood is excessively acid)
- have kidney problems
- have liver problems
- are pregnant or intend to become pregnant
- are breastfeeding or intend to breastfeed
- have pulmonary edema (collection of fluid into the lung tissue)
- have heart problems or have had heart problems
- have fluid overload (too much water in your body), where you have experienced high blood pressure, gaining weight in short period of time, swelling in the ankles and legs, and shortness of breath
- have diabetes
- have hereditary fructose intolerance. This is a condition where your body cannot break down fructose properly. This product may contain small amounts of fructose.

Other warnings you should know about:

Pediatric Patients:

In newborns and infants, your healthcare professional will measure blood ammonia frequently to check for the presence of a congenital abnormality of amino acid metabolism.

Laboratory Testing:

Your doctor will need to monitor how you are doing while you are on this medicine. This means that you will need to have laboratory tests done on a routine basis.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with CLINIMIX E:

- corticosteroids
- corticotropin
- diuretics such as amiloride, spironolactone, triamterene
- blood pressure drugs
- drugs that suppress your immune system such as tacrolimus or cyclosporine

How to take CLINIMIX E:

Usual dose:

Your doctor will give you CLINIMIX E based on factors such as age, weight, condition, and any tests results that they have done. They will ensure that you are getting sufficient calories so that the amino acids will be absorbed. Always be sure to check with your doctor if anything about your condition changes.

Overdose:

If your dose is too high or is infused too quickly, the following may happen:

- the amino acid content may make your blood too acidic;
- the dextrose content may increase the glucose in your blood and urine;

Giving too high a volume may cause fluid overload.

To help prevent these events, your doctor will routinely check your condition, and test your blood and urine.

If you think you, or a person you are caring for, have taken too much CLINIMIX E, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if

there are no symptoms.

Missed Dose:

If you feel a dose has been missed contact your healthcare provider.

What are possible side effects from using CLINIMIX E?

These are not all the possible side effects you may have when taking CLINIMIX E. If you experience any side effects not listed here, tell your healthcare professional.

If you notice any changes in the way you feel during or after the treatment, tell your healthcare professional or another member of your medical team immediately.

The tests your healthcare professional will perform while you are taking the medication should reduce the risk of side effects.

Side effects may include:

- headache
- sweating
- reddening and stinging at the point where the tubing enters the body

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Allergic reactions with symptoms such as fever or chills, shivering, skin rashes, breathing difficulties, severe headache, weak or rapid pulse, nausea, vomiting			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at temperatures between 15°C and 25°C protected from light and kept from freezing.

The prepared amino acids/dextrose admixture should be administered immediately. If not, it should be stored under refrigeration (2° - 8°C) and used within 24 hours.

Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

Keep out of reach and sight of children.

If you want more information about CLINIMIX E:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website (Baxter.ca), or by calling 1-888-719-9955.

This leaflet was prepared by Baxter Corporation, Mississauga, Ontario L5N 0C2, Canada.

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