HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use CLINIMIX E safely and effectively. See full prescribing information for CLINIMIX E.

CLINIMIX E (amino acids with electrolytes in dextrose with calcium) injection, for intravenous use Initial U.S. Approval: 1997

1 INDICATIONS AND USAGE

CLINIMIX E is indicated as a source of calories, protein, and electrolytes for patients requiring parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated. CLINIMIX E may be used to treat negative nitrogen balance in patients. (1.1)

2 DOSAGE AND ADMINISTRATION

2.1 Preparation Prior to Administration

- CLINIMIX E is for intravenous infusion only into a central or peripheral vein. The choice of catheter [see Warnings and Precautions (5.1)].
- Use a 0.22 micron filter for administration of CLINIMIX E. If a lipid is also administered, use a 1.2 micron filter. (2.2, 5.7)
- Infusion should be prepared for administration before adding a lipid emulsion. (2.2, 5.7)

2.2 Important Administration Instructions

- Attach administration set. Refer to complete directions accompanying set. (2.2)
- Prepare medication port. (2.2)
- Suspend container from eyelet support. (2.2)

2.3 Instructions for Use

- Lay the bag onto a flat surface. Grasp the container firmly on each side of the top of the container. (2.3)
- Spike and hang bag. (2.3)

3 DOSAGE FORMS AND STRENGTHS

CLINIMIX E injection is available in multiple strengths. See full prescribing information for detailed description of each formulation. (3, 11)

- Concomitant treatment with ceftriaxone in neonates (age less than 28 days). (4)
- Known hypersensitivity to one or more amino acids or dextrose. (4)
- Inborn errors of amino acid metabolism. (4)
- Patients with pulmonary edema or acidosis due to low cardiac output. (4)

4 CONTRAINDICATIONS

- Pulmonary Embolism due to Pulmonary Vascular Precipitates: if signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation. (5.1)

5 WARNINGS AND PRECAUTIONS

5.1 Pulmonary Edema due to Pulmonary Vascular Precipitates: if signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation. (5.1)

5.2 Precipitation with Ceftriaxone

- If the outlet or additive port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired. (5.2)

5.3 Hypersensitivity Reactions

- Do not administer ceftriaxone simultaneously with CLINIMIX E. (5.3)

5.4 Risk of Infections

- Carefully inspect the bag prior to administration. (5.4)

5.5 Refeeding Syndrome

- Do not administer ceftriaxone in neonates. (5.5)

5.6 Hyperglycemia/Hyperglycemic State

- Do not administer ceftriaxone in neonates. (5.6)

5.7 Vein Damage and Thrombosis

- Do not administer ceftriaxone in neonates. (5.7)

5.8 Hepatobiliary Disorders

- Do not administer ceftriaxone in neonates. (5.8)

5.9 Aluminum Toxicity

- Use a 0.22 micron filter for administration of CLINIMIX E. If a lipid is also administered, use a 1.2 micron filter. (12.3, 12.3)

5.10 Risk of Parenteral Nutrition Associated Liver Disease

- If a lipid is also administered, use a 1.2 micron filter. (12.3, 12.3)

5.11 Electrolyte Imbalance and Fluid Overload

- If a lipid is also administered, use a 1.2 micron filter. (12.3, 12.3)

5.12 Monitoring/Laboratory Tests

- If a lipid is also administered, use a 1.2 micron filter. (12.3, 12.3)

5.13 Hepatobiliary Disorders

- If a lipid is also administered, use a 1.2 micron filter. (12.3, 12.3)

5.14 Lactation

- If a lipid is also administered, use a 1.2 micron filter. (12.3, 12.3)

5.15 REFERENCES

- If a lipid is also administered, use a 1.2 micron filter. (12.3, 12.3)

10 OVERDOSAGE

- If a lipid is also administered, use a 1.2 micron filter. (12.3, 12.3)

16 HOW SUPPLIED/STORAGE AND HANDLING

- If a lipid is also administered, use a 1.2 micron filter. (12.3, 12.3)

17 PATIENT COUNSELING INFORMATION

- If a lipid is also administered, use a 1.2 micron filter. (12.3, 12.3)

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

6 ADVERSE REACTIONS

7 DRUG INTERACTIONS

8 USE IN SPECIFIC POPULATIONS

9 DRUG/LABORATORY TEST INTERACTIONS

10 ADVERSE REACTIONS

11 DRUG/LABORATORY TEST INTERACTIONS

12 CLINICAL PHARMACOLOGY

13 CLINICAL PHARMACOLOGY

14 CLINICAL PHARMACOLOGY

15 REFERENCES

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.
Lipid emulsion administration should be considered with prolonged use (more than 5 days).

Monitor levels of serum potassium during therapy. It may be necessary to add additional potassium to the CLINIMIX E admixture.

Prior to administration of CLINIMIX E correct severe fluid, electrolyte and acid-base disturbances.

Storage Once Lipids are Added:

- 7. After completing transfer, use appropriate plastic clamp or metal ferrule to seal off additive port.
- 6. Open clamp on transfer set.
- 5. Twist off protector on the additive port of the container.
- 4. Prepare lipid emulsion transfer set following instructions provided.
- 3. Prepare lip emulsion transfer set following instructions provided.
- 2. Mix by turning the bag upside down at least 3 times.
- 1. Lay the bag onto a flat surface. Grasp the bag firmly with both hands at the top corners.

Instructions on Storage

Storage After Removal of Overwrap:

- Once removed from the protective foil overwrap, mixed (peel seal activated) or unmixed (peel seal intact), CLINIMIX E Injection solutions may be stored under refrigeration for up to 9 days.
- Storage Once any Additive is Added:

  Use promptly after mixing. Any storage with additives should be under refrigeration and limited to a brief period of time, less than 24 hours. After removal from refrigeration, use promptly and complete the infusion within 24 hours. Any remaining mixture must be discarded.

2.4 Preparation and Addition of Lipid Emulsion

1. Prior to adding lipid emulsion, mix amino acid and dextrose injection as shown in Figures 1-3.
2. Prepare lip emulsion transfer set following instructions provided.
3. Attach transfer set to lipid emulsion container using aseptic technique.
4. Twist off protector on the additive port of the container.
5. Attach the transfer set to the exposed additive port.
6. Open clamp on transfer set.
7. After completing transfer, use appropriate plastic clamp or metal ferrule to seal off additive port tube.
8. Remove transfer set.

Storage Once Lipids are Added:

Use promptly after mixing. Any storage with additives should be under refrigeration and limited to a brief period of time, less than 24 hours. After removal from refrigeration, use promptly and complete the infusion within 24 hours. Any remaining mixture must be discarded.

2.5 Dosing Considerations

- The dosage of CLINIMIX E should be individualized based on the patient’s clinical condition (ability to adequately metabolize amino acids and dextrose), body weight and nutritional/fluid requirements, as well as additional energy given orally/intaneously to the patient.
- Prior to initiating CLINIMIX E the following patient information should be reviewed: review of all medications, gastrointestinal function and laboratory data such as electrolytes (including magnesium, calcium, and phosphorus), glucose, urea/creatinine, liver panel, complete blood count and triglyceride level (if adding lipid emulsion). Refer to the complete prescribing information of lipid emulsion for dosing information.
- CLINIMIX E formulations have varying concentrations of protein, carbohydrate and a standard concentration of electrolytes; thus infusion rates to achieve requirements will vary. Protein, caloric, fluid and electrolyte requirements all need to be taken into consideration when determining individual patient dosage needs.
- The dosage selection is based only on the recommended protein requirements. The maximum dextrose infusion rates and calorie and fluid requirements must also be considered when determining the clinically appropriate infusion rate for patients.
- CLINIMIX E meets the total nutritional requirements for protein and dextrose in stable patients and can be individualized to meet specific needs with the addition of nutrients.
- Total daily fluid requirements can be met beyond the volume of amino acids solution by supplementing with non-carbohydrate or carbohydrate-containing electrolyte solutions. In many patients, provision of adequate calories in the form of hypotonic dextrose may require the administration of exogenous insulin to prevent hyperglycemia and glycosuria.
- Prior to administration of CLINIMIX E correct severe fluid, electrolyte and acid-base disturbances.
- Monitor levels of serum potassium during therapy. It may be necessary to add additional potassium to the CLINIMIX E admixture.
- Lipid emulsion administration should be considered with prolonged use (more than 5 days) of CLINIMIX E in order to prevent essential fatty acid deficiency (EFAD). Serum lipids should be monitored for evidence of EFAD in patients maintained on fat-free parenteral nutrition. See prescribing information of lipid emulsion.
- 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.

2.6 Recommended Dosage in Adults

The recommended daily nutritional requirements for protein and dextrose compared to the amount of nutrition provided by CLINIMIX E are shown in Table 1.

As indicated on an individual basis, maintenance vitamins, additional electrolytes, trace elements and other components (including lipids) should be administered as required to prevent deficiencies and complications from developing.

The maximum infusion rates in adult patients are shown in Table 2. In addition to meeting protein needs, the administration rate should be 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 determination of blood glucose levels.

### Table 1: Nutritional Comparison – Adult Patients

<table>
<thead>
<tr>
<th>Nutritional Requirement</th>
<th>Recommended Nutritional Requirements</th>
<th>Recommended Clinical E Adult Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>10.8 to 17.5 (Nitrogen 0.32 to 0.48)</td>
<td>17.5 to 25.5 (Nitrogen 0.32 to 0.48)</td>
</tr>
<tr>
<td>Fluid</td>
<td>100 to 150 mL/kg/hr</td>
<td>150 to 225 mL/kg/hr</td>
</tr>
<tr>
<td>Acid</td>
<td>0.25 to 0.42 g/kg.day</td>
<td>0.42 to 0.64 g/kg.day</td>
</tr>
<tr>
<td>Maximum Infusion Rate</td>
<td>4.25/5 g/kg/day</td>
<td>6/10 g/kg/day</td>
</tr>
<tr>
<td>Maximum Infusion Rate</td>
<td>4.25/10 g/kg/day</td>
<td>8/15 g/kg/day</td>
</tr>
<tr>
<td>Maximum Infusion Rate</td>
<td>4.25/25 g/kg/day</td>
<td>15/30 g/kg/day</td>
</tr>
</tbody>
</table>

*Protein is provided as amino acids. When infused intravenously amino acids are metabolized and utilized as the building blocks of protein.

### Table 2: Maximum Infusion Rate in Adult Patients

<table>
<thead>
<tr>
<th>Maximum Infusion Rate in Adult Patients</th>
<th>Maximum Infusion Rate in Adult Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluid (mL/kg/hr)</td>
<td>Protein (g/kg/day)</td>
</tr>
<tr>
<td>Maximum Infusion Rate in Adult Patients</td>
<td>Maximum Infusion Rate in Adult Patients</td>
</tr>
<tr>
<td>Fluid (mL/kg/hr)</td>
<td>Protein (g/kg/day)</td>
</tr>
<tr>
<td>Fluid (mL/kg/hr)</td>
<td>Protein (g/kg/day)</td>
</tr>
<tr>
<td>Fluid (mL/kg/hr)</td>
<td>Protein (g/kg/day)</td>
</tr>
<tr>
<td>Fluid (mL/kg/hr)</td>
<td>Protein (g/kg/day)</td>
</tr>
</tbody>
</table>

*Rate limiting factor

2.7 Dosage Modifications in Patients with Renal Impairment

Prior to administration, correct severe fluid or electrolyte imbalances. Closely monitor serum electrolyte levels and adjust the volume of CLINIMIX E administered as required [See Warnings and Precautions (B.11)].

Patients with renal impairment not needing dialysis require 0.6 to 0.8 g of protein/kg/day. Serum electrolyte levels should be closely monitored. Patients on hemodialysis or continuous renal replacement therapy should receive 1.1 to 1.8 g of protein/kg/day up to a maximum of 2.5 g of protein/kg/day based on nutritional status and estimated protein losses. The CLINIMIX E dosage can be adjusted based on the severity of renal impairment, supplementing protein as indicated. If required, additional amino acids may be added to the CLINIMIX E bag or infused separately. Compatibility of additions should be evaluated by a pharmacist and additional orders may be directed to Baxter.

2.8 Recommended Dosage in Pediatric Patients

The dosage and constant infusion rate of intravenous dextrose must be selected with care in pediatric patients, particularly neonates and low weight infants, because of the increased risk of hyperglycemia/hypoglycemia [See Use in Specific Populations (8.4)]. Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants. The infusion rate and volume should be determined by the consulting physician experienced in pediatric intravenous fluid therapy.

In pediatric patients, CLINIMIX E is dosed on the basis of protein provided as amino acids. The recommended dosage, by age group is provided in Table 3. Infusion rates are based on protein and do not take carbohydrates, fluid or electrolytes into consideration. This product does not contain the amino acids cysteine and taurine, considered conditionally essential for neonates and infants. If possible, these amino acids should be added to this product if used in this pediatric population.

### Table 3: Preterm and Term Infants Less than 1 Month of Age

<table>
<thead>
<tr>
<th>Nutritional Requirement</th>
<th>Recommended Nutritional Requirements</th>
<th>Recommended Clinical E Dosage in Preterm and Term Infants Less than 1 Month of Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluid</td>
<td>3 to 4 mL/kg/hr</td>
<td>6 to 9 mL/kg/hr</td>
</tr>
<tr>
<td>Acid</td>
<td>0.32 to 0.48 g/kg.day</td>
<td>0.48 to 0.64 g/kg.day</td>
</tr>
<tr>
<td>Maximum Infusion Rate</td>
<td>3/40 g/kg/day</td>
<td>5/60 g/kg/day</td>
</tr>
<tr>
<td>Maximum Infusion Rate</td>
<td>3/60 g/kg/day</td>
<td>5/100 g/kg/day</td>
</tr>
<tr>
<td>Maximum Infusion Rate</td>
<td>3/100 g/kg/day</td>
<td>5/150 g/kg/day</td>
</tr>
<tr>
<td>Maximum Infusion Rate</td>
<td>3/150 g/kg/day</td>
<td>5/200 g/kg/day</td>
</tr>
</tbody>
</table>

*Protein is provided as amino acids. When infused intravenously amino acids are metabolized and utilized as the building blocks of protein.

### Table 4: Pediatric Patients 1 Month to Less than 1 Year of Age

<table>
<thead>
<tr>
<th>Nutritional Requirement</th>
<th>Recommended Nutritional Requirements</th>
<th>Recommended Clinical E Dosage in Infants 1 to 11 Months Less than 1 Year of Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluid</td>
<td>500 to 1000 mL/kg/hr</td>
<td>1000 to 2000 mL/kg/hr</td>
</tr>
<tr>
<td>Acid</td>
<td>0.3 to 0.42 g/kg.day</td>
<td>0.42 to 0.64 g/kg.day</td>
</tr>
<tr>
<td>Maximum Infusion Rate</td>
<td>4/60 g/kg/day</td>
<td>5/100 g/kg/day</td>
</tr>
<tr>
<td>Maximum Infusion Rate</td>
<td>4/100 g/kg/day</td>
<td>5/150 g/kg/day</td>
</tr>
<tr>
<td>Maximum Infusion Rate</td>
<td>4/150 g/kg/day</td>
<td>5/200 g/kg/day</td>
</tr>
</tbody>
</table>

*Protein is provided as amino acids. When infused intravenously amino acids are metabolized and utilized as the building blocks of protein.
### Table 5: Pediatric Patients 1 Year to Less than 11 Years of Age

| CLINIMIX® E 4.25/5 (4.25% Amino Acid Solution/5% Dextrose [Dextrose]) Injection | CLINIMIX® E 2.75/5 (2.75% Amino Acid Solution/5% Dextrose [Dextrose]) Injection | CLINIMIX® E 2.75/2 (2.75% Amino Acid Solution/2% Dextrose [Dextrose]) Injection | CLINIMIX® E 2.75/10 (2.75% Amino Acid Solution/10% Dextrose [Dextrose]) Injection | CLINIMIX® E 4.25/10 (4.25% Amino Acid Solution/10% Dextrose [Dextrose]) Injection | CLINIMIX® E 4.25/25 (4.25% Amino Acid Solution/25% Dextrose [Dextrose]) Injection | CLINIMIX® E 5/15 (5% Amino Acid Solution/15% Dextrose [Dextrose]) Injection | CLINIMIX® E 5/20 (5% Amino Acid Solution/20% Dextrose [Dextrose]) Injection |
|---|---|---|---|---|---|---|---|---|
| Dextrose Hydrolysate, USP (100 mL) | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| Taurine | 275 | 275 | 275 | 275 | 275 | 275 | 275 | 275 |
| Tocopheryl Acetate (0.32%) | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Electrolyte Profile | | | | | | | | |
| Sodium Chloride, USP | 125 | 125 | 125 | 125 | 125 | 125 | 125 | 125 |
| Calcium Chloride Dihydrate, USP | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| Potassium Chloride, USP | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |

### Table 6: Pediatric Patients 11 Years to 17 Years of Age

| CLINIMIX® E 4.25/5 (4.25% Amino Acid Solution/5% Dextrose [Dextrose]) Injection | CLINIMIX® E 2.75/5 (2.75% Amino Acid Solution/5% Dextrose [Dextrose]) Injection | CLINIMIX® E 2.75/2 (2.75% Amino Acid Solution/2% Dextrose [Dextrose]) Injection | CLINIMIX® E 2.75/10 (2.75% Amino Acid Solution/10% Dextrose [Dextrose]) Injection | CLINIMIX® E 4.25/10 (4.25% Amino Acid Solution/10% Dextrose [Dextrose]) Injection | CLINIMIX® E 4.25/25 (4.25% Amino Acid Solution/25% Dextrose [Dextrose]) Injection | CLINIMIX® E 5/15 (5% Amino Acid Solution/15% Dextrose [Dextrose]) Injection | CLINIMIX® E 5/20 (5% Amino Acid Solution/20% Dextrose [Dextrose]) Injection |
|---|---|---|---|---|---|---|---|---|
| Dextrose Hydrolysate, USP (100 mL) | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| Taurine | 275 | 275 | 275 | 275 | 275 | 275 | 275 | 275 |
| Tocopheryl Acetate (0.32%) | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Electrolyte Profile | | | | | | | | |
| Sodium Chloride, USP | 125 | 125 | 125 | 125 | 125 | 125 | 125 | 125 |
| Calcium Chloride Dihydrate, USP | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| Potassium Chloride, USP | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |

*Protein is provided as amino acids. When infused intravenously amino acids are metabolized and utilized as the building blocks of protein.

5.2 Precipitation with Ceftriaxone

Precipitation of ceftriaxone-calcium can occur when ceftriaxone is mixed with calcium-containing parenteral nutrition solutions, such as CLINIMIX® E, in the same intravenous administration line. Do not administer ceftriaxone concurrently with CLINIMIX® E via a Y-site. Deaths have occurred in neonates (less than 28 days of age) who received concomitant intravenous calcium-containing solutions with ceftriaxone precipitates in the lungs and kidneys, even when separate infusion lines were used. CLINIMIX® E is contraindicated in neonates receiving ceftriaxone [see Contraindications (4)]. Use in Specific Populations (8.4).

In patients older than 28 days (including adults), ceftriaxone and CLINIMIX® E may be administered sequentially if the infusion lines are thoroughly flushed between infusions with a compatible fluid.

5.3 Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis have been reported with CLINI-MIX E. Stop infusion immediately and treat patient accordingly if any signs or symptoms of a hypersensitivity reaction develops. Signs or symptoms may include: hypotension, hypotension, peripheral cyanosis, tachycardia, dyspnea, vomiting, nausea, urticaria, rash, pruritus, urticaria, hypotension, pyrexia, and chills.

5.4 Risk of Infections

Patients who require parenteral nutrition are at high risk of infections because the nutritional components of these solutions can support microbial growth. Infection and sepsis may also occur as a result of the use of intravenous catheters to administer parenteral nutrition. The risk of infection is increased in patients with malnutrition-associated immunosuppression, hyperglycemia exacerbated by dextrose infusion, long-term use and poor maintenance of intravenous catheters, or immunosuppressive effects of other concomitant conditions, drugs, or other components of the parenteral formula (e.g., lipid emulsion).

To decrease the risk of infection, ensure aseptic technique in catheter placement and maintenance, as well as aseptic technique in the preparation and administration of the nutritional formula.

Monitor for signs and symptoms (including fever and chills) of early infections, including...
Because of its potassium content, CLINIMIX E should be administered with caution in patients with cardiac failure. Diabetic patients are also at risk of developing hyperkalemic hyperglycemic state. Monitor blood glucose levels and treat hyperglycemia immediately.

7.1 Drugs that Can Cause Hyperkalemia

- Histadine
- Phenylalanine

Table 8: Formulas for Amino Acids

<table>
<thead>
<tr>
<th>Amino Acid</th>
<th>Formula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alanine</td>
<td>CH₃CH(NH₂)CH₂COOH</td>
</tr>
<tr>
<td>Aspartic acid</td>
<td>HOOC-CH(NH₂)-CH₂-COOH</td>
</tr>
<tr>
<td>cystine</td>
<td>S-S</td>
</tr>
<tr>
<td>Glutamic acid</td>
<td>HOOC-CH(NH₂)-CH₂-COOH</td>
</tr>
<tr>
<td>Glutathione</td>
<td>CH₃CH(NH₂)CH₂-S-(CH₂)₂-S-(CH₂)₂-S-(CH₂)₂-S-CH₃</td>
</tr>
<tr>
<td>Glycine</td>
<td>CH₂NH₂</td>
</tr>
<tr>
<td>Histadine</td>
<td>C₆H₁₃N₂O₂</td>
</tr>
<tr>
<td>Isoleucine</td>
<td>CH₃CH₂CH(NH₂)CH(CH₃)COOH</td>
</tr>
<tr>
<td>Lysine</td>
<td>CH₂NH(CH₃)CH₂CH₂CH₂CH₂CH₂NH₂</td>
</tr>
<tr>
<td>Methionine</td>
<td>CH₃CSCH₂CH₂CH₂CH₂NH₂</td>
</tr>
<tr>
<td>Phenylalanine</td>
<td>C₆H₅CH₂CH₂NH₂</td>
</tr>
<tr>
<td>Threonine</td>
<td>CH₃CH(OH)CH₂NH₂</td>
</tr>
<tr>
<td>Tryptophan</td>
<td>C₁₁H₁₂N₂O₂</td>
</tr>
<tr>
<td>Tyrosine</td>
<td>C₁₀H₇NO₄</td>
</tr>
<tr>
<td>Valine</td>
<td>CH₃CH₂CH(NH₂)CH₂COOH</td>
</tr>
</tbody>
</table>

7.2 Drug Interactions

7.3 Drugs that Can Cause Hyperkalemia

Because of its potassium content, CLINIMIX E should be administered with caution in pa-

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate or well-controlled studies in pregnant women with CLINIMIX E. Additional animal reproduction studies have not been conducted with amino acid solutions and electrolytes and dextrose. It is not known whether CLINIMIX E can cause fetal harm when administered to a pregnant woman.

The estimated background risk of major birth defects and miscarriage for the indicated pop-

8.2 Lactation

Risk Summary

It is not known whether CLINIMIX E is present in human milk. There are no data on the effects of CLINIMIX E on the breastfed infant or on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for CLINIMIX E and any potential adverse effects on the breastfed child from CLINIMIX E or the underlying maternal condition.

8.3 Pediatric Use

Safety and effectiveness of CLINIMIX E in pediatric patients have not been established by adequate and well-controlled studies. Use of dextrose, amino acid solutions and electrolytes in pediatric patients is based on clinical practice [see Dosage and Administration (2.8)].

Deaths have occurred in neonates (less than 28 days of age) who received concomitant intravenous calcium-containing solutions with ceftriaxone resulting from calcium-ceftriax-

8.4 Pediatric Use

10 OVERDOSAGE

An increased infusion rate of CLINIMIX E can cause hyperglycemia, hyperosmolality, and adverse effects on water and electrolyte balance [see Warnings and Precautions (5.8, 5.11)].

Severe hyperglycemia and severe diuretic hypernatremia, and their complications, can be fatal. Discontinue infusion and institute appropriate corrective measures in the event of overhy-

11 DESCRIPTION

CLINIMIX E sulfite-free (amino acids with electrolytes in dextrose with calcium) injection for infusion contains amino acids, electrolytes, and dextrose. CLINIMIX E contains no more than 25 mcg/L of aluminum. However, with prolonged paren-

Table 8: Formulas for Amino Acids

<table>
<thead>
<tr>
<th>Electrolytes</th>
<th>Formula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Acetate</td>
<td>Na₂H₃C₆H₅O₂</td>
</tr>
<tr>
<td>Potassium Phosphate, dibasic</td>
<td>K₂HPO₄</td>
</tr>
<tr>
<td>Magnesium Chloride</td>
<td>MgCl₂·6H₂O</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>NaCl</td>
</tr>
<tr>
<td>Essential Amino Acids</td>
<td></td>
</tr>
</tbody>
</table>
The injection port chamber contains dextrose with calcium. The formula for Calcium Chloride is: C₆H₁₂O₆ • H₂O. Dextrose, USP, is chemically designated D-glucose, monohydrate (C₆H₁₂O₆ • H₂O) and has the following structure:

![](image)

Dextrose is derived from corn. See Table 7 for composition, pH, osmolality, ionic concentration and caloric content of the admixed product (see Dosage Forms and Strengths [3]).

The dual chamber container is a lipid-compatible plastic container (PL 2401 Plastic). CLINIMIX E contains no more than 25 mcg/L of aluminum.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

CLINIMIX E is used as a supplement of nutrition in patients, providing macronutrients (amino acids and dextrose) and micronutrients (electrolytes) parenterally.

The administered dextrose is oxidized to carbon dioxide and water, yielding energy. The amino acids provide the structural units that make up proteins and are used to synthesize proteins and other biomolecules or are oxidized to urea and carbon dioxide as a source of energy.

12.3 Pharmacokinetics

The disposition of infused amino acids, dextrose, and electrolytes are essentially the same as those absorbed from food.

15 REFERENCES


16 HOW SUPPLIED/STORAGE AND HANDLING

CLINIMIX E (amino acids with electrolytes in dextrose with calcium) injection (sulfite-free) is available in 1000 mL and 2000 mL volumes (see Table 9).

Table 9: CLINIMIX Formulations

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Code</th>
<th>NDC Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLINIMIX E 2.75/10 sulfite-free (2.75% Amino Acid with Electrolytes in 10% Dextrose with Calcium Injection)</td>
<td>2B7716</td>
<td>0338-1143-03</td>
</tr>
<tr>
<td>CLINIMIX E 4/25/10 sulfite-free (4% Amino Acid with Electrolytes in 10% Dextrose with Calcium Injection)</td>
<td>2B7714</td>
<td>0338-1145-04</td>
</tr>
<tr>
<td>CLINIMIX E 4.25/5 sulfite-free (4.25% Amino Acid with Electrolytes in 5% Dextrose with Calcium Injection)</td>
<td>2B7710</td>
<td>0338-1144-03</td>
</tr>
<tr>
<td>CLINIMIX E 4.25/25 sulfite-free (4.25% Amino Acid with Electrolytes in 25% Dextrose with Calcium Injection)</td>
<td>2B7719</td>
<td>0338-1146-04</td>
</tr>
<tr>
<td>CLINIMIX E 5/25 sulfite-free (5% Amino Acid with Electrolytes in 25% Dextrose with Calcium Injection)</td>
<td>2B7717</td>
<td>0338-1147-03</td>
</tr>
<tr>
<td>CLINIMIX E 5/15 sulfite-free (5% Amino Acid with Electrolytes in 15% Dextrose with Calcium Injection)</td>
<td>2B7718</td>
<td>0338-1148-03</td>
</tr>
<tr>
<td>CLINIMIX E 5/10 sulfite-free (5% Amino Acid with Electrolytes in 10% Dextrose with Calcium Injection)</td>
<td>2B7711</td>
<td>0338-1149-04</td>
</tr>
<tr>
<td>CLINIMIX E 5/5 sulfite-free (5% Amino Acid with Electrolytes in 5% Dextrose with Calcium Injection)</td>
<td>2B7710</td>
<td>0338-1150-04</td>
</tr>
</tbody>
</table>

Minimize exposure of CLINIMIX E to heat and avoid excessive heat. Protect from freezing.

Store CLINIMIX E at room temperature (25°C/77°F) (may briefly store at up to 40°C/104°F). Refrigerated storage is limited to 9 days once the protective foil overwrap has been opened. Do not use if the protective foil overwrap has been previously opened or damaged. For storage of admixed solutions see Dosage and Administration (2.3, 2.4).

17 PATIENT COUNSELING INFORMATION

Inform patients, caregivers, or home healthcare providers of the following risks of CLINITMIX E:

- Pulmonary embolism due to pulmonary vascular precipitates (see Warnings and Precautions (5.1))
- Death in neonates due to calcium-ceftriaxone precipitates (see Warnings and Precautions (5.9))
- Hypersensitivity reactions (see Warnings and Precautions (5.3))
- Risk of Infections (see Warnings and Precautions (5.4))
- Vein damage and thrombosis (see Warnings and Precautions (5.7))
- Heparin-induced disorders (see Warnings and Precautions (5.8))
- Aluminum toxicity (see Warnings and Precautions (5.9))

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