CLIMIX- leucine, phenylalanine, lysine, methionine, isoleucine, valine, histidine, threonine, tryptophan, alanine, glycine, arginine, proline, serine, tyrosine, dextrose injection

CLIMIX (amino acids in dextrose) injection, for intravenous use
Initial U.S. Approval: 1997

INDICATIONS AND USAGE
CLIMIX is indicated as a source of calories and protein for patients requiring parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated. CLIMIX may be used to treat negative nitrogen balance in patients. (1)

DOSAGE AND ADMINISTRATION
See full prescribing information for information on preparation, administration, instructions for use, dosing considerations, including the recommended dosage in adults and pediatrics, and dosage modifications in patients with renal impairment. (2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8)

DOSAGE FORMS AND STRENGTHS
CLIMIX is available in multiple strengths. See full prescribing information for detailed description of each formulation. (3, 11)

CONTRAINDICATIONS

- 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)

WARNINGS AND PRECAUTIONS

- Pulmonary Embolism due to Pulmonary Vascular Precipitates: if signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation. (5.1)
- Hypersensitivity Reactions: monitor for signs and symptoms and discontinue infusion if reactions occur. (5.2)
- Risk of Infections, Refeeding Complications, and Hyperglycemia or Hyperosmolar Hyperglycemic State: monitor for signs and symptoms; monitor laboratory parameters. (5.3, 5.4, 5.5)
- Vein Damage and Thrombosis: solutions with osmolarity of ≥ 900 mOsm/L must be infused through a central catheter. (2.2, 5.6)
- Hepatobiliary Disorders: monitor liver function parameters and ammonia levels. (5.7)
- Aluminum Toxicity: increased risk in patients with renal impairment, including preterm infants. (5.8, 8.4)
- Parenteral Nutrition Associated Liver Disease: increased risk in patients who receive parenteral nutrition for extended periods of time, especially preterm infants; monitor liver function tests, if abnormalities occur consider discontinuation or dosage reduction. (5.9, 8.4)
- Electrolyte Imbalance and Fluid Overload: patients with cardiac insufficiency or renal impairment may require adjustment of fluid, protein and electrolyte content. (5.10, 8.4)

ADVERSE REACTIONS

Adverse reactions include diuresis, extravasation, glycosuria, hyperglycemia, and hyperosmolar coma. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Baxter Healthcare at 1-866-888-2472 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

USE IN SPECIFIC POPULATIONS

Pediatric Use: increased risk of hypoglycemia/hyperglycemia: monitor serum glucose concentrations. (8.4)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 10/2018
FULL PRESCRIBING INFORMATION: CONTENTS*
1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
  2.1 Preparation Prior to Administration
  2.2 Important Administration Instructions
  2.3 Instructions for Use
  2.4 Preparation and Addition of Lipid Emulsion
  2.5 Dosing Considerations
  2.6 Recommended Dosage in Adults
  2.7 Dosage Modifications in Patients with Renal Impairment
  2.8 Recommended Dosage in Pediatric Patients
  2.9 Discontinuation of CLINIMIX
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
  5.1 Pulmonary Embolism due to Pulmonary Vascular Precipitates
  5.2 Hypersensitivity Reactions
  5.3 Risk of Infections
  5.4 Refeeding Syndrome
  5.5 Hyperglycemia or Hyperosmolar Hyperglycemic State
  5.6 Vein Damage and Thrombosis
  5.7 Hepatobiliary Disorders
  5.8 Aluminum Toxicity
  5.9 Risk of Parenteral Nutrition Associated Liver Disease
  5.10 Electrolyte Imbalance and Fluid Overload
  5.11 Monitoring/Laboratory Tests
6 ADVERSE REACTIONS
8 USE IN SPECIFIC POPULATIONS
  8.1 Pregnancy
  8.2 Lactation
  8.4 Pediatric Use
  8.5 Geriatric Use
10 OVERDOSAGE
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
  12.1 Mechanism of Action
  12.3 Pharmacokinetics
15 REFERENCES
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION
* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE
CLINIMIX is indicated as a source of calories and protein for patients requiring parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated. CLINIMIX may be used to treat negative nitrogen balance in patients.
2 DOSAGE AND ADMINISTRATION

2.1 Preparation Prior to Administration

- Tear protective clear overwrap across top at slit and remove solution container. Small amounts of moisture may be found on the solution container from water permeating from inside the container. The amount of permeated water is insufficient to affect the solution significantly. If larger amounts of water are found, the container should be checked for tears or leaks.
- Inspect the container prior to activation. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Evaluate the following:
  - If the outlet or additive port protectors are damaged, detached, or not present, discard container as solution path sterility may be impaired.
  - Check to ensure seal between chambers is intact, solutions are contained in separate chambers, and the content of the individual chambers is clear, colorless or slightly yellow. Discard if the seal is broken or if the solution is bright yellow or yellowish brown.
  - Check for minute leaks by separately squeezing each chamber. If external leaks or leakage between the chambers are found, discard solution as sterility or stability may be impaired.

- Lipids and/or additives can be introduced to the container after opening seal between chambers. Because additives may be incompatible, evaluate all additions to the plastic container for compatibility. Activate chambers of container prior to introduction of additives. Mix thoroughly when additives have been introduced. Supplemental medication may be added with a 19 to 22 gauge needle through the medication port.
- 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 [see Warnings and Precautions (5.1)].
- Inspect the container to ensure precipitates have not formed during the mixing or addition of additives. A slight yellow color does not alter the quality and efficacy of this product. If lipid has been added, ensure the emulsion has not separated. Separation of the emulsion can be visibly identified by a yellowish streaking or the accumulation of yellowish droplets in the mixed emulsion. Discard the admixture if any of the above are observed.

2.2 Important Administration Instructions

- Set the vent to the closed position on a vented intravenous administration set to prevent air embolism.
- Use a dedicated line without any connections to avoid air embolism.
- CLINIMIX is for intravenous infusion only into a central or peripheral vein. The choice of a central or peripheral venous route should depend on the osmolarity of the final infusate. Solutions with osmolarity of 900 mOsm/L or greater must be infused through a central catheter [see Warnings and Precautions (5.6)].
  - For central vein infusion only: CLINIMIX 4.25/10, 5/15, 5/20
  - For central or peripheral vein infusion: CLINIMIX 4.25/5

- The solution should be inspected for precipitates before admixing, after admixing, and again before administration.
- Use a 0.22 micron filter for administration of CLINIMIX. If a lipid is also administered, use a 1.2 micron filter.
- If lipid emulsion is added, do not use administration sets and lines that contain di-2-ethylhexyl
2.3 Instructions for Use

1. Open by tearing protective clear overwrap, which includes an oxygen-absorbing sachet, across top at slit and remove solution container. Discard the oxygen-absorbing sachet after removal from the clear overwrap.
2. To proceed with activation, the container should be at room temperature. Lay the room temperature container onto a flat surface. Grasp the container firmly on each side of the top of the container (Figure 1).
3. Starting from the top, using some pressure, slowly roll the container to open seal between chambers as shown in Figure 2. Do not pull or rip the seal apart. The seal must be completely opened towards the port side of the container. The upper section of the seal towards the hanger side can remain unbroken.
4. Mix the contents thoroughly by inverting the container upside down to ensure a homogenous admixture (Figure 3).
5. Once the container is mixed, check for leaks.
6. Make additions (if prescribed).
   Because additives may be incompatible, evaluate all additions to the container for compatibility and stability of the resulting preparation. Consult with pharmacist, if available. Questions about compatibility may be directed to Baxter. If it is deemed advisable to introduce additives, use aseptic technique. For information on adding lipid emulsions see Dosage and Administration (2.4).
   a. Prepare medication port.
   b. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
   c. Mix solution and medication thoroughly (Figure 3). For high density medication (high specific gravity), such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.
7. Inspect final solution for discoloration and particulate matter. Check for leaks.
8. Spike and hang container.
   d. Suspend container from eyelet support.
   e. Twist off protector from outlet port at bottom of container (Figure 4).
   f. Attach administration set. Refer to complete directions accompanying set.

For single dose only. Discard unused portion.

Figures 1–4:
Instructions on Storage

Storage After Removal of Overwrap:

Once removed from the protective clear overwrap, mixed (peel seal activated) or unmixed (peel seal intact) CLINIMIX 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 lipid 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, no longer than 24 hours. After removal from refrigeration, use promptly and complete the infusion within 24 hours. Any mixture remaining must be discarded.

2.5 Dosing Considerations

- The dosage of CLINIMIX 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/enterally to the patient. Prior to initiating CLINIMIX the following patient information should be reviewed: all concomitant 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 formulations have varying concentrations of protein and carbohydrate; 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 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 hypertonic dextrose may require the administration of exogenous insulin to prevent hyperglycemia and glycosuria.
- Prior to administration of CLINIMIX correct severe fluid, electrolyte and acid-base disorders.
- Monitor levels of serum potassium during therapy. It may be necessary to add potassium to the CLINIMIX admixture.
- Lipid emulsion administration should be considered with prolonged use (more than 5 days) of CLINIMIX 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 are shown in Table 1.

As indicated on an individual basis, maintenance vitamins, 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 show in Table 2.

In addition to meeting protein needs, the administration rate should be governed, especially during the first few day 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 blood glucose levels.

Table 1: Nutritional Comparison –Adult Patients

<table>
<thead>
<tr>
<th>Recommended Nutritional</th>
<th>Recommended CLINIMIX Adult Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Requirements

<table>
<thead>
<tr>
<th>Patient Status</th>
<th>Requirements</th>
<th>CLINIMIX 4.25/5</th>
<th>CLINIMIX 4.25/10</th>
<th>CLINIMIX 5/15</th>
<th>CLINIMIX 5/20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stable Patients</td>
<td>Minimum needed to deliver adequate nutrition</td>
<td>19 to 40</td>
<td>19 to 40</td>
<td>16 to 40</td>
<td>16 to 40</td>
</tr>
<tr>
<td>Critically Ill Patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Fluid (mL/kg/day)**: 30 to 40

**Protein (g/kg/day)**: 0.8 to 1 (0.13 to 0.16) to 1.5 to 2 (0.24 to 0.32)

**Dextrose (g/kg/day)**: 
- Stable Patients: ≤10
- Critically Ill Patients: 0.95 to 2

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

<table>
<thead>
<tr>
<th>Maximum Infusion Rate (mL/kg/hour)</th>
<th>CLINIMIX 4.25/5</th>
<th>CLINIMIX 4.25/10</th>
<th>CLINIMIX 5/15</th>
<th>CLINIMIX 5/20</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.4</td>
<td>2.4</td>
<td>1.67</td>
<td>1.25</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Corresponding infusion rate</th>
<th>Amino Acid (g/kg/hour)</th>
<th>Dextrose (g/kg/hour)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Maximum Infusion Rate (mL/kg/hour)</strong></td>
<td>0.1*</td>
<td>0.12</td>
</tr>
<tr>
<td><strong>Corresponding infusion rate</strong></td>
<td><strong>0.1</strong></td>
<td><strong>0.24</strong></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 administered as required [see Warnings and Precautions (5.10)].

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 1.2 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 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 container or infused separately. Compatibility of additions should be evaluated by a pharmacist and questions 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 caution 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 is dosed on the basis of protein provided as amino acids. The
recommended dosage, by age group is provided in Tables 3 - 6. 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>Infusion Rate Range (mL/kg/hr)</th>
<th>Recommended Nutrition Requirements</th>
<th>Recommended CLINIMIX Dosage in Preterm and Term Infants Less than 1 Month of Age</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CLINIMIX 4.25/5</td>
<td>CLINIMIX 4.25/10</td>
</tr>
<tr>
<td>Fluid (mL/kg/day)</td>
<td>2.9 to 3.9</td>
<td>2.9 to 3.9</td>
</tr>
<tr>
<td>Protein* (g/kg/day) (Nitrogen g/kg/day)</td>
<td>3 to 4 (0.48 to 0.64)</td>
<td>3 to 4 (0.48 to 0.64)</td>
</tr>
<tr>
<td>Dextrose (g/kg/day)</td>
<td>7 to 20</td>
<td>3.5 to 4.7</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>Infusion Rate Range (mL/kg/hr)</th>
<th>Recommended Nutrition Requirements</th>
<th>Recommended CLINIMIX Dosage in Pediatric Patients 1 Month to Less than 1 Year of Age</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CLINIMIX 4.25/5</td>
<td>CLINIMIX 4.25/10</td>
</tr>
<tr>
<td>Fluid (mL/kg/day)</td>
<td>2 to 2.9</td>
<td>2 to 2.9</td>
</tr>
<tr>
<td>Protein* (g/kg/day) (Nitrogen g/kg/day)</td>
<td>2 to 3 (0.32 to 0.48)</td>
<td>2 to 3 (0.32 to 0.48)</td>
</tr>
<tr>
<td>Dextrose (g/kg/day)</td>
<td>7 to 20</td>
<td>2.4 to 3.5</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

<table>
<thead>
<tr>
<th>Recommended Nutritional Requirements</th>
<th>Recommend CLINIMIX Dosage in Pediatric Patients 1 Year to Less than 11 Years of Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLINIMIX 4.25/5</td>
<td>CLINIMIX 4.25/10</td>
</tr>
<tr>
<td>Infusion Rate Range (mL/kg/hr)</td>
<td>2 to 2.9</td>
</tr>
<tr>
<td>Fluid (mL/kg/day)</td>
<td>100 mL/kg for the first 10 kg + 50 mL/kg for the second 10 kg.</td>
</tr>
<tr>
<td>Protein* (g/kg/day) (Nitrogen g/kg/day)</td>
<td>2 to 3 (0.32 to 0.48)</td>
</tr>
<tr>
<td>Dextrose (g/kg/day)</td>
<td>7 to 20</td>
</tr>
</tbody>
</table>
Table 6: Pediatric Patients 11 Years to 17 Years of Age

<table>
<thead>
<tr>
<th>Requirements</th>
<th>CLINIMIX 4.25/5</th>
<th>CLINIMIX 4.25/10</th>
<th>CLINIMIX 5/15</th>
<th>CLINIMIX 5/20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infusion Rate Range (mL/kg/hr)</td>
<td>0.8 to 1.5</td>
<td>0.8 to 1.5</td>
<td>0.7 to 1.3</td>
<td>0.7 to 1.3</td>
</tr>
<tr>
<td>Fluid (mL/kg/day)</td>
<td>19 to 36</td>
<td>19 to 36</td>
<td>17 to 31</td>
<td>17 to 31</td>
</tr>
<tr>
<td>Protein* (g/kg/day) (Nitrogen g/kg/day)</td>
<td>0.8 to 1.5 (0.13 to 0.24)</td>
<td>0.8 to 1.5 (0.13 to 0.24)</td>
<td>0.8 to 1.5 (0.13 to 0.24)</td>
<td>0.8 to 1.5 (0.13 to 0.24)</td>
</tr>
<tr>
<td>Dextrose (g/kg/day)</td>
<td>5 to 9</td>
<td>1 to 1.8</td>
<td>1.9 to 3.6</td>
<td>2.5 to 4.7</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.

2.9 Discontinuation of CLINIMIX

To reduce the risk of hypoglycemia after discontinuation, a gradual decrease in flow rate in the last hour of infusion should be considered.

3 DOSAGE FORMS AND STRENGTHS

CLINIMIX is available in 1000 mL and 2000 mL dual chamber containers. The individual chambers contain essential and nonessential amino acids and dextrose. Table 7 describes the individual components of CLINIMIX.
<table>
<thead>
<tr>
<th>Strength of CLINIMIX</th>
<th>CLINIMIX 4.25/5 sulfite-free (4.25% Amino Acid in 5% Dextrose) Injection</th>
<th>CLINIMIX 4.25/10 sulfite-free (4.25% Amino Acid in 10% Dextrose) Injection</th>
<th>CLINIMIX 5/15 sulfite-free (5% Amino Acid in 15% Dextrose) Injection</th>
<th>CLINIMIX 5/20 sulfite-free (5% Amino Acid in 20% Dextrose) Injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dextrose Hydrous, USP (g/100 mL)</td>
<td>5</td>
<td>10</td>
<td>15</td>
<td>20</td>
</tr>
<tr>
<td>Amino Acids (g/100 mL)</td>
<td>4.25</td>
<td>4.25</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Total Nitrogen (mg/100 mL)</td>
<td>702</td>
<td>702</td>
<td>826</td>
<td>826</td>
</tr>
<tr>
<td>Leucine</td>
<td>311</td>
<td>311</td>
<td>365</td>
<td>365</td>
</tr>
<tr>
<td>Isoleucine</td>
<td>255</td>
<td>255</td>
<td>300</td>
<td>300</td>
</tr>
<tr>
<td>Valine</td>
<td>247</td>
<td>247</td>
<td>290</td>
<td>290</td>
</tr>
<tr>
<td>Lysine (added as the hydrochloride salt)</td>
<td>247</td>
<td>247</td>
<td>290</td>
<td>290</td>
</tr>
<tr>
<td>Phenylalanine</td>
<td>238</td>
<td>238</td>
<td>280</td>
<td>280</td>
</tr>
<tr>
<td>Histidine</td>
<td>204</td>
<td>204</td>
<td>240</td>
<td>240</td>
</tr>
<tr>
<td>Threonine</td>
<td>179</td>
<td>179</td>
<td>210</td>
<td>210</td>
</tr>
<tr>
<td>Methionine</td>
<td>170</td>
<td>170</td>
<td>200</td>
<td>200</td>
</tr>
<tr>
<td>Tryptophan</td>
<td>77</td>
<td>77</td>
<td>90</td>
<td>90</td>
</tr>
<tr>
<td>Alanine</td>
<td>880</td>
<td>880</td>
<td>1035</td>
<td>1035</td>
</tr>
<tr>
<td>Arginine</td>
<td>489</td>
<td>489</td>
<td>575</td>
<td>575</td>
</tr>
<tr>
<td>Glycine</td>
<td>438</td>
<td>438</td>
<td>515</td>
<td>515</td>
</tr>
<tr>
<td>Proline</td>
<td>289</td>
<td>289</td>
<td>340</td>
<td>340</td>
</tr>
<tr>
<td>Serine</td>
<td>213</td>
<td>213</td>
<td>250</td>
<td>250</td>
</tr>
<tr>
<td>Tyrosine</td>
<td>17</td>
<td>17</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Acetate†</td>
<td>37</td>
<td>37</td>
<td>42</td>
<td>42</td>
</tr>
<tr>
<td>Chloride‡</td>
<td>17</td>
<td>17</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>pH§ (Range)</td>
<td>6.0 (4.5 to 7.0)</td>
<td>6.0 (4.5 to 7.0)</td>
<td>6.0 (4.5 to 7.0)</td>
<td>6.0 (4.5 to 7.0)</td>
</tr>
<tr>
<td>Osmolarity (mOsmol/L) (calc)</td>
<td>675</td>
<td>930</td>
<td>1255</td>
<td>1505</td>
</tr>
<tr>
<td>Caloric Content (kcal/L)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>From Dextrose</td>
<td>170</td>
<td>340</td>
<td>510</td>
<td>680</td>
</tr>
<tr>
<td>From Amino Acids</td>
<td>170</td>
<td>170</td>
<td>200</td>
<td>200</td>
</tr>
<tr>
<td>TOTAL (Dextrose and Amino Acids)</td>
<td>340</td>
<td>510</td>
<td>710</td>
<td>880</td>
</tr>
</tbody>
</table>

* Balanced by ions from amino acids.
4 CONTRAINDICATIONS

The use of CLINIMIX is contraindicated in:

- Patients with known hypersensitivity to one or more amino acids or dextrose [see Warnings and Precautions (5.2)].
- Patients with inborn errors of amino acid metabolism due to risk of severe metabolic and neurologic complications.
- Patients with pulmonary edema or acidosis due to low cardiac output.

5 WARNINGS AND PRECAUTIONS

5.1 Pulmonary Embolism due to Pulmonary Vascular Precipitates

Pulmonary vascular precipitates causing pulmonary vascular emboli and pulmonary distress have been reported in patients receiving parenteral nutrition. In some cases, fatal outcomes due to pulmonary embolism have occurred. CLINIMIX contains no added phosphorus. Patients, especially those with hypophosphatemia, may require the addition of phosphate. To prevent hypocalcemia, calcium supplementation should always accompany phosphate administration. Excessive addition of calcium and phosphate increases the risk of the formation of calcium phosphate precipitates. Precipitates have been reported even in the absence of phosphate salt in the solution. Precipitation following passage through an in-line filter and suspected in vivo precipitate formation has also been reported. If signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation. In addition to inspection of the solution [see Dosage and Administration (2.1, 2.2, 2.3, 2.4)], the infusion set and catheter should also periodically be checked for precipitates.

5.2 Hypersensitivity Reactions

Hypersensitivity/infusion reactions including anaphylaxis have been reported with CLINIMIX. Stop infusion immediately and treat patient accordingly if any signs or symptoms of a hypersensitivity reaction develop. Signs or symptoms may include: hypotension, hypertension, peripheral cyanosis, tachycardia, dyspnea, vomiting, nausea, urticaria, rash, pruritus, erythema, hyperhidrosis, pyrexia, and chills.

5.3 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 formulation (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 laboratory test results (including leukocytosis and hyperglycemia) and frequent checks of the parenteral access device and insertion site for edema, redness and discharge.

5.4 Refeeding Syndrome
Refeeding severely undernourished patients may result in refeeding syndrome, characterized by the intracellular shift of potassium, phosphorus, and magnesium as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. To prevent these complications, monitor severely undernourished patients and slowly increase nutrient intakes.

5.5 Hyperglycemia or Hyperosmolar Hyperglycemic State

When using CLINIMIX in patients with diabetes mellitus, impaired glucose tolerance may worsen hyperglycemia. Administration of dextrose at a rate exceeding the patient’s utilization rate may lead to hyperglycemia, coma, and death. Patients with underlying confusion and renal impairment who receive dextrose infusions, may be at greater risk of developing hyperosmolar hyperglycemic state. Monitor blood glucose levels and treat hyperglycemia to maintain optimum levels while administering CLINIMIX. Insulin may be administered or adjusted to maintain optimal blood glucose levels during CLINIMIX administration.

5.6 Vein Damage and Thrombosis

Solutions with osmolarity of 900 mOsm/L or greater must be infused through a central catheter. CLINIMIX solutions containing more than 5% dextrose have an osmolarity greater than or equal to 900 mOsm/L. CLINIMIX 4.25/10, 5/15 and 5/20 are indicated for administration into a central vein only, such as the superior vena cava [see Dosage and Administration (2.2)]. The infusion of hypertonic nutrient injections into a peripheral vein may result in vein irritation, vein damage, and/or thrombosis.

CLINIMIX 4.25/5 is indicated for peripheral administration, or may be infused into a central vein [see Dosage and Administration (2.2)]. The primary complication of peripheral access is venous thrombophlebitis, which manifests as pain, erythema, tenderness or a palpable cord. Remove the catheter as soon as possible, if thrombophlebitis develops.

5.7 Hepatobiliary Disorders

Hepatobiliary disorders are known to develop in some patients without preexisting liver disease who receive parenteral nutrition, including cholecystitis, cholelithiasis, cholestasis, hepatic steatosis, fibrosis and cirrhosis, possibly leading to hepatic failure. The etiology of these disorders is thought to be multifactorial and may differ between patients.

Increase in blood ammonia levels and hyperammonemia may occur in patients receiving amino acid solutions. In some patients this may indicate hepatic insufficiency or the presence of an inborn error of amino acid metabolism [see Contraindications (4)].

Monitor liver function parameters and ammonia levels. Patients developing 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.

5.8 Aluminum Toxicity

CLINIMIX contains no more than 25 mcg/L of aluminum. However, with prolonged parenteral administration in patients with renal impairment, the aluminum contained in CLINIMIX may reach toxic levels. Preterm infants are at a greater risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Patients with renal impairment, including preterm infants, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day, accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

5.9 Risk of Parenteral Nutrition Associated Liver Disease

Parenteral Nutrition Associated Liver Disease (PNALD) has been reported in patients who receive parenteral nutrition for extended periods of time, especially preterm infants, and can present as cholestasis or steatohepatitis. The exact etiology is unknown and is likely multifactorial. If CLINIMIX treated patients develop liver test abnormalities consider discontinuation or dosage reduction.
5.10 Electrolyte Imbalance and Fluid Overload

Patients with renal impairment, such as pre-renal azotemia, renal obstruction, and protein-losing nephropathy may be at increased risk of electrolyte and fluid volume imbalance. Patients with cardiac insufficiency due to left ventricular systolic dysfunction are susceptible to excess fluid accumulation. Use CLINIMIX with caution in patients with cardiac insufficiency or renal impairment. CLINIMIX dosage may require adjustment with specific attention to fluid, protein, and electrolyte content in these patients.

Monitor renal function parameters. Patients developing signs of renal impairment should be assessed early by a clinician knowledgeable in renal disease in order to determine the appropriate CLINIMIX dosage and other treatment options.

5.11 Monitoring/Laboratory Tests

Monitor fluid and electrolyte status, serum osmolarity, blood glucose, liver and kidney function, blood count and coagulation parameters throughout treatment.

Patients receiving CLINIMIX should be monitored frequently and their electrolyte requirements individualized.

6 ADVERSE REACTIONS

The following serious adverse reactions are discussed in greater detail in other sections of the prescribing information.

- Pulmonary embolism due to pulmonary vascular precipitates [see Warnings and Precautions (5.1)]
- Hypersensitivity reactions [see Warnings and Precautions (5.2)]
- Risk of Infections [see Warnings and Precautions (5.3)]
- Refeeding syndrome [see Warnings and Precautions (5.4)]
- Hyperglycemia or hyperosmolar hyperglycemic state [see Warnings and Precautions (5.5)]
- Vein damage and thrombosis [see Warnings and Precautions (5.6)]
- Hepatobiliary disorders [see Warnings and Precautions (5.7)]
- Parenteral Nutrition Associated Liver Disease [see Warnings and Precautions (5.9)]
- Electrolyte imbalance and fluid overload [see Warnings and Precautions (5.10)]

The following adverse reactions from voluntary reports or clinical studies have been reported with CLINIMIX. Because many of these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- Diuresis
- Extravasation
- Glycosuria
- Hyperglycemia
- Hyperosmolar coma

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate or well-controlled studies in pregnant women with CLINIMIX. Additionally, animal reproduction studies have not been conducted with amino acids and electrolytes and dextrose. It
is not known whether CLINIMIX can cause fetal harm when administered to a pregnant woman. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. However, the estimated background risk in the U.S. general population of major birth defects is 2 to 4% and of miscarriage is 15 to 20% of clinically recognized pregnancies.

Clinical Considerations

Disease-Associated Maternal and/or Embryo-Fetal Risk

Based on clinical practice guidelines, parenteral nutrition should be considered in cases of severe maternal malnutrition where nutritional requirements cannot be fulfilled by the enteral route because of the risks to the fetus associated with severe malnutrition, such as preterm delivery, low birth weight, intrauterine growth restriction, congenital malformations and perinatal mortality.

8.2 Lactation

Risk Summary

It is not known whether CLINIMIX is present in human milk. There are no data on the effects of CLINIMIX 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 and any potential adverse effects on the breastfed child from CLINIMIX or from the underlying maternal condition.

8.4 Pediatric Use

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

Newborns, especially those born premature and with low birth weight, are at increased risk of developing hypo- or hyperglycemia and therefore need close monitoring during treatment with intravenous glucose solutions to ensure adequate glycemic control in order to avoid potential long term adverse effects. Hypoglycemia in the newborn can cause prolonged seizures, coma and brain damage. Hyperglycemia has been associated with intraventricular hemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotizing enterocolitis, bronchopulmonary dysplasia, prolonged length of hospital stay, and death. Plasma electrolyte concentrations should be closely monitored in the pediatric population as this population may have impaired ability to regulate fluids and electrolytes. Because of immature renal function, preterm infants receiving prolonged treatment with CLINIMIX may be at risk of aluminum toxicity [see Warnings and Precautions (5.8)].

Patients, including pediatric patients, may be at risk for Parenteral Nutrition Associated Liver Disease (PNALD) [see Warnings and Precautions (5.9)].

Hyperammonemia is of special significance in infants (birth to two years). This reaction appears to be related to a deficiency of the urea cycle amino acids of genetic or product origin. It is essential that blood ammonia be measured frequently in infants [See Warnings and Precautions (5.7)].

8.5 Geriatric Use

Clinical studies of CLINIMIX did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from other younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

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

10 OVERDOSAGE
An increased infusion rate of CLINIMIX cause hyperglycemia, hyperosmolality, and adverse effects on water and electrolyte balance [see Warnings and Precautions (5.5, 5.10)].

Severe hyperglycemia and severe dilutional hyponatremia, and their complications, can be fatal. Discontinue infusion and institute appropriate corrective measures in the event of overhydration or solute overload during therapy, with particular attention to respiratory and cardiovascular systems.

For current information on the management of poisoning or overdosage, contact the National Poison Control Center at 1-800-222-1222 or www.poison.org.

11 DESCRIPTION

CLINIMIX sulfite-free (amino acids in dextrose) injection for intravenous use consists of sterile, nonpyrogenic, hypertonic solutions in a dual chamber container.

The outlet port chamber contains essential and nonessential amino acids. The formulas for the individual amino acids found in CLINIMIX sulfite-free (amino acids in dextrose) injections are provided in Table 8.

Table 8: Formulas for Amino Acids

<table>
<thead>
<tr>
<th>Essential Amino Acids</th>
<th>Formula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leucine</td>
<td>(CH₃)₂ CHCH₂CH (NH₂) COOH</td>
</tr>
<tr>
<td>Isoleucine</td>
<td>CH₃CH₂CH (CH₃) CH (NH₂) COOH</td>
</tr>
<tr>
<td>Valine</td>
<td>(CH₃)₂ CHCH (NH₂) COOH</td>
</tr>
<tr>
<td>Lysine (added as the hydrochloride salt)</td>
<td>H₂N (CH₂)₄ CH (NH₂) COOH</td>
</tr>
<tr>
<td>Phenylalanine</td>
<td>(C₆H₅) CH₂ CH (NH₂) COOH</td>
</tr>
<tr>
<td>Histadine</td>
<td>(C₃H₃N₂) CH₂CH (NH₂) COOH</td>
</tr>
<tr>
<td>Threonine</td>
<td>CH₃CH (OH) CH (NH₂) COO</td>
</tr>
<tr>
<td>Methionine</td>
<td>CH₃S (CH₂)₂ CH (NH₂) COOH</td>
</tr>
<tr>
<td>Tryptophan</td>
<td>(C₈H₆N) CH₂ CH (NH₂) COOH</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nonessential Amino Acids</th>
<th>Formula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alanine</td>
<td>CH₃CH (NH₂) COOH</td>
</tr>
<tr>
<td>Arginine</td>
<td>H₂NC (NH) NH (CH₂)₃ CH (NH₂) COOH</td>
</tr>
<tr>
<td>Glycine</td>
<td>H₂NCH₂COOH</td>
</tr>
<tr>
<td>Proline</td>
<td>[(CH₂)₃ NH CH] COOH</td>
</tr>
<tr>
<td>Serine</td>
<td>HOCH₂CH (NH₂) COOH</td>
</tr>
<tr>
<td>Tyrosine</td>
<td>[C₆H₄ (OH)] CH₂CH (NH₂) COOH</td>
</tr>
</tbody>
</table>

The injection port chamber contains dextrose. Dextrose, USP, is chemically designated D-glucose, monohydrate (C₆H₁₂O₆ • H₂O) and has the following structure:
12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action
CLINIMIX is used as a supplement of nutrition in patients, providing macronutrients (amino acids and dextrose) parenterally.

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.

The administered dextrose is oxidized to carbon dioxide and water, yielding energy.

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

15 REFERENCES

16 HOW SUPPLIED/STORAGE AND HANDLING
CLINIMIX (amino acids in dextrose) injection (sulfite-free) is available in 1000 mL and 2000mL volumes (See Table 9).

<table>
<thead>
<tr>
<th>Table 9: CLINIMIX Formulations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>After mixing, the product represents</strong></td>
</tr>
<tr>
<td>CLINIMIX 4.25/5 sulfite-free (4.25% Amino Acid in 5% Dextrose) Injection</td>
</tr>
</tbody>
</table>
Minimize exposure of CLINIMIX to heat and avoid excessive heat.
Protect from freezing.
Store CLINIMIX 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 clear overwrap has been opened.
Do not use if the protective clear 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 CLINIMIX:

- Pulmonary embolism due to pulmonary vascular precipitates [see Warnings and Precautions (5.1)]
- Hypersensitivity reactions [see Warnings and Precautions (5.2)]
- Risk of Infections [see Warnings and Precautions (5.3)]
- Refeeding syndrome [see Warnings and Precautions (5.4)]
- Hyperglycemia or hyperosmolar hyperglycemic state [see Warnings and Precautions (5.5)]
- Vein damage and thrombosis [see Warnings and Precautions (5.6)]
- Hepatobiliary disorders [see Warnings and Precautions (5.7)]
- Aluminum toxicity [see Warnings and Precautions (5.8)]
- Parenteral Nutrition Associated Liver Disease (PNALD) [see Warnings and Precautions (5.9)]
- Electrolyte imbalance and fluid overload [see Warnings and Precautions (5.10)]

Baxter Healthcare Corporation
Deerfield, IL 60015 USA
Printed in USA
Baxter and Clinimix are registered trademarks of Baxter International Inc.
07-19-00-0372

<table>
<thead>
<tr>
<th>CLINIMIX 4.25/10 sulfite-free (4.25% Amino Acid in 10% Dextrose) Injection</th>
<th>Code 2B7727 NDC 0338113403</th>
<th>Code 2B7705 NDC 0338109104</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLINIMIX 5/15 sulfite-free (5% Amino Acid in 15% Dextrose) Injection</td>
<td>Code 2B7730 NDC 0338113703</td>
<td>Code 2B7709 NDC 0338109904</td>
</tr>
<tr>
<td>CLINIMIX 5/20 sulfite-free (5% Amino Acid in 20% Dextrose) Injection</td>
<td>Code 2B7731 NDC 0338113803</td>
<td>Code 2B7710 NDC 0338110104</td>
</tr>
</tbody>
</table>
CLINIMIX
2.75/5
SULFITE-FREE
(2.75% Amino Acids in 5% Dextrose) Injection

500 mL INJECTION PORT CHAMBER
10% Dextrose Injection USP

500 mL OUTLET PORT CHAMBER
5.5% Amino Acid Injection

Rx Only

ACTIVATE SEAL AND MIX THOROUGHLY BEFORE USE

SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION
AFTER MIXING THE PRODUCT REPRESENTS 1000 mL
REFRIGERATED STORAGE IS LIMITED TO 9 DAYS

Contents of each 100 mL of the admixed injection:
Dextrose Hydrous USP 5 g
Essential Amino Acids
Leucine 201 mg
Isoleucine 166 mg
Valine 160 mg
Lysine (added as the hydrochloride salt) 159 mg
Phenylalanine 154 mg
Histidine 132 mg
Threonine 116 mg
Methionine 110 mg
Tryptophan 50 mg
Nonessential Amino Acids
Alanine 570 mg
Arginine 316 mg
Glycine 293 mg
Proline 187 mg
Serine 139 mg
Tyrosine 11 mg
mEq/L
Acetate 24
Chloride 11
Balanced by ions from amino acids
pH Adjusted with Glacial Acetic Acid
Sterile
Single dose container

Baxter Healthcare Corporation
Deerfield IL 60015 USA
Made in USA

Container Label

LOT EXP
2B7728 NDC 0338-1132-03
CLINIMIX
2.75/5
SULFITE-FREE
(2.75% Amino Acid in 5% Dextrose) Injection

500 mL INJECTION PORT CHAMBER
10% Dextrose Injection USP

500 mL OUTLET PORT CHAMBER
5.5% Amino Acid Injection

Rx Only

ACTIVATE SEAL AND MIX THOROUGHLY BEFORE USE

SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION
AFTER MIXING THE PRODUCT REPRESENTS 1000 mL
REFRIGERATED STORAGE IS LIMITED TO 9 DAYS
A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY AND EFFICACY OF THIS PRODUCT
ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY
CONTENTS OF EACH 100 mL OF THE ADMIXED INJECTION

DEXTROSE HYDROUS USP 5 g

**ESSENTIAL AMINO ACIDS**
- LEUCINE 201 mg
- ISOLEUCINE 165 mg
- VALINE 160 mg
- LYSINE (ADDED AS THE HYDROCHLORIDE SALT) 159 mg
- PHENYLALANINE 154 mg
- HISTIDINE 132 mg
- THREONINE 116 mg
- METHIONINE 110 mg
- TRYPTOPHAN 50 mg

**NONESSENTIAL AMINO ACIDS**
- ALANINE 570 mg
- ARGinine 316 mg
- GLYCINE 283 mg
- PROLINE 187 mg
- SERINE 138 mg
- TYROSINE 11 mg

mEq/L
- ACETATE 24
- CHLORIDE 11

BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID
STERILE
SINGLE DOSE CONTAINER

*Baxter*

**BAXTER HEALTHCARE CORPORATION**
DEERFIELD IL 60015 USA
MADE IN USA
**CLINIMIX 4.25/10 SULFITE-FREE**

*(4.25% Amino Acids in 10% Dextrose)*

**Injection**

- **CENTRAL LINE INFUSION ONLY**
- **500 mL INJECTION PORT CHAMBER**
- **20% Dextrose Injection USP**
- **500 mL OUTLET PORT CHAMBER**
- **8.5% Amino Acid Injection**

**Rx Only**

**ACTIVATE SEAL AND MIX THOROUGHLY BEFORE USE**

SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION

AFTER MIXING THE PRODUCT REPRESENTS 1000 mL

**Contents of Each 100 mL of the admixed injection**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dextrose Anhydrous USP</td>
<td>10g</td>
</tr>
<tr>
<td>Essential Amino Acids</td>
<td></td>
</tr>
<tr>
<td>Leucine</td>
<td>311mg</td>
</tr>
<tr>
<td>Isoleucine</td>
<td>235mg</td>
</tr>
<tr>
<td>Valine</td>
<td>247mg</td>
</tr>
<tr>
<td>Lysine (Added as the Hydrochloride Salt)</td>
<td>247mg</td>
</tr>
<tr>
<td>Phenylalanine</td>
<td>236mg</td>
</tr>
<tr>
<td>Histidine</td>
<td>204mg</td>
</tr>
<tr>
<td>Threonine</td>
<td>176mg</td>
</tr>
<tr>
<td>Methionine</td>
<td>176mg</td>
</tr>
<tr>
<td>Tryptophan</td>
<td>77mg</td>
</tr>
<tr>
<td>Non-Essential Amino Acids</td>
<td></td>
</tr>
<tr>
<td>Alanine</td>
<td>880mg</td>
</tr>
<tr>
<td>Arginine</td>
<td>489mg</td>
</tr>
<tr>
<td>Glucose</td>
<td>438mg</td>
</tr>
<tr>
<td>Proline</td>
<td>285mg</td>
</tr>
<tr>
<td>Serine</td>
<td>213mg</td>
</tr>
<tr>
<td>Tyrosine</td>
<td>17mg</td>
</tr>
<tr>
<td>mEq/L</td>
<td></td>
</tr>
<tr>
<td>Acetate</td>
<td>27</td>
</tr>
<tr>
<td>Chloride</td>
<td>17</td>
</tr>
</tbody>
</table>

BALANCED BY IONS FROM AMINO ACIDS

pH ADJUSTED WITH GLACIAL ACETIC ACID

STERILE

SINGLE DOSE CONTAINER

STORAGE (25°C/77°F)

AVOID EXCESSIVE HEAT

PROTECT FROM FREEZING

SEE PRESCRIBING INFORMATION

**Baxter Healthcare Corporation**

Deerfield, IL 60015 USA

MADE IN USA

Container Label

LOT EXP

2B7727 NDC 0338-1134-03

**CLINIMIX 4.25/10 SULFITE-FREE**

*(4.25% Amino Acids in 10% Dextrose)*

**Injection**

- **500 mL INJECTION PORT CHAMBER**
- **20% Dextrose Injection USP**
- **500 mL OUTLET PORT CHAMBER**
- **8.5% Amino Acid Injection**

**Rx Only**

**ACTIVATE SEAL AND MIX THOROUGHLY BEFORE USE**

SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION

AFTER MIXING THE PRODUCT REPRESENTS 1000 mL
REFRIGERATED STORAGE IS LIMITED TO 9 DAYS
A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY AND EFFICACY OF THIS PRODUCT
ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY
CONTENTS OF EACH 100 mL OF THE ADMIXED INJECTION
DEXTROSE HYDROUS USP 10 g
ESSENTIAL AMINO ACIDS
LEUCINE 311 mg
ISOLEUCINE 255 mg
VALINE 247 mg
LYSINE (ADDED AS THE HYDROCHLORIDE SALT) 247 mg
PHENYLALANINE 238 mg
HISTIDINE 204 mg
THREONINE 179 mg
METHIONINE 170 mg
TRYPTOPHAN 77 mg
NONSESENTIAL AMINO ACIDS
ALANINE 880 mg
ARGININE 489 mg
GLYCINE 438 mg
PROLINE 289 mg
SERINE 213 mg
TYROSINE 17 mg
mEq/L
ACETATE 37
CHLORIDE 17
BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID
STERILE
SINGLE DOSE CONTAINER
ROOM TEMPERATURE (25°C/77°F)
AVOID EXCESSIVE HEAT
PROTECT FROM FREEZING
SEE PRESCRIBING INFORMATION

Baxter
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA
LOT EXP
2B7701 NDC 0338-1083-04

CLINIMIX 2.75/5
sulfite-free
(2.75% Amino Acid in 5% Dextrose)
Injection

1000 mL INJECTION PORT CHAMBER
10% Dextrose Injection USP

1000 mL OUTLET PORT CHAMBER
5.5% Amino Acid Injection

Rx Only

CHECK FOR MINUTE LEAKS BY SQUEEZING EACH CHAMBER OF THE BAG
BEFORE USE GRASP EACH SIDE OF THE TOP OF THE BAG AND ROLL BAG TO OPEN SEAL BETWEEN CHAMBERS
MIX THOROUGHLY
AFTER MIXING THE PRODUCT REPRESENTS 2000 mL

ADDITIVES MAY BE INCOMPATIBLE. CONSULT WITH PHARMACIST IF AVAILABLE. WHEN INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE
MIX THOROUGHLY, DO NOT STORE

DOSE INTRAVENOUSLY AS DIRECTED BY A PHYSICIAN. DO NOT USE UNLESS SOLUTION IS CLEAR. REFRIGERATED STORAGE AFTER MIXING LIMITED TO 24 HOURS, DISCARD UNUSED PORTION
SEE ACCOMPANYING DIRECTIONS FOR USE
CAUTIONS MUST NOT BE USED IN SERIES CONNECTIONS. DISCONTINUE INFUSION IF ADVERSE REACTION OCCURS

CLARITY DUAL CHAMBER CONTAINER PL 2801 PLASTIC

Baxter Healthcare Corporation
Clinic Nutrition Division
Deerfield, IL 60015 USA
Maderia, Italy
Paterson, N.J.
Baxter, CliniMIX and Clarity are trademarks of Baxter International Inc.

Container Label
THE TOP OF THE BAG AND ROLL BAG TO OPEN SEAL BETWEEN CHAMBERS
MIX THOROUGHLY
AFTER MIXING THE PRODUCT
REPRESENTS 2000 mL
ADDITIVES MAY BE INCOMPATIBLE CONSULT WITH PHARMACIST IF AVAILABLE WHEN INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE
MIX THOROUGHLY DO NOT STORE DOSAGE INTRAVENOUSLY AS DIRECTED BY A PHYSICIAN DO NOT USE UNLESS SOLUTION IS CLEAR REFRIGERATED STORAGE AFTER MIXING LIMITED TO 24 HOURS DISCARD UNUSED PORTION
SEE ACCOMPANYING DIRECTIONS FOR USE CAUTIONS MUST NOT BE USED IN SERIES CONNECTIONS DISCONTINUE INFUSION IF ADVERSE REACTION OCCURS CLARITY DUAL CHAMBER CONTAINER PL 2401 PLASTIC CONTENTS OF EACH 100 mL OF THE ADMixed INJECTION DEXTROSE HYDROUS USP 5 g
ESSENTIAL AMINO ACIDS LEUCINE 201 mg ISOLEUCINE 165 mg VALINE 160 mg LYSINE (ADDED AS THE HYDROCHLORIDE SALT) 159 mg PHENYLALANINE 154 mg HISTIDINE 132 mg THREONINE 116 mg METHIONINE 110 mg TRYPTOPHAN 50 mg NONESSENTIAL AMINO ACIDS ALANINE 570 mg ARGinine 316 mg GLYCINE 283 mg PROLINE 187 mg SERINE 138 mg TYROSINE 11 mg mEq/L ACETATE 24 CHLORIDE 11
BALANCED BY IONS FROM AMINO ACIDS pH ADJUSTED WITH GLACIAL ACETIC ACID
pH 6.0 (4.5 TO 7.0) HYPERTONIC
OSMOLARITY 525 mOsmol/L (CALC)
STERILE NONPYROGENIC
SINGLE DOSE CONTAINER

Baxter
BAXTER HEALTHCARE CORPORATION
CLINTEC NUTRITION DIVISION
DEERFIELD IL 60015 USA
MADE IN USA
PATENT PENDING
BAXTER CLINIMIX AND CLARITY ARE TRADEMARKS
OF BAXTER INTERNATIONAL INC

CLINIMIX
4.25/5
SULFITE-FREE
(4.25% Amino Acids in 5% Dextrose)
Injection

500 mL INJECTION PORT CHAMBER
10% Dextrose Injection USP
500 mL OUTLET PORT CHAMBER
8.5% Amino Acid Injection

Rx Only

ACTIVATE SEAL AND
MIX THOROUGHLY BEFORE USE

CONTENTS OF EACH 100 mL OF THE ADMIXED
INJECTION
DEXTROSE HYDROUS USP 4 g
ESSENTIAL AMINO ACIDS
LEUCINE 311 mg
ISOLEUCINE 236 mg
VALINE 247 mg
LYSINE (ADDED AS THE HYDROCHLORIDE SALT) 247 mg
PHENYLALANINE 236 mg
HISTIDINE 204 mg
THRONE 175 mg
METHIONINE 175 mg
TRYPTOPHAN 77 mg

NONESSENTIAL AMINO ACIDS
ALANINE 966 mg
ARGININE 486 mg
GLYCOSE 436 mg
PROLINE 286 mg
SERINE 212 mg
TYROSINE 17 mg

mEq/L
ACETATE 27
CHLORIDE 17

BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID
STERILE
SINGLE DOSE CONTAINER

ROOM TEMPERATURE (20°C/68°F)
AVOID EXCESSIVE HEAT
PROTECT FROM FREEZING
SEE PREScribing INFORMATION

Lot Exp
2B7726 NDC 0338-1133-03
CLINIMIX
4.25/5
SULFITE-FREE
(4.25% Amino Acids in 5% Dextrose)
Injection
500 mL INJECTION PORT CHAMBER
10% Dextrose Injection USP
500 mL OUTLET PORT CHAMBER
8.5% Amino Acid Injection
ACTIVATE SEAL AND
MIX THOROUGHLY BEFORE USE
SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON
ACTIVATION
AFTER MIXING THE PRODUCT REPRESENTS 1000 mL
REFRIGERATED STORAGE IS LIMITED TO 9 DAYS
A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY
AND EFFICACY OF THIS PRODUCT
ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY
CONTENTS OF EACH 100 mL OF THE ADMIXED
INJECTION
DEXTROSE HYDROUS USP 5 g
ESSENTIAL AMINO ACIDS
LEUCINE 311 mg
ISOLEUCINE 255 mg
VALINE 247 mg
LYSINE (ADDED AS THE
HYDROCHLORIDE SALT) 247 mg
PHENYLALANINE 238 mg
HISTIDINE 204 mg
THREONINE 179 mg
METHIONINE 170 mg
TRYPTOPHAN 77 mg
NONESSENTIAL AMINO ACIDS
ALANINE 880 mg
ARGININE 489 mg
GLYCINE 438 mg
PROLINE 289 mg
SERINE 213 mg
TYROSINE 17 mg
mEq/L
ACETATE 37
CHLORIDE 17
BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID
STERILE
SINGLE DOSE CONTAINER
ROOM TEMPERATURE (25°C/77°F)
AVOID EXCESSIVE HEAT
PROTECT FROM FREEZING
SEE PRESCRIBING INFORMATION

Baxter

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA

CONTENTS OF EACH 100 mL OF THE
ADixed INJECTION
DEXTROSE HYDROUS USP 5 g
ESSENTIAL AMINO ACIDS
LEUCINE 311 mg
ISOLEUCINE 255 mg
VALINE 247 mg
LYSINE (ADDED AS THE
HYDROCHLORIDE SALT) 247 mg
PHENYLALANINE 238 mg
HISTIDINE 204 mg
THREONINE 179 mg
METHIONINE 170 mg
TRYPTOPHAN 77 mg
NONSESENTIAL AMINO ACIDS
ALANINE 800 mg
ARGININE 489 mg
GLYINE 458 mg
PROLINE 289 mg
SERINE 213 mg
TYROINE 17 mg
mEq/L
ACETATE 57
CHLORIDE 17
BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID
STERILE
SINGLE DOSE CONTAINER
ROOM TEMPERATURE (25°C/77°F)
AVOID EXCESSIVE HEAT
PROTECT FROM FREEZING
SEE PRESCRIBING INFORMATION

ACTIVATE SEAL AND
MIX THOROUGHLY BEFORE USE

SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON
ACTIVATION
AFTER MIXING THE PRODUCT REPRESENTS 200 mL
REFRIGERATED STORAGE IS LIMITED TO 9 DAYS
A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY
AND EFFICACY OF THIS PRODUCT
ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY
ACTIVATE SEAL AND MIX THOROUGHLY BEFORE USE
SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION
AFTER MIXING THE PRODUCT REPRESENTS 2000 mL
REFRIGERATED STORAGE IS LIMITED TO 9 DAYS
A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY AND EFFICACY OF THIS PRODUCT
ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY
CONTENTS OF EACH 100 mL OF THE ADMIXED INJECTION
DEXTROSE HYDROUS USP 5 g

ESSENTIAL AMINO ACIDS
LEUCINE 311 mg
ISOLEUCINE 255 mg
VALINE 247 mg
LYSINE (ADDED AS THE HYDROCHLORIDE SALT) 247 mg
PHENYLALANINE 238 mg
HISTIDINE 204 mg
THREONINE 179 mg
METHIONINE 170 mg
TRYPTOPHAN 77 mg

NONESSENTIAL AMINO ACIDS
ALANINE 880 mg
ARGININE 489 mg
GLYCINE 438 mg
PROLINE 289 mg
SERINE 213 mg
TYROSINE 17 mg
mEq/L
ACETATE 37
CHLORIDE 17
BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID
STERILE
SINGLE DOSE CONTAINER
ROOM TEMPERATURE (25°C/77°F)
AVOID EXCESSIVE HEAT
PROTECT FROM FREEZING
SEE PRESCRIBING INFORMATION

Baxter
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA

2B7705 NDC 0338-1091-04
CLINIMIX 4.25/10
SULFITE-FREE
(4.25% Amino Acids in 10% Dextrose)
Injection

CENTRAL LINE INFUSION ONLY
1000 mL INJECTION PORT CHAMBER
20% Dextrose Injection USP
1000 mL OUTLET PORT CHAMBER
8.5% Amino Acid Injection

Rx Only

ACTIVATE SEAL AND
MIX THOROUGHLY BEFORE USE

SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON
ACTIVATION
AFTER MIXING THE PRODUCT REPRESENTS 2000 mL
REFRIGERATED STORAGE IS LIMITED TO 9 DAYS
A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY
AND EFFICACY OF THIS PRODUCT
ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY

LOT EXP
CONTENTS OF EACH 100 mL OF THE
ADmixed INJECTION
DEXTROSE HYDROUS USP 10 g
ESSENTIAL AMINO ACIDS
LEUCINE 311 mg
ISOLEUCINE 255 mg
VALINE 247 mg
LYSINE (ADDED AS THE
HYDROCHLORIDE SALT) 247 mg
PHENYLALANINE 234 mg
HISTIDINE 204 mg
THREONINE 179 mg
METHIONINE 170 mg
TRYPTOPHAN 77 mg
NONSESENTIAL AMINO ACIDS
ARGININE 489 mg
GLYCINE 438 mg
PROLINE 289 mg
SERINE 213 mg
TYROSINE 17 mg
mEq/L
ACETATE 37
CHLORIDE 17

BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID
STERILE
SINGLE DOSE CONTAINER
ROOM TEMPERATURE (25°C/77°F)
AVOID EXCESSIVE HEAT
PROTECT FROM FREEZING
SEE PRESCRIBING INFORMATION

Baxter
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA

Container Label
LOT EXP
2B7705 NDC 0338-1091-04
CLINIMIX 4.25/10
SULFITE-FREE
(4.25% Amino Acid
in 10% Dextrose) Injection

1000 mL INJECTION PORT CHAMBER
20% Dextrose Injection USP

1000 mL OUTLET PORT CHAMBER
8.5% Amino Acid Injection

Rx Only

**ACTIVATE SEAL AND MIX THOROUGHLY BEFORE USE**

SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION

AFTER MIXING THE PRODUCT REPRESENTS 2000 mL

REFRIGERATED STORAGE IS LIMITED TO 9 DAYS

A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY AND EFFICACY OF THIS PRODUCT

ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY

CONTENTS OF EACH 100 mL OF THE ADMIXED INJECTION

DEXTROSE HYDROUS USP 10 g

**ESSENTIAL AMINO ACIDS**

LEUCINE 311 mg
ISOLEUCINE 255 mg
VALINE 247 mg
LYSINE (ADDED AS THE HYDROCHLORIDE SALT) 247 mg
PHENYLALANINE 238 mg
HISTIDINE 204 mg
THREONINE 179 mg
METHIONINE 170 mg
TRYPTOPHAN 77 mg

**NONESSENTIAL AMINO ACIDS**

ALANINE 880 mg
ARGININE 489 mg
GLYCINE 438 mg
PROLINE 289 mg
SERINE 213 mg
TYROSINE 17 mg

mEq/L
ACETATE 37
CHLORIDE 17

BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID

STERILE
SINGLE DOSE CONTAINER
ROOM TEMPERATURE (25°C/77°F)
AVOID EXCESSIVE HEAT
PROTECT FROM FREEZING
SEE PRESCRIBING INFORMATION

Baxter
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA

LOT EXP
2B7728 NDC 0338-1035-03

CLINIMIX
4.25/20
SULFITE-FREE
(4.25% Amino Acids in 20% Dextrose)
Injection

500 mL INJECTION PORT CHAMBER
40% Dextrose Injection USP

500 mL OUTLET PORT CHAMBER
8.5% Amino Acid Injection

Rx Only

CONTENTS OF EACH 100 ML OF THE ADMixed INJECTION
Dextrose Anhydrous USP 20 g

ESSENTIAL AMINO ACIDS
Leucine 211 mg
Isoleucine 255 mg
Valine 247 mg

Lysine (Added as the Hydrochloride Salt) 247 mg
Phenylalanine 238 mg
Histidine 204 mg
Threonine 179 mg
Methionine 170 mg
Tryptophan 77 mg

NONESSENTIAL AMINO ACIDS
Alanine 980 mg
Arginine 490 mg
Glycine 439 mg
Proline 299 mg
Serine 213 mg
Tyrosine 17 mg

mEq/L
Acetate 37
Chloride 17

Balanced by Ions from Amino Acids
pH Adjusted with Glacial Acetic Acid
STERILE
SINGLE DOSE CONTAINER

ACTIVATE SEAL AND MIX THOROUGHLY BEFORE USE

SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION
AFTER MIXING THE PRODUCT REPRESENTS 1000 ML
REFRIGERATED STORAGE IS LIMITED TO 9 DAYS
A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY AND EFFECTIVENESS OF THIS PRODUCT
ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY

Container Label

Baxter
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA
ACTIVATE SEAL AND
MIX THOROUGHLY BEFORE USE
SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON
ACTIVATION
AFTER MIXING THE PRODUCT REPRESENTS 1000 mL
REFRIGERATED STORAGE IS LIMITED TO 9 DAYS
A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY
AND EFFICACY OF THIS PRODUCT
ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY
CONTENTS OF EACH 100 mL OF THE
ADMIXED INJECTION
DEXTROSE HYDROUS USP 20 g

ESSENTIAL AMINO ACIDS
LEUCINE 311 mg
ISOLEUCINE 255 mg
VALINE 247 mg
LYSINE (ADDED AS THE
HYDROCHLORIDE SALT) 247 mg
PHENYLALANINE 238 mg
HISTIDINE 204 mg
THREONINE 179 mg
METHIONINE 170 mg
TRYPTOPHAN 77 mg

NONESSENTIAL AMINO ACIDS
ALANINE 880 mg
ARGININE 489 mg
GLYCINE 438 mg
PROLINE 289 mg
SERINE 213 mg
TYROSINE 17 mg

mEq/L
ACETATE 37
CHLORIDE 17

BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID
STERILE
SINGLE DOSE CONTAINER

Baxter
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA
CLINIMIX 4.25/20
SULFITE-FREE
(4.25% Amino Acids in 20% Dextrose)
Injection

CONTENTS OF EACH 100 mL OF THE ADMIXED INJECTION
DEXTROSE HYDROUS USP 20 g
ESSENTIAL AMINO ACIDS
LEUCINE 111 mg
ISOLEUCINE 95 mg
VALINE 247 mg
LYSINE (ADDED AS THE HYDROCHLORIDE SALT) 247 mg
PHENYLALANINE 238 mg
HISTIDINE 204 mg
THREONINE 179 mg
METHIONINE 170 mg
TRYPTOPHAN 77 mg
NONESSENTIAL AMINO ACIDS
ALANINE 880 mg
ARGININE 499 mg
GLYCOX 498 mg
PROLINE 366 mg
SERINE 253 mg
TYROSINE 17 mg
mEq/L
ACETATE 37
CHLORIDE 17
BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID
STERILE
SINGLE DOSE CONTAINER

ACTIVATE SEAL AND MIX THOROUGHLY BEFORE USE
SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON
ACTIVATION
AFTER MIXING THE PRODUCT REPRESENTS 2000 mL
A SLIGHTY YELLOW COLOR DOES NOT ALTER THE QUALITY
AND EFFICACY OF THIS PRODUCT
ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY

LOT EXP
2B7706 NDC 0338-1093-04
CLINIMIX 4.25/20
SULFITE-FREE
(4.25% Amino Acid in 20% Dextrose)
Injection
1000 mL INJECTION PORT CHAMBER
40% Dextrose Injection USP
1000 mL OUTLET PORT CHAMBER
8.5% Amino Acid Injection
Rx Only
ACTIVATE SEAL AND MIX THOROUGHLY BEFORE USE
SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON
ACTIVATION
AFTER MIXING THE PRODUCT REPRESENTS 2000 mL
REFRIGERATED STORAGE IS LIMITED TO 9 DAYS
A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY
AND EFFICACY OF THIS PRODUCT
ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY
CONTENTS OF EACH 100 mL OF THE
ADMIXED INJECTION
DEXTROSE HYDROUS USP 20 g

ESSENTIAL AMINO ACIDS
LEUCINE 311 mg
ISOLEUCINE 255 mg
VALINE 247 mg
LYSINE (ADDED AS THE
HYDROCHLORIDE SALT) 247 mg
PHENYLALANINE 238 mg
HISTIDINE 204 mg
THREONINE 179 mg
METHIONINE 170 mg
TRYPTOPHAN 77 mg

NONESSENTIAL AMINO ACIDS
ALANINE 880 mg
ARGININE 489 mg
GLYCINE 438 mg
PROLINE 289 mg
SERINE 213 mg
TYROSINE 17 mg

mEq/L
ACETATE 37
CHLORIDE 17

BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID
STERILE
SINGLE DOSE CONTAINER

Baxter
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA
2B7729 NDC 0338-1136-03

CLINIMIX 4.25/25
SULFITE-FREE
(4.25% Amino Acids in 25% Dextrose)
Injection

CENTRAL LINE INFUSION ONLY

500 mL INJECTION PORT CHAMBER
50% Dextrose Injection USP

500 mL OUTLET PORT CHAMBER
8.5% Amino Acid Injection

Rx Only

ACTIVATE SEAL AND MIX THOROUGHLY BEFORE USE

SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION

AFTER MIXING THE PRODUCT REPRESENTS 1000 mL

REFRIGERATED STORAGE IS LIMITED TO 9 DAYS

CONTENTS OF EACH 100 mL OF THE ADMIXED INJECTION
DEXTROSE HYDROUS USP 25 g

ESSENTIAL AMINO ACIDS
LEUCINE 311 mg
ISOLEUCINE 255 mg
VALINE 247 mg
LYSINE (ADDED AS THE HYDROCHLORIDE SALT) 247 mg
PHENYLALANINE 236 mg
PROLINE 204 mg
THREONINE 179 mg
METHIONINE 170 mg
TRYPTOPHAN 77 mg

NONESSENTIAL AMINO ACIDS
ALANINE 990 mg
ARGININE 489 mg
GLYCINE 438 mg
PROLINE 299 mg
SERINE 213 mg
TYROSINE 17 mg

mEq/L
ACETATE 57
CHLORIDE 17

BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID
STERILE
SINGLE DOSE CONTAINER

SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION

AFTER MIXING THE PRODUCT REPRESENTS 1000 mL

REFRIGERATED STORAGE IS LIMITED TO 9 DAYS

Container Label
A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY AND EFFICACY OF THIS PRODUCT
ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY
CONTENTS OF EACH 100 mL OF THE ADMIXED INJECTION
DEXTROSE HYDROUS USP 25 g

ESSENTIAL AMINO ACIDS
LEUCINE 311 mg
ISOLEUCINE 255 mg
VALINE 247 mg
LYSINE (ADDED AS THE HYDROCHLORIDE SALT) 247 mg
PHENYLALANINE 238 mg
HISTIDINE 204 mg
THREONINE 179 mg
METHIONINE 170 mg
TRYPTOPHAN 77 mg

NONESSENTIAL AMINO ACIDS
ALANINE 880 mg
ARGININE 489 mg
GLYCINE 438 mg
PROLINE 289 mg
SERINE 213 mg
TYROSINE 17 mg

mEq/L
ACETATE 37
CHLORIDE 17

BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID
STERILE
SINGLE DOSE CONTAINER

Baxter
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA
LOT EXP
2B7707 NDC 0338-1095-04

CLINIMIX
4.25/25
SULFITE-FREE
(4.25% Amino Acids in 25% Dextrose)
Injection

1000 mL INJECTION PORT CHAMBER
50% Dextrose Injection USP

1000 mL OUTLET PORT CHAMBER
8.5% Amino Acid Injection

Rx Only

ACTIVATE SEAL AND
MIX THOROUGHLY BEFORE USE

SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON
ACTIVATION

AFTER MIXING THE PRODUCT REPRESENTS 2000 mL

CONTENTS OF EACH 100 mL OF THE
ADMIXED INJECTION

DEXTROSE HYDROUS USP
25 g

ESSENTIAL AMINO ACIDS
LEUCINE
311 mg
ISO LEUCINE
265 mg
VALINE
267 mg
LYSINE (ADDED AS THE
HYDROCHLORIDE SALT)
267 mg
PHENYLALANINE
238 mg
HISTIDINE
204 mg
THREONINE
179 mg
METHIONINE
170 mg
TRYPTOPHAN
17 mg

NONESSENTIAL AMINO ACIDS
ALANINE
980 mg
ARGININE
489 mg
GLYCINE
439 mg
PROLINE
299 mg
SERINE
213 mg
TYROSINE
17 mg

mEq/L
ACETATE
97
CHLORIDE
17

BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID
STERILE
SINGLE DOSE CONTAINER

BAXTER
BAXTER HEALTHCARE CORPORATION
GLENVIEW, IL, USA
MADE IN USA

Container Label
REFRIGERATED STORAGE IS LIMITED TO 9 DAYS
A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY
AND EFFICACY OF THIS PRODUCT
ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY

CONTENTS OF EACH 100 mL OF THE
ADMIXED INJECTION

DEXTROSE HYDROUS USP 25 g

ESSENTIAL AMINO ACIDS
LEUCINE 311 mg
ISOLEUCINE 255 mg
VALINE 247 mg
LYSINE (ADDED AS THE
HYDROCHLORIDE SALT) 247 mg
PHENYLALANINE 238 mg
HISTIDINE 204 mg
THREONINE 179 mg
METHIONINE 170 mg
TRYPTOPHAN 77 mg

NONESSENTIAL AMINO ACIDS
ALANINE 880 mg
ARGININE 489 mg
GLYCINE 438 mg
PROLINE 289 mg
SERINE 213 mg
TYROSINE 17 mg

mEq/L
ACETATE 37
CHLORIDE 17

BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID
STERILE
SINGLE DOSE CONTAINER

Baxter
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA
LOT EXP
2B7730 NDC 0338-1137-03
CLINIMIX
5/15
SULFITE-FREE
(5% Amino Acid in 15% Dextrose)
Injection
500 mL INJECTION PORT CHAMBER
30% Dextrose Injection USP
500 mL OUTLET PORT CHAMBER
10% Amino Acid Injection
Rx Only
ACTIVATE SEAL AND MIX THOROUGHLY BEFORE USE
SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION
AFTER MIXING THE PRODUCT REPRESENTS 1000 mL
REFRIGERATED STORAGE IS LIMITED TO 9 DAYS
A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY
AND EFFICACY OF THIS PRODUCT
ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY
CONTENTS OF EACH 100 mL OF THE
ADMIXED INJECTION
DEXTROSE HYDROUS USP 15 g

ESSENTIAL AMINO ACIDS
LEUCINE 365 mg
ISOLEUCINE 300 mg
VALINE 290 mg
LYSINE (ADDED AS THE
HYDROCHLORIDE SALT) 290 mg
PHENYLALANINE 280 mg
HISTIDINE 240 mg
THREONINE 210 mg
METHIONINE 200 mg
TRYPTOPHAN 90 mg

NONESSENTIAL AMINO ACIDS
ALANINE 1035 mg
ARGININE 575 mg
GLYCINE 515 mg
PROLINE 340 mg
SERINE 250 mg
TYROSINE 20 mg

mEq/L
ACETATE 42
CHLORIDE 20

BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID
STERILE
SINGLE DOSE CONTAINER
ROOM TEMPERATURE (25°C/77°F)
AVOID EXCESSIVE HEAT
PROTECT FROM FREEZING
SEE PRESCRIBING INFORMATION

Baxter
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA
LOT EXP
2B7709 NDC 0338-1099-04
CLINIMIX
5/15
SULFITE-FREE
(5% Amino Acid in 15% Dextrose)
Injection
1000 mL INJECTION PORT CHAMBER
30% Dextrose Injection USP
1000 mL OUTLET PORT CHAMBER
10% Amino Acid Injection
Rx Only
ACTIVATE SEAL AND
MIX THOROUGHLY BEFORE USE
SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON
ACTIVATION

AFTER MIXING THE PRODUCT REPRESENTS 2000 mL

REFRIGERATED STORAGE IS LIMITED TO 9 DAYS

A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY
AND EFFICACY OF THIS PRODUCT

ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY

CONTENTS OF EACH 100 mL OF THE
ADMIXED INJECTION

DEXTROSE HYDROUS USP 15 g

**ESSENTIAL AMINO ACIDS**

- LEUCINE 365 mg
- ISOLEUCINE 300 mg
- VALINE 290 mg
- LYSINE (ADDED AS THE HYDROCHLORIDE SALT) 290 mg
- PHENYLALANINE 280 mg
- HISTIDINE 240 mg
- THREONINE 210 mg
- METHIONINE 200 mg
- TRYPTOPHAN 90 mg

**NONSESENTIAL AMINO ACIDS**

- ALANINE 1035 mg
- ARGinine 575 mg
- GLYCINE 515 mg
- PROLINE 340 mg
- SERINE 250 mg
- TYROSINE 20 mg

mEq/L

- ACETATE 42
- CHLORIDE 20

BALANCED BY IONS FROM AMINO ACIDS

pH ADJUSTED WITH GLACIAL ACETIC ACID

STERILE

SINGLE DOSE CONTAINER

ROOM TEMPERATURE (25°C/77°F)

AVOID EXCESSIVE HEAT

PROTECT FROM FREEZING

SEE PRESCRIBING INFORMATION

**Baxter**

**BAXTER HEALTHCARE CORPORATION**

**DEERFIELD IL 60015 USA**

**MADE IN USA**
**CLAISMIX**

5/20

SULFITE-FREE

(5% Amino Acids in 20% Dextrose)

Injection

**CENTRAL LINE INFUSION ONLY**

500 mL INJECTION PORT CHAMBER
40% Dextrose Injection USP

500 mL OUTLET PORT CHAMBER
10% Amino Acid Injection

Rx Only

**ACTIVATE SEAL AND MIX THOROUGHLY BEFORE USE**

**LOT EXP**

2B7731 NDC 0338-1138-03

**CLAISMIX**

5/20

SULFITE-FREE

(5% Amino Acids in 20% Dextrose)

Injection

500 mL INJECTION PORT CHAMBER
40% Dextrose Injection USP

500 mL OUTLET PORT CHAMBER
10% Amino Acid Injection

Rx Only

**ACTIVATE SEAL AND MIX THOROUGHLY BEFORE USE**

SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION
AFTER MIXING THE PRODUCT REPRESENTS 1000 mL
REFRIGERATED STORAGE IS LIMITED TO 9 DAYS
A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY
AND EFFICACY OF THIS PRODUCT
ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY

CONTENTS OF EACH 100 mL OF THE
ADMIXED INJECTION

DEXTROSE HYDROUS USP 20 g

**ESSENTIAL AMINO ACIDS**
LEUCINE 365 mg
ISOLEUCINE 300 mg
VALINE 290 mg
LYSINE (ADDED AS THE HYDROCHLORIDE SALT) 290 mg
PHENYLALANINE 280 mg
HISTIDINE 240 mg
THREONINE 210 mg
METHIONINE 200 mg
TRYPTOPHAN 90 mg

**NONSESENTIAL AMINO ACIDS**
ALANINE 1035 mg
ARGININE 575 mg
GLYCINE 515 mg
PROLINE 340 mg
SERINE 250 mg
TYROSINE 20 mg

mEq/L
ACETATE 42
CHLORIDE 20

BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID

STERILE
SINGLE DOSE CONTAINER

ROOM TEMPERATURE (25°C/77°F)
AVOID EXCESSIVE HEAT
PROTECT FROM FREEZING
SEE PRESCRIBING INFORMATION

Baxter
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA
Container Label

LOT EXP
2B7710 NDC 0338-1101-04

CLINIMIX
5/20
SULFITE-FREE
(5% Amino Acid in 20% Dextrose) Injection

1000 mL INJECTION PORT CHAMBER
40% Dextrose Injection USP

1000 mL OUTLET PORT CHAMBER
10% Amino Acid Injection

Rx Only

ACTIVATE SEAL AND MIX THOROUGHLY BEFORE USE

SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON

ACTIVATION
AFTER MIXING THE PRODUCT REPRESENTS 2000 mL
REFRIGERATED STORAGE IS LIMITED TO 9 DAYS
A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY
AND Efficacy OF THIS PRODUCT
ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY

CONTENTS OF EACH 100 mL OF THE ADMIXED INJECTION
DEXTROSE HYDROUS USP
20 g

ESSENTIAL AMINO ACIDS
LEUCINE 965 mg
ISOLEUCINE 300 mg
VALINE 290 mg
LYSINE (ADDED AS THE HYDROCHLORIDE SALT) 290 mg
PHENYLALANINE 290 mg
HISTIDINE 240 mg
THREONINE 210 mg
METHIONINE 200 mg
TRYPTOPHAN 90 mg

NONESSENTIAL AMINO ACIDS
ALANINE 1035 mg
ARGININE 575 mg
GLYCINE 515 mg
PROLINE 340 mg
SERINE 250 mg
TYROSINE 20 mg

mEq/L
ACETATE 42
CHLORIDE 20

BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID
STERILE
SINGLE DOSE CONTAINER
ROOM TEMPERATURE (25°C/77°F)
AVOID EXCESSIVE HEAT
PROTECT FROM FREEZING
SEE PRESCRIBING INFORMATION

Baxter
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA

Container Label
ACTIVATION
AFTER MIXING THE PRODUCT REPRESENTS 2000 mL
REFRIGERATED STORAGE IS LIMITED TO 9 DAYS
A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY
AND EFFICACY OF THIS PRODUCT
ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY
CONTENTS OF EACH 100 mL OF THE
ADMIXED INJECTION
DEXTROSE HYDROUS USP 20 g

**ESSENTIAL AMINO ACIDS**
LEUCINE 365 mg
ISOLEUCINE 300 mg
VALINE 290 mg
LYSINE (ADDED AS THE
HYDROCHLORIDE SALT) 290 mg
PHENYLALANINE 280 mg
HISTIDINE 240 mg
THREONINE 210 mg
METHIONINE 200 mg
TRYPTOPHAN 90 mg

**NONSESENTIAL AMINO ACIDS**
ALANINE 1035 mg
ARGININE 575 mg
GLYCINE 515 mg
PROLINE 340 mg
SERINE 250 mg
TYROSINE 20 mg

mEq/L
ACETATE 42
CHLORIDE 20

BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID
STERILE
SINGLE DOSE CONTAINER
ROOM TEMPERATURE (25°C/77°F)
AVOID EXCESSIVE HEAT
PROTECT FROM FREEZING
SEE PRESCRIBING INFORMATION

Baxter
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA
## Container Label

<table>
<thead>
<tr>
<th>LOT EXP</th>
<th>2B7732 NDC 0338-1139-03</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLINIMIX</td>
<td>5/25</td>
</tr>
<tr>
<td>SULFITE-FREE</td>
<td>(5% Amino Acids in 25% Dextrose)</td>
</tr>
<tr>
<td>Injection</td>
<td></td>
</tr>
<tr>
<td>500 mL INJECTION PORT CHAMBER</td>
<td>50% Dextrose Injection USP</td>
</tr>
<tr>
<td>500 mL OUTLET PORT CHAMBER</td>
<td>10% Amino Acid Injection</td>
</tr>
<tr>
<td>Rx Only</td>
<td></td>
</tr>
<tr>
<td><strong>ACTIVATE SEAL AND MIX THOROUGHLY BEFORE USE</strong></td>
<td></td>
</tr>
<tr>
<td>SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION</td>
<td></td>
</tr>
<tr>
<td>AFTER MIXING THE PRODUCT REPRESENTS 1000 mL</td>
<td></td>
</tr>
<tr>
<td>REFRIGERATED STORAGE IS LIMITED TO 9 DAYS</td>
<td></td>
</tr>
<tr>
<td>A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY AND EFFICACY OF THIS PRODUCT</td>
<td></td>
</tr>
<tr>
<td>ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY</td>
<td></td>
</tr>
</tbody>
</table>

### Contents of Each 100 mL of the ADMixed Injection
- **Dextrose Hydrate USP** 25 g
- **Essential Amino Acids**
  - Leucine: 365 mg
  - Isoleucine: 305 mg
  - Valine: 290 mg
  - Lysine (Added as the Hydrochloride Salt): 260 mg
  - Phenylalanine: 260 mg
  - Histidine: 240 mg
  - Threonine: 210 mg
  - Methionine: 200 mg
  - Tryptophan: 90 mg
- **Nonessential Amino Acids**
  - Alanine: 1035 mg
  - Arginine: 575 mg
  - Glutamine: 515 mg
  - Proline: 340 mg
  - Serine: 250 mg
  - Tyrosine: 20 mg
- **mEq/L**
  - Acetate: 42
  - Chloride: 20
- BALANCED BY IONS FROM AMINO ACIDS
- pH ADJUSTED WITH GLACIAL ACETIC ACID
- STERILE
- SINGLE DOSAGE CONTAINER

**Baxter Healthcare Corporation**
**Deerfield, IL 60015 USA**
**MADE IN USA**
A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY AND EFFICACY OF THIS PRODUCT
ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY
CONTENTS OF EACH 100 mL OF THE ADMIXED INJECTION
DEXTROSE HYDROUS USP 25 g

**ESSENTIAL AMINO ACIDS**
LEUCINE 365 mg
ISOLEUCINE 300 mg
VALINE 290 mg
LYSINE (ADDED AS THE HYDROCHLORIDE SALT) 290 mg
PHENYLALANINE 280 mg
HISTIDINE 240 mg
THREONINE 210 mg
METHIONINE 200 mg
TRYPTOPHAN 90 mg

**NONESSENTIAL AMINO ACIDS**
ALANINE 1035 mg
ARGININE 575 mg
GLYCINE 515 mg
PROLINE 340 mg
SERINE 250 mg
TYROSINE 20 mg

mEq/L
ACETATE 42
CHLORIDE 20

BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID
STERILE
SINGLE DOSE CONTAINER

Baxter
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA
LOT EXP
2B7711 NDC 0338-1103-04
CLINIMIX
5/25
SULFITE-FREE
(5% Amino Acid in 25% Dextrose) Injection

1000 mL INJECTION PORT CHAMBER
50% Dextrose Injection USP

1000 mL OUTLET PORT CHAMBER
10% Amino Acid Injection

Rx Only

ACTIVATE SEAL AND MIX THOROUGHLY BEFORE USE
SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION

AFTER MIXING THE PRODUCT REPRESENTS 2000 mL

REFRIGERATED STORAGE IS LIMITED TO 9 DAYS

A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY AND EFFICACY OF THIS PRODUCT

ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY

CONTENTS OF EACH 100 mL OF THE ADMIXED INJECTION

DEXTROSE HYDROUS USP 25 g

**ESSENTIAL AMINO ACIDS**
LEUCINE 365 mg
ISOLEUCINE 300 mg
VALINE 290 mg
LYSINE (ADDED AS THE HYDROCHLORIDE SALT) 290 mg
PHENYLALANINE 280 mg
HISTIDINE 240 mg
THREONINE 210 mg
METHIONINE 200 mg
TRYPTOPHAN 90 mg

**NONESSENTIAL AMINO ACIDS**
ALANINE 1035 mg
ARGININE 575 mg
GLYCINE 515 mg
PROLINE 340 mg
SERINE 250 mg
TYROSINE 20 mg

mEq/L
ACETATE 42
CHLORIDE 20

BALANCED BY IONS FROM AMINO ACIDS
pH ADJUSTED WITH GLACIAL ACETIC ACID

STERILE
SINGLE DOSE CONTAINER

Baxter
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA

**CLINIMIX**
leucine, phenylalanine, lysine, methionine, isoleucine, valine, histidine, threonine, tryptophan, alanine, glycine, arginine, proline, serine, tyrosine, dextrose injection

**Product Information**

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td>NDC:0338-1132</td>
</tr>
</tbody>
</table>
**Route of Administration**

<table>
<thead>
<tr>
<th>Active Ingredient/Active Moiety</th>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEUCINE (UNII: GMW67QNF9C)</td>
<td>LEUCINE</td>
<td></td>
<td>201 mg in 100 mL</td>
</tr>
<tr>
<td>PHENYLALANINE (UNII: 47E5017Y3R)</td>
<td>PHENYLALANINE</td>
<td></td>
<td>154 mg in 100 mL</td>
</tr>
<tr>
<td>LYSINE (UNII: K3Z4F929H6)</td>
<td>LYSINE</td>
<td></td>
<td>159 mg in 100 mL</td>
</tr>
<tr>
<td>METHIONINE (UNII: AE28F7PNPL)</td>
<td>METHIONINE</td>
<td></td>
<td>110 mg in 100 mL</td>
</tr>
<tr>
<td>ISOLEUCINE (UNII: 04Y7590D77)</td>
<td>ISOLEUCINE</td>
<td></td>
<td>165 mg in 100 mL</td>
</tr>
<tr>
<td>VALINE (UNII: HG18B9YRS7)</td>
<td>VALINE</td>
<td></td>
<td>160 mg in 100 mL</td>
</tr>
<tr>
<td>HISTIDINE (UNII: 4QD397987E)</td>
<td>HISTIDINE</td>
<td></td>
<td>132 mg in 100 mL</td>
</tr>
<tr>
<td>THREONINE (UNII: 2ZD004190S)</td>
<td>THREONINE</td>
<td></td>
<td>116 mg in 100 mL</td>
</tr>
<tr>
<td>TRYPTOPHAN (UNII: 8DUH1N1BX)</td>
<td>TRYPTOPHAN</td>
<td></td>
<td>50 mg in 100 mL</td>
</tr>
<tr>
<td>ALANINE (UNII: OF5P57N2ZX)</td>
<td>ALANINE</td>
<td></td>
<td>570 mg in 100 mL</td>
</tr>
<tr>
<td>GLYCINE (UNII: TE7660X0IC)</td>
<td>GLYCINE</td>
<td></td>
<td>283 mg in 100 mL</td>
</tr>
<tr>
<td>ARGinine (UNII: 94ZLA3W45F)</td>
<td>ARGinine</td>
<td></td>
<td>316 mg in 100 mL</td>
</tr>
<tr>
<td>PROLINE (UNII: 9DLQ4CIU6V)</td>
<td>PROLINE</td>
<td></td>
<td>187 mg in 100 mL</td>
</tr>
<tr>
<td>SERINE (UNII: 452VL9Y9402)</td>
<td>SERINE</td>
<td></td>
<td>138 mg in 100 mL</td>
</tr>
<tr>
<td>TYROSINE (UNII: 42HK56048U)</td>
<td>TYROSINE</td>
<td></td>
<td>11 mg in 100 mL</td>
</tr>
<tr>
<td>DEXTROSE (UNII: FY9XDZ35W2)</td>
<td>DEXTROSE</td>
<td></td>
<td>5 g in 100 mL</td>
</tr>
</tbody>
</table>

**Inactive Ingredients**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETIC ACID</td>
<td></td>
</tr>
<tr>
<td>WATER</td>
<td></td>
</tr>
<tr>
<td>NITROGEN</td>
<td></td>
</tr>
</tbody>
</table>

**Packaging**

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0338-1132-03</td>
<td>1000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/29/1997</td>
<td>05/14/2018</td>
</tr>
</tbody>
</table>

**Marketing Information**

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020734</td>
<td>09/29/1997</td>
<td>05/14/2018</td>
</tr>
</tbody>
</table>

**CLINIMIX**

leucine, phenylalanine, lysine, methionine, isoleucine, valine, histidine, threonine, tryptophan, alanine, glycine, arginine, proline, serine, tyrosine, dextrose injection

**Product Information**

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>Route of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td>NDC:0338-1083</td>
<td>INTRAVENOUS</td>
</tr>
</tbody>
</table>
**Active Ingredient/Active Moiety**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEUCINE (UNII: GMW67QNF9C) (LEUCINE - UNII:GMW67QNF9C)</td>
<td>LEUCINE</td>
<td>201 mg in 100 mL</td>
</tr>
<tr>
<td>PHENYLALANINE (UNII: 47E5O17Y3R) (PHENYLALANINE - UNII:47E5O17Y3R)</td>
<td>PHENYLALANINE</td>
<td>154 mg in 100 mL</td>
</tr>
<tr>
<td>LYSINE (UNII: K3Z4F929H6) (LYSINE - UNII:K3Z4F929H6)</td>
<td>LYSINE</td>
<td>159 mg in 100 mL</td>
</tr>
<tr>
<td>METHIONINE (UNII: AE2E8F7PNPL) (METHIONINE - UNII:AE2E8F7PNPL)</td>
<td>METHIONINE</td>
<td>110 mg in 100 mL</td>
</tr>
<tr>
<td>ISOLEUCINE (UNII: 04Y7590D77) (ISOLEUCINE - UNII:04Y7590D77)</td>
<td>ISOLEUCINE</td>
<td>165 mg in 100 mL</td>
</tr>
<tr>
<td>VALINE (UNII: HG18B9YRS7) (VALINE - UNII:HG18B9YRS7)</td>
<td>VALINE</td>
<td>160 mg in 100 mL</td>
</tr>
<tr>
<td>HISTIDINE (UNII: 4QD397987E) (HISTIDINE - UNII:4QD397987E)</td>
<td>HISTIDINE</td>
<td>132 mg in 100 mL</td>
</tr>
<tr>
<td>THREONINE (UNII: 2ZD004190S) (THREONINE - UNII:2ZD004190S)</td>
<td>THREONINE</td>
<td>116 mg in 100 mL</td>
</tr>
<tr>
<td>TRYPTOPHAN (UNII: 8DUHIN1IBX) (TRYPTOPHAN - UNII:8DUHIN1IBX)</td>
<td>TRYPTOPHAN</td>
<td>50 mg in 100 mL</td>
</tr>
<tr>
<td>ALANINE (UNII: OF5P57N2ZX) (ALANINE - UNII:OF5P57N2ZX)</td>
<td>ALANINE</td>
<td>570 mg in 100 mL</td>
</tr>
<tr>
<td>GLYCINE (UNII: TE7660XO1C) (GLYCINE - UNII:TE7660XO1C)</td>
<td>GLYCINE</td>
<td>283 mg in 100 mL</td>
</tr>
<tr>
<td>ARGININE (UNII: 94ZLA3W45F) (ARGININE - UNII:94ZLA3W45F)</td>
<td>ARGININE</td>
<td>316 mg in 100 mL</td>
</tr>
<tr>
<td>PROLINE (UNII: 4DLQ4CIU6V) (PROLINE - UNII:4DLQ4CIU6V)</td>
<td>PROLINE</td>
<td>187 mg in 100 mL</td>
</tr>
<tr>
<td>SERINE (UNII: 452VLY9402) (SERINE - UNII:452VLY9402)</td>
<td>SERINE</td>
<td>138 mg in 100 mL</td>
</tr>
<tr>
<td>TYROSINE (UNII: 82HK56048U) (TYROSINE - UNII:82HK56048U)</td>
<td>TYROSINE</td>
<td>11 mg in 100 mL</td>
</tr>
<tr>
<td>DEXTROSE (UNII: 1Y9XDZ35W2) (DEXTROSE - UNII:1Y9XDZ35W2)</td>
<td>DEXTROSE</td>
<td>5 g in 100 mL</td>
</tr>
</tbody>
</table>

**Inactive Ingredients**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETIC ACID (UNII: Q40Q9N063P)</td>
<td></td>
</tr>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
<tr>
<td>NITROGEN (UNII: N762921K75)</td>
<td></td>
</tr>
</tbody>
</table>

**Packaging**

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0338-1083-04</td>
<td>2000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/29/1997</td>
<td>05/14/2018</td>
</tr>
</tbody>
</table>

**Marketing Information**

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020734</td>
<td>09/29/1997</td>
<td>05/14/2018</td>
</tr>
</tbody>
</table>

**CLINIMIX**

leucine, phenylalanine, lysine, methionine, isoleucine, valine, histidine, threonine, tryptophan, alanine, glycine, arginine, proline, serine, tyrosine, dextrose injection

**Product Information**

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>NDC:0338-1133</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INTRAVENOUS</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Active Ingredient/Active Moiety**
<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEUCINE</td>
<td>LEUCINE</td>
<td>311 mg in 100 mL</td>
</tr>
<tr>
<td>PHENYLALANINE</td>
<td>PHENYLALANINE</td>
<td>238 mg in 100 mL</td>
</tr>
<tr>
<td>LYSINE</td>
<td>LYSINE</td>
<td>247 mg in 100 mL</td>
</tr>
<tr>
<td>METHIONINE</td>
<td>METHIONINE</td>
<td>170 mg in 100 mL</td>
</tr>
<tr>
<td>ISOLEUCINE</td>
<td>ISOLEUCINE</td>
<td>255 mg in 100 mL</td>
</tr>
<tr>
<td>VALINE</td>
<td>VALINE</td>
<td>247 mg in 100 mL</td>
</tr>
<tr>
<td>HISTIDINE</td>
<td>HISTIDINE</td>
<td>204 mg in 100 mL</td>
</tr>
<tr>
<td>THREONINE</td>
<td>THREONINE</td>
<td>179 mg in 100 mL</td>
</tr>
<tr>
<td>TRYPTOPHAN</td>
<td>TRYPTOPHAN</td>
<td>77 mg in 100 mL</td>
</tr>
<tr>
<td>ALANINE</td>
<td>ALANINE</td>
<td>880 mg in 100 mL</td>
</tr>
<tr>
<td>GLYCINE</td>
<td>GLYCINE</td>
<td>438 mg in 100 mL</td>
</tr>
<tr>
<td>ARGinine</td>
<td>ARGinine</td>
<td>489 mg in 100 mL</td>
</tr>
<tr>
<td>PROLINE</td>
<td>PROLINE</td>
<td>289 mg in 100 mL</td>
</tr>
<tr>
<td>SERINE</td>
<td>SERINE</td>
<td>213 mg in 100 mL</td>
</tr>
<tr>
<td>TYROSINE</td>
<td>TYROSINE</td>
<td>17 mg in 100 mL</td>
</tr>
<tr>
<td>DEXTROSE</td>
<td>DEXTROSE</td>
<td>5 g in 100 mL</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETIC ACID</td>
<td></td>
</tr>
<tr>
<td>WATER</td>
<td></td>
</tr>
<tr>
<td>NITROGEN</td>
<td></td>
</tr>
</tbody>
</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0338-1133-03</td>
<td>1000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/29/1997</td>
<td></td>
</tr>
</tbody>
</table>

### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020734</td>
<td>09/29/1997</td>
<td></td>
</tr>
</tbody>
</table>

### CLINIMIX

leucine, phenylalanine, lysine, methionine, isoleucine, valine, histidine, threonine, tryptophan, alanine, glycine, arginine, proline, serine, tyrosine, dextrose injection

### Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>NDC:0338-1089</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INTRAVENOUS</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEUCINE</td>
<td>LEUCINE</td>
<td>311 mg in 100 mL</td>
</tr>
</tbody>
</table>
**PHENYLALANINE** (UNII: 47E5O17Y3R) (PHENYLALANINE - UNII:47E5O17Y3R) 238 mg in 100 mL

**LYSINE** (UNII: K3Z4F929H6) (LYSINE - UNII:K3Z4F929H6) 247 mg in 100 mL

**METHIONINE** (UNII: AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL) 170 mg in 100 mL

**ISOLEUCINE** (UNII: 04Y7590D77) (ISOLEUCINE - UNII:04Y7590D77) 255 mg in 100 mL

**VALINE** (UNII: HG18B9YRS7) (VALINE - UNII:HG18B9YRS7) 247 mg in 100 mL

**HISTIDINE** (UNII: 4QD397987E) (HISTIDINE - UNII:4QD397987E) 204 mg in 100 mL

**THREONINE** (UNII: 2ZD004190S) (THREONINE - UNII:2ZD004190S) 179 mg in 100 mL

**TRYPTOPHAN** (UNII: 8DUH1N11BX) (TRYPTOPHAN - UNII:8DUH1N11BX) 77 mg in 100 mL

**ALANINE** (UNII: OF5P57N2ZX) (ALANINE - UNII:OF5P57N2ZX) 880 mg in 100 mL

**GLYCINE** (UNII: TE7660X101C) (GLYCINE - UNII:TE7660X101C) 438 mg in 100 mL

**ARGININE** (UNII: 94ZLA3W45F) (ARGININE - UNII:94ZLA3W45F) 489 mg in 100 mL

**PROLINE** (UNII: 9DLQ4CIU6V) (PROLINE - UNII:9DLQ4CIU6V) 289 mg in 100 mL

**SERINE** (UNII: 452VLY9402) (SERINE - UNII:452VLY9402) 213 mg in 100 mL

**TYROSINE** (UNII: 42HK56048U) (TYROSINE - UNII:42HK56048U) 17 mg in 100 mL

**DEXTROSE** (UNII: IY9XDZ35W2) (DEXTROSE - UNII:IY9XDZ35W2) 5 g in 100 mL

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETIC ACID (UNII: Q40Q9N063P)</td>
<td></td>
</tr>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
<tr>
<td>NITROGEN (UNII: N762921K75)</td>
<td></td>
</tr>
</tbody>
</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0338-1089-04</td>
<td>2000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/29/1997</td>
<td></td>
</tr>
</tbody>
</table>

### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020734</td>
<td>09/29/1997</td>
<td></td>
</tr>
</tbody>
</table>

### CLINIMIX

**leucine, phenylalanine, lysine, methionine, isoleucine, valine, histidine, threonine, tryptophan, alanine, glycine, arginine, proline, serine, tyrosine, dextrose injection**

### Product Information

**Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0338-1134
**Route of Administration** | INTRAVENOUS

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEUCINE (UNII: GMW67QNF9C) (LEUCINE - UNII:GMW67QNF9C)</td>
<td>LEUCINE</td>
<td>311 mg in 100 mL</td>
</tr>
<tr>
<td>PHENYLALANINE (UNII: 47E5O17Y3R) (PHENYLALANINE - UNII:47E5O17Y3R)</td>
<td>PHENYLALANINE</td>
<td>238 mg in 100 mL</td>
</tr>
<tr>
<td>LYSINE (UNII: K3Z4F929H6) (LYSINE - UNII:K3Z4F929H6)</td>
<td>LYSINE</td>
<td>247 mg in 100 mL</td>
</tr>
</tbody>
</table>
METHIONINE (UNII: AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL) METHIONINE 170 mg in 100 mL
ISO LEUCINE (UNII: 04Y7590D77) (ISO LEUCINE - UNII:04Y7590D77) ISO LEUCINE 255 mg in 100 mL
VALINE (UNII: HG18B9YRS7) (VALINE - UNII:HG18B9YRS7) VALINE 247 mg in 100 mL
HISTIDINE (UNII: 4QD397987E) (HISTIDINE - UNII:4QD397987E) HISTIDINE 204 mg in 100 mL
THREONINE (UNII: 2ZD004190S) (THREONINE - UNII:2ZD004190S) THREONINE 179 mg in 100 mL
TRYPTOPHAN (UNII: 8DUH1N11BX) (TRYPTOPHAN - UNII:8DUH1N11BX) TRYPTOPHAN 77 mg in 100 mL
ALANINE (UNII: OF5P57N2ZX) (ALANINE - UNII:OF5P57N2ZX) ALANINE 880 mg in 100 mL
GLYCINE (UNII: TE7660XO1C) (GLYCINE - UNII:TE7660XO1C) GLYCINE 438 mg in 100 mL
ARGININE (UNII: 94ZLA3W45F) (ARGININE - UNII:94ZLA3W45F) ARGinine 489 mg in 100 mL
PROLINE (UNII: 9DLQ4CIU6V) (PROLINE - UNII:9DLQ4CIU6V) PROLINE 289 mg in 100 mL
SERINE (UNII: 452VLY9402) (SERINE - UNII:452VLY9402) SERINE 213 mg in 100 mL
TYROSINE (UNII: 42HK56048U) (TYROSINE - UNII:42HK56048U) TYROSINE 17 mg in 100 mL
DEXTROSE (UNII: IY9XDZ35W2) (DEXTROSE - UNII:IY9XDZ35W2) DEXTROSE 10 g in 100 mL

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETIC ACID (UNII: Q40Q9N063P)</td>
<td></td>
</tr>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
<tr>
<td>NITROGEN (UNII: N762921K75)</td>
<td></td>
</tr>
</tbody>
</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0338-1134-03</td>
<td>1000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>03/20/2012</td>
<td></td>
</tr>
</tbody>
</table>

### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020734</td>
<td>03/20/2012</td>
<td></td>
</tr>
</tbody>
</table>

### CLINIMIX

leucine, phenylalanine, lysine, methionine, isoleucine, valine, histidine, threonine, tryptophan, alanine, glycine, arginine, proline, serine, tyrosine, dextrose injection

### Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>NDC:0338-1091</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INTRAVENOUS</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEUCINE (UNII: GMW67QNF9C) (LEUCINE - UNII:GMW67QNF9C)</td>
<td>LEUCINE</td>
<td>311 mg in 100 mL</td>
</tr>
<tr>
<td>PHENYLALANINE (UNII: 47E5017Y3R) (PHENYLALANINE - UNII:47E5017Y3R)</td>
<td>PHENYLALANINE</td>
<td>238 mg in 100 mL</td>
</tr>
<tr>
<td>LYSINE (UNII: K3Z4F929H6) (LYSINE - UNII:K3Z4F929H6)</td>
<td>LYSINE</td>
<td>247 mg in 100 mL</td>
</tr>
<tr>
<td>METHIONINE (UNII: AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL)</td>
<td>METHIONINE</td>
<td>170 mg in 100 mL</td>
</tr>
<tr>
<td>ISO LEUCINE (UNII: 04Y7590D77) (ISO LEUCINE - UNII:04Y7590D77)</td>
<td>ISO LEUCINE</td>
<td>255 mg in 100 mL</td>
</tr>
<tr>
<td>Ingredient Name</td>
<td>Basis of Strength</td>
<td>Strength</td>
</tr>
<tr>
<td>-----------------</td>
<td>-------------------</td>
<td>----------</td>
</tr>
<tr>
<td>LEUCINE</td>
<td>LEUCINE</td>
<td>311 mg in 100 mL</td>
</tr>
<tr>
<td>PHENYLALANINE</td>
<td>PHENYLALANINE</td>
<td>238 mg in 100 mL</td>
</tr>
<tr>
<td>LYSINE</td>
<td>LYSINE</td>
<td>247 mg in 100 mL</td>
</tr>
<tr>
<td>METHIONINE</td>
<td>METHIONINE</td>
<td>170 mg in 100 mL</td>
</tr>
<tr>
<td>ISOLEUCINE</td>
<td>ISOLEUCINE</td>
<td>255 mg in 100 mL</td>
</tr>
<tr>
<td>VALINE</td>
<td>VALINE</td>
<td>247 mg in 100 mL</td>
</tr>
<tr>
<td>HISTIDINE</td>
<td>HISTIDINE</td>
<td>204 mg in 100 mL</td>
</tr>
</tbody>
</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0338-1091-04</td>
<td>2000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/29/1997</td>
<td></td>
</tr>
</tbody>
</table>

### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020734</td>
<td>09/29/1997</td>
<td></td>
</tr>
</tbody>
</table>

### CLINIMIX
leucine, phenylalanine, lysine, methionine, isoleucine, valine, histidine, threonine, tryptophan, alanine, glycine, arginine, proline, serine, tyrosine, dextrose injection

### Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>NDC:0338-1135</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INTRAVENOUS</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**Inactive Ingredients**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETIC ACID</td>
<td></td>
</tr>
<tr>
<td>WATER</td>
<td></td>
</tr>
<tr>
<td>NITROGEN</td>
<td></td>
</tr>
</tbody>
</table>
## Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETIC ACID</td>
<td></td>
</tr>
<tr>
<td>WATER</td>
<td></td>
</tr>
<tr>
<td>NITROGEN</td>
<td></td>
</tr>
</tbody>
</table>

## Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0338-1135-03</td>
<td>1000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/29/1997</td>
<td>05/14/2018</td>
</tr>
</tbody>
</table>

## Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020734</td>
<td>09/29/1997</td>
<td>05/14/2018</td>
</tr>
</tbody>
</table>

## CLINIMIX
leucine, phenylalanine, lysine, methionine, isoleucine, valine, histidine, threonine, tryptophan, alanine, glycine, arginine, proline, serine, tyrosine, dextrose injection

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>NDC:0338-1093</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INTRAVENOUS</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEUCINE</td>
<td>LEUCINE</td>
<td>311 mg in 100 mL</td>
</tr>
<tr>
<td>PHENYLALANINE</td>
<td>PHENYLALANINE</td>
<td>238 mg in 100 mL</td>
</tr>
<tr>
<td>LYSINE</td>
<td>LYSINE</td>
<td>247 mg in 100 mL</td>
</tr>
<tr>
<td>METHIONINE</td>
<td>METHIONINE</td>
<td>170 mg in 100 mL</td>
</tr>
<tr>
<td>ISOLEUCINE</td>
<td>ISOLEUCINE</td>
<td>255 mg in 100 mL</td>
</tr>
<tr>
<td>VALINE</td>
<td>VALINE</td>
<td>247 mg in 100 mL</td>
</tr>
<tr>
<td>HISTIDINE</td>
<td>HISTIDINE</td>
<td>204 mg in 100 mL</td>
</tr>
<tr>
<td>THREONINE</td>
<td>THREONINE</td>
<td>179 mg in 100 mL</td>
</tr>
<tr>
<td>TRYPTOPHAN</td>
<td>TRYPTOPHAN</td>
<td>77 mg in 100 mL</td>
</tr>
<tr>
<td>ALANINE</td>
<td>ALANINE</td>
<td>880 mg in 100 mL</td>
</tr>
</tbody>
</table>
GLYCINE (UNII: TE7660XO1C) (GLYCINE - UNII:TE7660XO1C)  438 mg  in 100 mL
ARGININE (UNII: 94ZLA3W45F) (ARGININE - UNII:94ZLA3W45F)  489 mg  in 100 mL
PROLINE (UNII: 9DLQ4CIU6V) (PROLINE - UNII:9DLQ4CIU6V)  289 mg  in 100 mL
SERINE (UNII: 452VLY9402) (SERINE - UNII:452VLY9402)  213 mg  in 100 mL
TYROSINE (UNII: 42HK56048U) (TYROSINE - UNII:42HK56048U)  77 mg  in 100 mL
DEXTROSE (UNII: IY9XDZ35W2) (DEXTROSE - UNII:IY9XDZ35W2)  20 g  in 100 mL

Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETIC ACID (UNII: Q40Q9N063P)</td>
<td></td>
</tr>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
<tr>
<td>NITROGEN (UNII: N762921K75)</td>
<td></td>
</tr>
</tbody>
</table>

Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0338-1093-04</td>
<td>2000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/29/1997</td>
<td>05/14/2018</td>
</tr>
</tbody>
</table>

Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020734</td>
<td>09/29/1997</td>
<td>05/14/2018</td>
</tr>
</tbody>
</table>

CLINIMIX

leucine, phenylalanine, lysine, methionine, isoleucine, valine, histidine, threonine, tryptophan, alanine, glycine, arginine, proline, serine, tyrosine, dextrose injection

Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>NDC:0338-1136</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Route of Administration

| Route of Administration | |
|-------------------------| |
| INTRAVENOUS | |

Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEUCINE (UNII: GMW67QNF9C) (LEUCINE - UNII:GMW67QNF9C)</td>
<td>LEUCINE</td>
<td>311 mg  in 100 mL</td>
</tr>
<tr>
<td>PHENYLALANINE (UNII: 47E5O17Y3R) (PHENYLALANINE - UNII:47E5O17Y3R)</td>
<td>PHENYLALANINE</td>
<td>238 mg  in 100 mL</td>
</tr>
<tr>
<td>LYSINE (UNII: K3Z4F929H6) (LYSINE - UNII:K3Z4F929H6)</td>
<td>LYSINE</td>
<td>247 mg  in 100 mL</td>
</tr>
<tr>
<td>METHIONINE (UNII: AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL)</td>
<td>METHIONINE</td>
<td>170 mg  in 100 mL</td>
</tr>
<tr>
<td>ISOLEUCINE (UNII: 04Y7590D77) (ISOLEUCINE - UNII:04Y7590D77)</td>
<td>ISOLEUCINE</td>
<td>255 mg  in 100 mL</td>
</tr>
<tr>
<td>VALINE (UNII: HG18B9YRS7) (VALINE - UNII:HG18B9YRS7)</td>
<td>VALINE</td>
<td>247 mg  in 100 mL</td>
</tr>
<tr>
<td>HISTIDINE (UNII: 4QD397987E) (HISTIDINE - UNII:4QD397987E)</td>
<td>HISTIDINE</td>
<td>204 mg  in 100 mL</td>
</tr>
<tr>
<td>THREONINE (UNII: 2ZD004190S) (THREONINE - UNII:2ZD004190S)</td>
<td>THREONINE</td>
<td>179 mg  in 100 mL</td>
</tr>
<tr>
<td>TRYPTOPHAN (UNII: 8DUH1N1IBX) (TRYPTOPHAN - UNII:8DUH1N1IBX)</td>
<td>TRYPTOPHAN</td>
<td>77 mg  in 100 mL</td>
</tr>
<tr>
<td>ALANINE (UNII: OF5P57N2XX) (ALANINE - UNII:OF5P57N2XX)</td>
<td>ALANINE</td>
<td>880 mg  in 100 mL</td>
</tr>
<tr>
<td>GLYCINE (UNII: TE7660XO1C) (GLYCINE - UNII:TE7660XO1C)</td>
<td>GLYCINE</td>
<td>438 mg  in 100 mL</td>
</tr>
<tr>
<td>ARGinine (UNII: 94ZLA3W45F) (ARGININE - UNII:94ZLA3W45F)</td>
<td>ARGinine</td>
<td>489 mg  in 100 mL</td>
</tr>
</tbody>
</table>
**Inactive Ingredients**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETIC ACID</td>
<td></td>
</tr>
<tr>
<td>WATER</td>
<td></td>
</tr>
<tr>
<td>NITROGEN</td>
<td></td>
</tr>
</tbody>
</table>

**Packaging**

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0338-1136-03</td>
<td>1000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/29/1997</td>
<td>02/29/2020</td>
</tr>
</tbody>
</table>

**Marketing Information**

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020734</td>
<td>09/29/1997</td>
<td>02/29/2020</td>
</tr>
</tbody>
</table>

**Product Information**

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td>NDC:0338-1095</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Route of Administration</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>INTRAVENOUS</td>
<td></td>
</tr>
</tbody>
</table>

**Active Ingredient/Active Moiety**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEUCINE (UNII: GMW67QNF9C) (LEUCINE - UNII:GMW67QNF9C)</td>
<td>LEUCINE</td>
<td>311 mg in 100 mL</td>
</tr>
<tr>
<td>PHENYLALANINE (UNII: 47E5017Y3R) (PHENYLALANINE - UNII:47E5017Y3R)</td>
<td>PHENYLALANINE</td>
<td>238 mg in 100 mL</td>
</tr>
<tr>
<td>LYSINE (UNII: K3Z4F929H6) (LYSINE - UNII:K3Z4F929H6)</td>
<td>LYSINE</td>
<td>247 mg in 100 mL</td>
</tr>
<tr>
<td>METHIONINE (UNII: AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL)</td>
<td>METHIONINE</td>
<td>170 mg in 100 mL</td>
</tr>
<tr>
<td>ISOLEUCINE (UNII: 04Y7590D77) (ISOLEUCINE - UNII:04Y7590D77)</td>
<td>ISOLEUCINE</td>
<td>255 mg in 100 mL</td>
</tr>
<tr>
<td>VALINE (UNII: HG18B9YRS7) (VALINE - UNII:HG18B9YRS7)</td>
<td>VALINE</td>
<td>247 mg in 100 mL</td>
</tr>
<tr>
<td>HISTIDINE (UNII: 4QD397987E) (HISTIDINE - UNII:4QD397987E)</td>
<td>HISTIDINE</td>
<td>204 mg in 100 mL</td>
</tr>
<tr>
<td>THREONINE (UNII: 2DD004190S) (THREONINE - UNII:2DD004190S)</td>
<td>THREONINE</td>
<td>179 mg in 100 mL</td>
</tr>
<tr>
<td>TRYPTOPHAN (UNII: 8DUHIN11BX) (TRYPTOPHAN - UNII:8DUHIN11BX)</td>
<td>TRYPTOPHAN</td>
<td>77 mg in 100 mL</td>
</tr>
<tr>
<td>ALANINE (UNII: OF5P57N2ZX) (ALANINE - UNII:OF5P57N2ZX)</td>
<td>ALANINE</td>
<td>880 mg in 100 mL</td>
</tr>
<tr>
<td>GLYCINE (UNII: TE7660XO1C) (GLYCINE - UNII:TE7660XO1C)</td>
<td>GLYCINE</td>
<td>438 mg in 100 mL</td>
</tr>
<tr>
<td>ARGinine (UNII: 94ZLA3W45F) (ARGINine - UNII:94ZLA3W45F)</td>
<td>ARGinine</td>
<td>489 mg in 100 mL</td>
</tr>
<tr>
<td>PROLINE (UNII: 9DLQ4CIU6V) (PROLINE - UNII:9DLQ4CIU6V)</td>
<td>PROLINE</td>
<td>289 mg in 100 mL</td>
</tr>
<tr>
<td>SERINE (UNII: 452VLY9402) (SERINE - UNII:452VLY9402)</td>
<td>SERINE</td>
<td>213 mg in 100 mL</td>
</tr>
</tbody>
</table>
**Inactive Ingredients**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETIC ACID</td>
<td></td>
</tr>
<tr>
<td>WATER</td>
<td></td>
</tr>
<tr>
<td>NITROGEN</td>
<td></td>
</tr>
</tbody>
</table>

**Packaging**

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0338-1095-04</td>
<td>2000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/29/1997</td>
<td>05/14/2018</td>
</tr>
</tbody>
</table>

**Marketing Information**

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020734</td>
<td>09/29/1997</td>
<td>05/14/2018</td>
</tr>
</tbody>
</table>

**CLINIMIX**

leucine, phenylalanine, lysine, methionine, isoleucine, valine, histidine, threonine, tryptophan, alanine, glycine, arginine, proline, serine, tyrosine, dextrose injection

**Product Information**

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN PRESCRIPTION DRUG</th>
<th>Item Code (Source)</th>
<th>NDC:0338-1137</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>INTRAVENOUS</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Active Ingredient/Active Moiety**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEUCINE</td>
<td>LEUCINE</td>
<td>365 mg in 100 mL</td>
</tr>
<tr>
<td>PHENYLALANINE</td>
<td>PHENYLALANINE</td>
<td>280 mg in 100 mL</td>
</tr>
<tr>
<td>LYSINE</td>
<td>LYSINE</td>
<td>290 mg in 100 mL</td>
</tr>
<tr>
<td>METHIONINE</td>
<td>METHIONINE</td>
<td>200 mg in 100 mL</td>
</tr>
<tr>
<td>ISOLEUCINE</td>
<td>ISOLEUCINE</td>
<td>300 mg in 100 mL</td>
</tr>
<tr>
<td>VALINE</td>
<td>VALINE</td>
<td>290 mg in 100 mL</td>
</tr>
<tr>
<td>HISTIDINE</td>
<td>HISTIDINE</td>
<td>240 mg in 100 mL</td>
</tr>
<tr>
<td>THREONINE</td>
<td>THREONINE</td>
<td>210 mg in 100 mL</td>
</tr>
<tr>
<td>TRYPTOPHAN</td>
<td>TRYPTOPHAN</td>
<td>90 mg in 100 mL</td>
</tr>
<tr>
<td>ALANINE</td>
<td>ALANINE</td>
<td>10.35 mg in 100 mL</td>
</tr>
<tr>
<td>GLYCINE</td>
<td>GLYCINE</td>
<td>515 mg in 100 mL</td>
</tr>
<tr>
<td>ARGinine</td>
<td>ARGinine</td>
<td>575 mg in 100 mL</td>
</tr>
<tr>
<td>PROLINE</td>
<td>PROLINE</td>
<td>340 mg in 100 mL</td>
</tr>
<tr>
<td>SERINE</td>
<td>SERINE</td>
<td>250 mg in 100 mL</td>
</tr>
<tr>
<td>TYROSINE</td>
<td>TYROSINE</td>
<td>20 mg in 100 mL</td>
</tr>
<tr>
<td>DEXTROSE</td>
<td>DEXTROSE</td>
<td>15 g in 100 mL</td>
</tr>
</tbody>
</table>
### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETIC ACID (UNII: Q40Q9N063P)</td>
<td></td>
</tr>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
<tr>
<td>NITROGEN (UNII: N762921K75)</td>
<td></td>
</tr>
</tbody>
</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0338-1137-03</td>
<td>1000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/29/1997</td>
<td></td>
</tr>
</tbody>
</table>

### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020734</td>
<td>09/29/1997</td>
<td></td>
</tr>
</tbody>
</table>

### CLINIMIX

leucine, phenylalanine, lysine, methionine, isoleucine, valine, histidine, threonine, tryptophan, alanine, glycine, arginine, proline, serine, tyrosine, dextrose injection

### Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Route of Administration</th>
<th>Item Code (Source)</th>
<th>NDC:0338-1099</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td>INTRAVENOUS</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEUCINE (UNII: GMW67QNF9C) (LEUCINE - UNII:GMW67QNF9C)</td>
<td>LEUCINE</td>
<td>365 mg in 100 mL</td>
</tr>
<tr>
<td>PHENYLALANINE (UNII: 47E5O17Y3R) (PHENYLALANINE - UNII:47E5O17Y3R)</td>
<td>PHENYLALANINE</td>
<td>280 mg in 100 mL</td>
</tr>
<tr>
<td>LYSINE (UNII: K3Z4F929H6) (LYSINE - UNII:K3Z4F929H6)</td>
<td>LYSINE</td>
<td>290 mg in 100 mL</td>
</tr>
<tr>
<td>METHIONINE (UNII: AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL)</td>
<td>METHIONINE</td>
<td>200 mg in 100 mL</td>
</tr>
<tr>
<td>ISOLEUCINE (UNII: 0Y7590D77) (ISOLEUCINE - UNII:0Y7590D77)</td>
<td>ISOLEUCINE</td>
<td>300 mg in 100 mL</td>
</tr>
<tr>
<td>VALINE (UNII: HG1B99R7S) (VALINE - UNII:HG1B99R7S)</td>
<td>VALINE</td>
<td>290 mg in 100 mL</td>
</tr>
<tr>
<td>HISTIDINE (UNII: 4QD397987E) (HISTIDINE - UNII:4QD397987E)</td>
<td>HISTIDINE</td>
<td>240 mg in 100 mL</td>
</tr>
<tr>
<td>THREONINE (UNII: 22D004190S) (THREONINE - UNII:22D004190S)</td>
<td>THREONINE</td>
<td>210 mg in 100 mL</td>
</tr>
<tr>
<td>TRYPTOPHAN (UNII: 8DUHI11B1) (TRYPTOPHAN - UNII:8DUHI11B1)</td>
<td>TRYPTOPHAN</td>
<td>90 mg in 100 mL</td>
</tr>
<tr>
<td>ALANINE (UNII: OF5P57N22Z) (ALANINE - UNII:OF5P57N22Z)</td>
<td>ALANINE</td>
<td>1035 mg in 100 mL</td>
</tr>
<tr>
<td>GLYCINE (UNII: TE7660X0IC) (GLYCINE - UNII:TE7660X0IC)</td>
<td>GLYCINE</td>
<td>515 mg in 100 mL</td>
</tr>
<tr>
<td>ARGININE (UNII: 94ZLA3W45F) (ARGININE - UNII:94ZLA3W45F)</td>
<td>ARGININE</td>
<td>575 mg in 100 mL</td>
</tr>
<tr>
<td>PROLINE (UNII: 9DL4CIU6V) (PROLINE - UNII:9DL4CIU6V)</td>
<td>PROLINE</td>
<td>340 mg in 100 mL</td>
</tr>
<tr>
<td>SERINE (UNII: 452VLY9402) (SERINE - UNII:452VLY9402)</td>
<td>SERINE</td>
<td>250 mg in 100 mL</td>
</tr>
<tr>
<td>TYROSINE (UNII: 42HK56048U) (TYROSINE - UNII:42HK56048U)</td>
<td>TYROSINE</td>
<td>20 mg in 100 mL</td>
</tr>
<tr>
<td>DEXTROSE (UNII: FY9XDZ35W2) (DEXTROSE - UNII:FY9XDZ35W2)</td>
<td>DEXTROSE</td>
<td>15 g in 100 mL</td>
</tr>
</tbody>
</table>
# Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETIC ACID (UNII: Q40Q9N063P)</td>
<td></td>
</tr>
<tr>
<td>WATER (UNII: 059QF0K00R)</td>
<td></td>
</tr>
<tr>
<td>NITROGEN (UNII: N762921K75)</td>
<td></td>
</tr>
</tbody>
</table>

# Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0338-1099-04</td>
<td>2000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/29/1997</td>
</tr>
</tbody>
</table>

# Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020734</td>
<td>09/29/1997</td>
<td></td>
</tr>
</tbody>
</table>

# CLINIMIX

leucine, phenylalanine, lysine, methionine, isoleucine, valine, histidine, threonine, tryptophan, alanine, glycine, arginine, proline, serine, tyrosine, dextrose injection

# Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>NDC:0338-1138</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Route of Administration</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>INTRAVENOUS</td>
<td></td>
</tr>
</tbody>
</table>

# Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEUCINE (UNII: GMW67QN9F9C) (LEUCINE - UNII:GMW67QN9F9C)</td>
<td>LEUCINE</td>
<td>365 mg in 100 mL</td>
</tr>
<tr>
<td>PHENYLALANINE (UNII: 47E5O17Y3R) (PHENYLALANINE - UNII:47E5O17Y3R)</td>
<td>PHENYLALANINE</td>
<td>280 mg in 100 mL</td>
</tr>
<tr>
<td>LYSINE (UNII: K3Z4F929H6) (LYSINE - UNII:K3Z4F929H6)</td>
<td>LYSINE</td>
<td>290 mg in 100 mL</td>
</tr>
<tr>
<td>METHIONINE (UNII: AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL)</td>
<td>METHIONINE</td>
<td>200 mg in 100 mL</td>
</tr>
<tr>
<td>ISOLEUCINE (UNII: 04Y7590D77) (ISOLEUCINE - UNII:04Y7590D77)</td>
<td>ISOLEUCINE</td>
<td>300 mg in 100 mL</td>
</tr>
<tr>
<td>VALINE (UNII: HG18B9YRS7) (VALINE - UNII:HG18B9YRS7)</td>
<td>VALINE</td>
<td>290 mg in 100 mL</td>
</tr>
<tr>
<td>HISTIDINE (UNII: 4QD397987E) (HISTIDINE - UNII:4QD397987E)</td>
<td>HISTIDINE</td>
<td>240 mg in 100 mL</td>
</tr>
<tr>
<td>THREONINE (UNII: 2DD0D4190S) (THREONINE - UNII:2DD0D4190S)</td>
<td>THREONINE</td>
<td>210 mg in 100 mL</td>
</tr>
<tr>
<td>TRYPTOPHAN (UNII: 8DUHIN1IBX) (TRYPTOPHAN - UNII:8DUHIN1IBX)</td>
<td>TRYPTOPHAN</td>
<td>90 mg in 100 mL</td>
</tr>
<tr>
<td>ALANINE (UNII: OF5P57N22X) (ALANINE - UNII:OF5P57N22X)</td>
<td>ALANINE</td>
<td>1035 mg in 100 mL</td>
</tr>
<tr>
<td>GLYCINE (UNII: TE7660XO1C) (GLYCINE - UNII:TE7660XO1C)</td>
<td>GLYCINE</td>
<td>515 mg in 100 mL</td>
</tr>
<tr>
<td>ARGinine (UNII: 94ZLA3W45F) (ARGinine - UNII:94ZLA3W45F)</td>
<td>ARGinine</td>
<td>575 mg in 100 mL</td>
</tr>
<tr>
<td>PROLINE (UNII: 9DLQ4CIU6V) (PROLINE - UNII:9DLQ4CIU6V)</td>
<td>PROLINE</td>
<td>340 mg in 100 mL</td>
</tr>
<tr>
<td>SERINE (UNII: 452VLY9402) (SERINE - UNII:452VLY9402)</td>
<td>SERINE</td>
<td>250 mg in 100 mL</td>
</tr>
<tr>
<td>TYROSINE (UNII: 42HK56048U) (TYROSINE - UNII:42HK56048U)</td>
<td>TYROSINE</td>
<td>20 mg in 100 mL</td>
</tr>
<tr>
<td>DEXTROSE (UNII: IY9XDZ35W2) (DEXTROSE - UNII:IY9XDZ35W2)</td>
<td>DEXTROSE</td>
<td>20 g in 100 mL</td>
</tr>
</tbody>
</table>

# Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
</table>
LEUCINE (UNII: GMW67QNF9C) (LEUCINE - UNII:GMW67QNF9C)
PHENYLALANINE (UNII: 47E5O17Y3R) (PHENYLALANINE - UNII:47E5O17Y3R)
LYSINE (UNII: K3Z4F929H6) (LYSINE - UNII:K3Z4F929H6)
METHIONINE (UNII: AE28F7PNPL) (METHIONINE - UNII:AЕ28F7PNPL)
ISOLEUCINE (UNII: 04Y7590D77) (ISOLEUCINE - UNII:04Y7590D77)
VALINE (UNII: HG18B9YRS7) (VALINE - UNII:HG18B9YRS7)
HISTIDINE (UNII: 4QD397987E) (HISTIDINE - UNII:4QD397987E)
THREONINE (UNII: 2ZD004190S) (THREONINE - UNII:2ZD004190S)
TRYPTOPHAN (UNII: 8DUHIN1IBX) (TRYPTOPHAN - UNII:8DUHIN1IBX)
ALANINE (UNII: OF5PS7N2XX) (ALANINE - UNII:OF5PS7N2XX)
GLYCINE (UNII: TE7660X01C) (GLYCINE - UNII:TE7660X01C)
ARGININE (UNII: 94ZLA3W45F) (ARGININE - UNII:94ZLA3W45F)
PROLINE (UNII: 9DLQ4CIU6V) (PROLINE - UNII:9DLQ4CIU6V)
SERINE (UNII: 452VLY9402) (SERINE - UNII:452VLY9402)
TYROSYNE (UNII: 42HK56048U) (TYROSYNE - UNII:42HK56048U)
DEXTROSE (UNII: 89XDZ35W2) (DEXTROSE - UNII:89XDZ35W2)

Inactive Ingredients

ACETIC ACID (UNII: Q40Q9N063P)
WATER (UNII: 059QF0KO0R)
## Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0338-1101-04</td>
<td>2000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/29/1997</td>
<td></td>
</tr>
</tbody>
</table>

## Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020734</td>
<td>09/29/1997</td>
<td></td>
</tr>
</tbody>
</table>

## CLINIMIX

leucine, phenylalanine, lysine, methionine, isoleucine, valine, histidine, threonine, tryptophan, alanine, glycine, arginine, proline, serine, tyrosine, dextrose injection

## Product Information

**Product Type**: HUMAN PRESCRIPTION DRUG  
**Route of Administration**: INTRAVENOUS  
**Item Code (Source)**: NDC:0338-1139

## Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEUCINE (UNII: GMW67QNF9C)</td>
<td>LEUCINE</td>
<td>365 mg in 100 mL</td>
</tr>
<tr>
<td>PHENYLALANINE (UNII: 47E5O17Y3R)</td>
<td>PHENYLALANINE</td>
<td>280 mg in 100 mL</td>
</tr>
<tr>
<td>LYSINE (UNII: K3Z4F929H6)</td>
<td>LYSINE</td>
<td>290 mg in 100 mL</td>
</tr>
<tr>
<td>METHIONINE (UNII: AE28F7PNPL)</td>
<td>METHIONINE</td>
<td>200 mg in 100 mL</td>
</tr>
<tr>
<td>ISOLEUCINE (UNII: 04Y7590D77)</td>
<td>ISOLEUCINE</td>
<td>300 mg in 100 mL</td>
</tr>
<tr>
<td>VALINE (UNII: HG18B9YRS7)</td>
<td>VALINE</td>
<td>290 mg in 100 mL</td>
</tr>
<tr>
<td>HISTIDINE (UNII: 4QD397987E)</td>
<td>HISTIDINE</td>
<td>240 mg in 100 mL</td>
</tr>
<tr>
<td>THREONINE (UNII: 2ZD00419OS)</td>
<td>THREONINE</td>
<td>210 mg in 100 mL</td>
</tr>
<tr>
<td>TRYPTOPHAN (UNII: 8DUHIN11BX)</td>
<td>TRYPTOPHAN</td>
<td>90 mg in 100 mL</td>
</tr>
<tr>
<td>ALANINE (UNII: OF5P57N2ZX)</td>
<td>ALANINE</td>
<td>10.35 mg in 100 mL</td>
</tr>
<tr>
<td>GLYCINE (UNII: TE7660X01C)</td>
<td>GLYCINE</td>
<td>515 mg in 100 mL</td>
</tr>
<tr>
<td>ARGinine (UNII: 94ZLA3W45F)</td>
<td>ARGinine</td>
<td>575 mg in 100 mL</td>
</tr>
<tr>
<td>PROLINE (UNII: 9DLQ4CIU6V)</td>
<td>PROLINE</td>
<td>340 mg in 100 mL</td>
</tr>
<tr>
<td>SERINE (UNII: 452VLY9402)</td>
<td>SERINE</td>
<td>250 mg in 100 mL</td>
</tr>
<tr>
<td>TYROSINE (UNII: 42HK56048U)</td>
<td>TYROSINE</td>
<td>20 mg in 100 mL</td>
</tr>
<tr>
<td>DEXTROSE (UNII: FY9XDZ35W2)</td>
<td>DEXTROSE</td>
<td>25 g in 100 mL</td>
</tr>
</tbody>
</table>

## Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETIC ACID</td>
<td></td>
</tr>
<tr>
<td>WATER</td>
<td></td>
</tr>
<tr>
<td>NITROGEN</td>
<td></td>
</tr>
</tbody>
</table>
Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0338-1139-03</td>
<td>1000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/29/1997</td>
<td>02/29/2020</td>
</tr>
</tbody>
</table>

Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020734</td>
<td>09/29/1997</td>
<td>02/29/2020</td>
</tr>
</tbody>
</table>

CLINIMIX
leucine, phenylalanine, lysine, methionine, isoleucine, valine, histidine, threonine, tryptophan, alanine, glycine, arginine, proline, serine, tyrosine, dextrose injection

Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>NDC:0338-1103</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Route of Administration |  |
|-------------------------| | |
| INTRAVENOUS             | |

Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEUCINE (UNII: GMW67QNF9C)</td>
<td>LEUCINE</td>
<td>365 mg in 100 mL</td>
</tr>
<tr>
<td>LYSINE (UNII: K3Z4F929H6)</td>
<td>LYSINE</td>
<td>290 mg in 100 mL</td>
</tr>
<tr>
<td>METHIONINE (UNII: AE28F7P9NPL) (METHIONINE - UNII:AE28F7P9NPL)</td>
<td>METHIONINE</td>
<td>200 mg in 100 mL</td>
</tr>
<tr>
<td>ISOLEUCINE (UNII: 04Y7590D77) (ISOLEUCINE - UNII:04Y7590D77)</td>
<td>ISOLEUCINE</td>
<td>300 mg in 100 mL</td>
</tr>
<tr>
<td>VALINE (UNII: HG18B9YRS7) (VALINE - UNII:HG18B9YRS7)</td>
<td>VALINE</td>
<td>290 mg in 100 mL</td>
</tr>
<tr>
<td>HISTIDINE (UNII: 4QD397987E) (HISTIDINE - UNII:4QD397987E)</td>
<td>HISTIDINE</td>
<td>240 mg in 100 mL</td>
</tr>
<tr>
<td>THREONINE (UNII: 2ZD004190S) (THREONINE - UNII:2ZD004190S)</td>
<td>THREONINE</td>
<td>210 mg in 100 mL</td>
</tr>
<tr>
<td>TRYPTOPHAN (UNII: 8DUH1N1IBX) (TRYPTOPHAN - UNII:8DUH1N1IBX)</td>
<td>TRYPTOPHAN</td>
<td>90 mg in 100 mL</td>
</tr>
<tr>
<td>ALANINE (UNII: OF5P57N2Z2X) (ALANINE - UNII:OF5P57N2Z2X)</td>
<td>ALANINE</td>
<td>1035 mg in 100 mL</td>
</tr>
<tr>
<td>GLYCINE (UNII: TE7660XOIC) (GLYCINE - UNII:TE7660XOIC)</td>
<td>GLYCINE</td>
<td>515 mg in 100 mL</td>
</tr>
<tr>
<td>ARGinine (UNII: 94ZLA3W45F) (ARGinine - UNII:94ZLA3W45F)</td>
<td>ARGinine</td>
<td>575 mg in 100 mL</td>
</tr>
<tr>
<td>PROLINE (UNII: 9DLQ4CIU6V) (PROLINE - UNII:9DLQ4CIU6V)</td>
<td>PROLINE</td>
<td>340 mg in 100 mL</td>
</tr>
<tr>
<td>SERINE (UNII: 452VLY9402) (SERINE - UNII:452VLY9402)</td>
<td>SERINE</td>
<td>250 mg in 100 mL</td>
</tr>
<tr>
<td>TYROSINE (UNII: 42HK56048U) (TYROSINE - UNII:42HK56048U)</td>
<td>TYROSINE</td>
<td>20 mg in 100 mL</td>
</tr>
<tr>
<td>DEXTROSE (UNII: IY9XDZ35W2) (DEXTROSE - UNII:IY9XDZ35W2)</td>
<td>DEXTROSE</td>
<td>25 g in 100 mL</td>
</tr>
</tbody>
</table>

Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETIC ACID (UNII: Q40Q9N063P)</td>
<td></td>
</tr>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
<tr>
<td>NITROGEN (UNII: N762921K75)</td>
<td></td>
</tr>
</tbody>
</table>

Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0338-1139-03</td>
<td>1000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/29/1997</td>
<td>02/29/2020</td>
</tr>
</tbody>
</table>
**Marketing Information**

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020734</td>
<td>09/29/1997</td>
<td>05/14/2018</td>
</tr>
</tbody>
</table>

**Labeler** - Baxter Healthcare Corporation (005083209)

**Establishment**

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
</table>

Revised: 10/2018