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

CLINIMIX (amino acids in dextrose) injection, for intravenous use

Initial U.S. Approval: 1997 RECENT MAJOR CHANGES

Dosage and Administration, Instructions for Use (2.3, 2.7)	04/2021
Warnings and Precautions (5.5)	04/2021
Dosage and Administration (2.1, 2.3, 2.4, 2.6, 2.8)	09/2020

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. (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 kidney disease. (2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8)

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

- 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

CONTRAINDICATIONS

- <u>Pulmonary Embolism due to Pulmonary Vascular Precipitates</u>: 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 \geq 900 mOsm/L must be infused through a central catheter. (2.2, 5.6)
- <u>Hepatobiliary Disorders</u>: monitor liver function parameters and ammonia levels. (5.7) <u>Aluminum Toxicity</u>: increased risk in patients with impaired kidney function, including preterm infants.
- (5884)
- 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 kidney disease 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 Corporation at 1-866-888-2472 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

.... USE IN SPECIFIC POPULATIONS -<u>Pediatric Use</u>: increased risk of hypoglycemia/hyperglycemia: monitor serum glucose concentrations. (8.4) See 17 for PATIENT COUNSELING INFORMATION.

Revised: 4/2021

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 Kidney Disease
- 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 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

- CLINIMIX is available in a three port container configuration and a two port container configuration.
 - o *Three Port Container*: the ports consist of one medication port, one additive port and one outlet port. Additives can be introduced to the container through the medication port and lipids through the additive port on the three port container.
 - o *Two Port Container*: the ports consist of one medication port and one outlet port. Additives, including lipids, can be introduced to the container through the medication port on the two port container.
- Tear protective overwrap 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)].

- o For central vein infusion only: CLINIMIX 4.25/10, 5/15, 5/20, 8/10, 8/14
- o For central or peripheral vein infusion: CLINIMIX 4.25/5, 6/5
- 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-2ethylhexyl phthalate (DEHP). Administration sets that contain polyvinyl chloride (PVC) components have DEHP as a plasticizer.

2.3 Instructions for Use

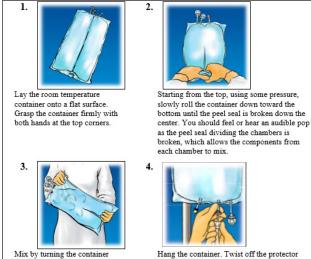
- 1. Open by tearing protective overwrap at slit and remove solution container. The two port container includes an oxygen-absorbing sachet. Discard the oxygen-absorbing sachet after removal from the overwrap.
- 2. To proceed with activation, the container should be at room temperature. Lay the room temperature 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.
 - a. Suspend container from eyelet support.
 - b. Twist off protector from outlet port at bottom of container (Figure 4).
 - c. Attach administration set. Refer to complete directions accompanying set.

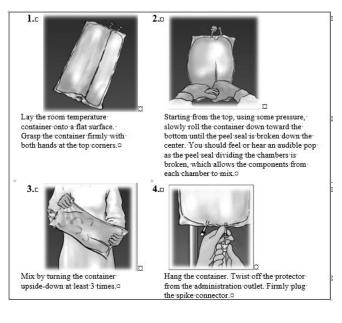
For single dose only. Discard unused portion.

Figures 1-4 (Three Port Container):



Mix by turning the container upside-down at least 3 times

from the administration outlet. Firmly plug the spike connector



Instructions on Storage

Storage After Removal of Overwrap:

Once removed from the protective 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.

Protect the activated parenteral nutrition solution from light.

2.4 Preparation and Addition of Lipid Emulsion

Three Port Container

- 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.
- After completing transfer, use appropriate plastic clamp or metal ferrule to seal off additive port tube.
- 8. Remove transfer set.
- Mix contents of container thoroughly. Inspect final solution for discoloration and particulate matter. Check for leaks.

Two Port Container

- 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. Prepare medication port.
- 5. Using a 19 to 22 gauge needle, puncture resealable medication port.
- 6. Open clamp on transfer set and transfer lipid emulsion.
- 7. Remove needle.
- 8. Mix contents of container thoroughly. Inspect final solution for discoloration and particulate matter. Check for leaks.

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
--	--------	----------

		Recommended CLINIMIX Adult Dosage								
	CLINIMIX	CLINIMIX	CLINIMIX	CLINIMIX	CLINIMIX	CLINIMIX	CLINIMIX			
	4.25/5	4.25/10	5/15	5/20	6/5	8/10	8/14			
Fluid (mL/kg/day)	19 to 40	19 to 40	16 to 40	16 to 40	13 to 33	10 to 25	10 to 25			
Protein [*] (g/kg/day)	0.8 to 1.7	0.8 to 1.7	0.8 to 2							
(Nitrogen	(0.13 to	(0.13 to	(0.13 to	(0.13 to	(0.13 to	(0.13 to	(0.13 to			
g/kg/day)	0.27)	0.27)	0.32)	0.32)	0.32)	0.32)	0.32)			
Dextrose	0 05 to 2	1.0 to 4	2.4 to 6	3.2 to 8	0.65 to	1 to 2.5	1.4 to			
(g/kg/day)	0.95 10 2	1.9 10 4	2.4 10 0	5.2 10 0	1.65	1102.5	3.5			

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

Table 2: Maximum	Infusion Rat	e in Adult	Patients
------------------	--------------	------------	----------

		Maximum Infusion Rates in Adults Patients								
		CLINIMIX 4.25/5	CLINIMIX 4.25/10	CLINIMIX 5/15	CLINIMIX 5/20	CLINIMIX 6/5	CLINIMIX 8/10	CLINIMIX 8/14		
Maximum Infu (mL/kg/ł	2.4	2.4	1.67	1.25	1.67	1.3	1.3			
Corresponding	Amino Acid (g/kg/hour)		0.1*	0.08	0.06	0.1^{*}	0.1*	0.1*		
infusion rate	Dextrose (g/kg/hour)	0.12	0.24	0.25*	0.25*	0.08	0.13	0.18		

* Rate limiting factor

2.7 Dosage Modifications in Patients with Kidney Disease

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)].

Chronic kidney disease patients with less than nephrotic range proteinuria require 0.8 g of protein/kg/day. Chronic kidney disease patients with nephrotic range proteinuria require 0.8g of protein/kg/day plus 1g of protein for each gram of proteinuria. Patients needing dialysis should receive from 1.2 of protein/kg/day up to a maximum of 2.5 g of protein/kg/day depending on the nutritional status and the dialysis modality. Serum electrolyte levels should be closely monitored. The CLINIMIX dosage can be adjusted

based on the severity of kidney disease, 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.

	Recom	Recommended CLINIMIX Dosage in Preterm and Term Infants Less than 1 Month of Age									
	CLINIMIX	CLINIMIX	CLINIMIX	CLINIMIX	CLINIMIX	CLINIMIX	CLINIMIX				
	4.25/5	4.25/10	5/15	5/20	6/5	8/10	8/14				
Infusion Rate Range (mL/kg/hr)	2.9 to 3.9	2.9 to 3.9	2.5 to 3.3	2.5 to 3.3	2.1 to 2.8	1.6 to 2.1	1.6 to 2.1				
Fluid (mL/kg/day)	70 to 94	70 to 94	60 to 79	60 to 79	50 to 67	38.4 to 50	38.4 to 50				
Protein [*] (g/kg/day) (Nitrogen g/kg/day)	3 to 4 (0.48 to 0.64)	3 to 4 (0.48 to 0.64)	3 to 4 (0.48 to 0.64)	3 to 4 (0.48 to 0.64)	3 to 4 (0.48 to 0.64)	3 to 4 (0.48 to 0.64)	3 to 4 (0.48 to 0.64)				
Dextrose (g/kg/day)	3.5 to 4.7	7 to 9.4	9 to 11.9	12 to 15.8	2.5 to 3.4	3.8 to 5	5.4 to 7				

* 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

	Recommended CLINIMIX Dosage in Pediatric Patients 1 Month to										
		Less than 1 Year of Age									
	CLINIMIX	CLINIMIX CLINIMIX CLINIMIX CLINIMIX CLINIMIX CLINIMIX CLINIMI									
	4.25/5	4.25/10	5/15	5/20	6/5	8/10	8/14				
Infusion Rate Range (mL/kg/hr)	2 to 2.9	2 to 2.9	1.7 to 2.5	1.7 to 2.5	1.4 to 2.1	1 to 1.6	1 to 1.6				
Fluid (mL/kg/day)	48 to 70	48 to 70	41 to 60	41 to 60	33.6 to 50	24 to 38.4	24 to 38.4				
Protein [*] (g/kg/day) (Nitrogen g/kg/day)	2 to 3 (0.32 to 0.48)	2 to 3 (0.32 to 0.48)	2 to 3 (0.32 to 0.48)	2 to 3 (0.32 to 0.48)	2 to 3 (0.32 to 0.48)	2 to 3 (0.32 to 0.48)	2 to 3 (0.32 to 0.48)				
Dextrose (g/kg/day)	2.4 to 3.5	4.8 to 7	6.1 to 9	8.2 to 12	1.7 to 2.5	2.4 to 3.8	3.4 to 5.4				

* 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

	Recomm	Recommended CLINIMIX Dosage in Pediatric Patients 1 Year to Less than 11 Years of Age								
	CLINIMIX	CLINIMIX				CLINIMIX	CLINIMIX			
	4.25/5	4.25/10	5/15	5/20	6/5	8/10	8/14			
Infusion Rate Range (mL/kg/hr)	1 to 2	1 to 2	0.8 to 1.7	0.8 to 1.7	0.7 to 1.4	0.5 to 1	0.5 to 1			
Fluid (mL/kg/day)	24 to 48	24 to 48	19 to 41	19 to 41	16.8 to 33.6	12 to 24	12 to 24			
Protein [*] (g/kg/day)	1 to 2	1 to 2	1 to 2	1 to 2	1 to 2	1 to 2	1 to 2			
(Nitrogen	(0.16 to	(0.16 to	(0.16 to	(0.16 to	(0.16 to	(0.16 to	(0.16 to			
g/kg/day)	0.32)	0.32)	0.32)	0.32)	0.32)	0.32)	0.32)			
Dextrose	1.2 to	2.4 to	2.9 to	3.8 to	0.8 to	1.2 to	1.7 to			
(g/kg/day)	2.4	4.8	6.1	8.2	1.7	2.4	3.4			

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

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

		17 Years of Age								
	CLINIMIX									
	4.25/5	4.25/10	5/15	5/20	6/5	8/10	8/14			
Infusion Rate	0.8 to	0.8 to	0.7 to	0.7 to	0.6 to 1	0.4 to	0.4 to			
Range (mL/kg/hr)	1.5	1.5	1.3	1.3	0.0 10 1	0.8	0.8			
Fluid (mL/kg/day)	10 to 26	10 to 26	17 to 31	17 to 31	14.4 to	9.6 to	9.6 to			
i lulu (IIIL/Kg/udy)	19 10 50	19 10 50			24	19.2	19.2			
Protein*(g/kg/day)	0.8 to	0.8 to	0.8 to	0.8 to	0.8 to	0.8 to	0.8 to			
(Nitrogen	1.5	1.5	1.5	1.5	1.5	1.5	1.5			
g/kg/day)	(0.13 to	(0.13 to	(0.13 to	(0.13 to	(0.13 to	(0.13 to	(0.13 to			
	0.24)	0.24)	0.24)	0.24)	0.24)	0.24)	0.24)			
Dextrose	1 to 1.8	1.9 to	2.5 to	3.4 to	0.7 to	1 to 1.9	1.4			
(g/kg/day)	1 10 1.0	3.6	4.7	6.2	1.2	1 (0 1.9	to.2.7			

* 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 injection 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.

Strength of C		CLINIMIX	CLINIMIX4.25/10	CLINIMIX	CLINIMIX	CLINIMIX	CLINIMIX	CLINIMIX
		4.25/5 sulfite-free (4.25% Amino Acid		5/15 sulfite-free (5% Amino Acid in	5/20 sulfite-free (5% Amino Acid in	6/5 sulfite-free (6% Amino Acic in	8/10 sulfite-free (8% Amino Acid in	8/14 sulfite-fre (8% Amino Aci in
		in 5% Dextrose) Injection	in 10% Dextrose) Injection		20% Dextrose) Injection		10% Dextrose) Injection	
	Dextrose Hydrous, USP (g/100 mL)	5	10	15	20	5	10	14
	Amino Acids (g/100 mL)	4.25	4.25	5	5	6	8	8
	Total Nitrogen (mg/100 mL)	702	702	826	826	990	1320	1320
	Leucine	311	311	365	365	438	584	584
	Isoleucine	255	255	300	300	360	480	480
Essential Amino Acido	Valine	247	247	290	290	348	464	464
	Lysine (added as the hydrochloride salt)		247	290	290	348	464	464
(mg/100 mL)	Phenylalanine	238	238	280	280	336	448	448
	Histidine	204	204	240	240	288	384	384
	Threonine	179	179	210	210	252	336	336
	Methionine	170	170	200	200	240	320	320
	Tryptophan	77	77	90	90	108	144	144
	Alanine	880	880	1035	1035	1242	1656	1656
	Arginine	489	489	575	575	690	920	920
Nonessential Amino Acids	Glycine	438	438	515	515	618	824	824
(mg/100 mL)	Proline	289	289	340	340	408	544	544
(IIIg/100 IIIL)	Serine	213	213	250	250	300	400	400
	Tyrosine	17	17	20	20	24	32	32
	Acetate [†]	37	37	42	42	53	71	71
Anion Profile (mEq/L)*	Chloride [‡]	17	17	20	20	24	32	32
	pH [§] (Range)	6.0 (4.5 to 7.0)	6.0 (4.5 to 7.0)	6.0 (4.5 to 7.0)	6.0 (4.5 to 7.0)	6.0 (4.5 to 7.0)	6.0 (4.5 to 7.0)	6.0 (4.5 to 7.0)
	Osmolarity (mOsmol/L) (calc)	675	930	1255	1505	850	1308	1520
Caloric Content	From Dextrose	170	340	510	680	170	343	477
(kcal/L)	From Amino Acids	170	170	200	200	240	320	320
	TOTAL (Dextrose and Amino Acids)	340	510	710	880	410	663	797

* Balanced by ions from amino acids.

+ Derived from glacial acetic acid (for pH adjustment).

- § Contributed by Usine hydrochloride and hydrochloric acid (for pH adjustment).
 § pH of sulfite-free amino acid injection in the outlet port chamber may be adjusted with glacial acetic acid and pH of dextrose injection port chamber may be adjusted with hydrochloric acid.

4 CONTRAINDICATIONS

The use of CLINIMIX is contraindicated in:

- ٠ 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 dehydration, resulting in a transient reduction in glomerular filtration rate and pre-renal azotemia, may be a 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, 5/20, 8/10 and 8/14 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 and 6/5 are 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. The aluminum contained in CLINIMIX may reach toxic levels with prolonged administration in patients with impaired kidney function. 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 impaired kidney function, 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 abnormal renal function due to pre-renal azotemia, renal obstruction, or intrinsic kidney disease 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 kidney disease. 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 kidney disease should be assessed early by a clinician knowledgeable in kidney 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.

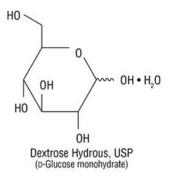
11 DESCRIPTION

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.

Essential Amino Acids	
Leucine	(CH ₃) ₂ CHCH ₂ CH (NH ₂) COOH
Isoleucine	CH ₃ CH ₂ CH (CH ₃) CH (NH ₂) COOH
Valine	(CH ₃) ₂ CHCH (NH ₂) COOH
Lysine (added as the hydrochloride salt)	H_2N (CH ₂) ₄ CH (NH ₂) COOH
Phenylalanine	(C ₆ H ₅) CH ₂ CH (NH ₂) COOH
Histidine	(C ₃ H ₃ N ₂) CH ₂ CH (NH ₂) COOH
Threonine	CH ₃ CH (OH) CH (NH ₂) COO
Methionine	CH_3S (CH_2)2 CH (NH_2) COOH
Tryptophan	(C ₈ H ₆ N) CH ₂ CH (NH ₂) COOH
Nonessential Amino Acids	
Alanine	CH ₃ CH (NH ₂) COOH
Arginine	H ₂ NC (NH) NH (CH ₂)3 CH (NH ₂) COOH
Glycine	H ₂ NCH ₂ COOH
Proline	[(CH ₂) ₃ NH CH] COOH
Serine	HOCH ₂ CH (NH ₂) COOH
Tyrosine	[C ₆ H ₄ (OH)] CH ₂ CH (NH ₂) COOH

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



Dextrose is derived from corn.

See Table 7 for composition, pH, osmolarity, ionic concentration and caloric content of the admixed product [see Dosage Forms and Strengths (3)].

The dual chamber container is a lipid-compatible plastic container (PL 2401 Plastic).

CLINIMIX contains no more than 25 mcg/L of aluminum.

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.

16 HOW SUPPLIED/STORAGE AND HANDLING

CLINIMIX (amino acids in dextrose) injection (sulfite-free) is available in 1000 mL and 2000 mL volumes (See Table 9).

Table 9: CLINIMIX Formulations (per 07-19-00-3604 and BE-30-03-648)
----------------------------------	-------------------------------------

After mixing, the product represents	1000 mL Code and NDC Number	2000 mL Code and NDC Number
CLINIMIX 4.25/5 sulfite-free (4.25% Amino Acid in 5% Dextrose) Injection	Code 2B7726 NDC 0338-1133-03	Code 2B7704 NDC 0338-1089-04
CLINIMIX 4.25/10 sulfite-free (4.25% Amino Acid in 10% Dextrose) Injection	Code 2B7727 NDC 0338-1134-03	Code 2B7705 NDC 0338-1091-04
CLINIMIX 5/15 sulfite-free (5% Amino Acid in 15% Dextrose) Injection	Code 2B7730 NDC 0338-1137-03	Code 2B7709 NDC 0338-1099-04
CLINIMIX 5/20 sulfite-free (5% Amino Acid in 20% Dextrose) Injection	Code 2B7731 NDC 0338-1138-03	Code 2B7710 NDC 0338-1101-04
CLINIMIX 6/5 sulfite-free (6% Amino Acid in 5% Dextrose) Injection	Code EADB9913 NDC 0338-0198-06	
CLINIMIX 8/10 sulfite-free (8% Amino Acid in 10% Dextrose) Injection	Code EADB9933 NDC 0338-0188-06	Code EADB9935 NDC 0338-0194-04
CLINIMIX 8/14 sulfite-free (8% Amino Acid in 14% Dextrose) Injection	Code EADB9953 NDC 0338-0180-06	Code EADB9955 NDC 0338-0184-04

Table 9: CLINIMIX Formulations (per BE-30-04-047)

After mixing, the product represents	1000 mL Code and NDC Number	2000 mL Code and NDC Number
CLINIMIX 4.25/5 sulfite-free (4.25% Amino Acid in 5% Dextrose) Injection	Code 2B7726L NDC 0338-7001-01	Code 2B7704L NDC 0338-7003-01
CLINIMIX 4.25/10 sulfite-free (4.25% Amino Acid in 10% Dextrose) Injection	Code 2B7727L NDC 0338-7005-01	Code 2B7705L NDC 0338-7007-01
CLINIMIX 5/15 sulfite-free (5% Amino Acid in 15% Dextrose) Injection	Code 2B7730L NDC 0338-7009-01	Code 2B7709L NDC 0338-7011-01
CLINIMIX 5/20 sulfite-free (5% Amino Acid in 20% Dextrose) Injection	Code 2B7731L NDC 0338-7013-01	Code 2B7710L NDC 0338-7015-01
CLINIMIX 6/5 sulfite-free (6% Amino Acid in 5% Dextrose) Injection	Code EADB9913 NDC 0338-0198-06	
CLINIMIX 8/10 sulfite-free (8% Amino Acid in 10% Dextrose) Injection	Code EADB9933 NDC 0338-0188-06	Code EADB9935 NDC 0338-0194-04

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 overwrap has been opened.

Do not use if the protective 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 $\ensuremath{\mathsf{CLINIMIX}}$:

- 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

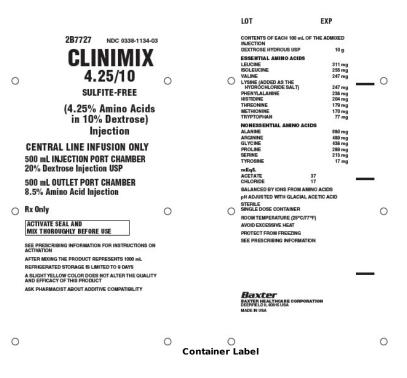
Deerfield, IL 60015 USA

Baxter and Clinimix are registered trademarks of Baxter International Inc. 07-19-00-360 [Applies to Baxter Healthcare Corporation, Jayuya – Puerto Rico manufacturing plant]

BE-30-03-648 [Applies to Baxter SA, Lessines – Belgium manufacturing plant for Clinimix 6/5, Clinimix 8/10 and Clinimix 8/14]

BE-30-04-047 [Applies to Baxter SA, Lessines – Belgium manufacturing plant for the other Clinimix formulations]

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL



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

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 Logo BAXTER HEALTHCARE CORPORATION

DEERFIELD IL 60015 USA MADE IN USA

				LOT	EXP	
0	287726 NDC 0338-1133-03 CLINIMIX 4.25/5 SULFITE-FREE (4.25% Amino Acids in 5% Dextrose) Injection	0	0	CONTENTS OF EACH 100 mL INJECTION DEXTROSE HYDROUGU USP ESSENTIAL AMINO ACIDS ELICINE EDULEUNE EDULEUNE LYSING (ADDED AS THE LYSING (ADDED AS THE HYDROCHLODE SALT) PHEIYTALAMINE HISTIDINE METHICINIE METHICINIE ACQUINE ACQUINE SERVICE SERVICE SERVICE SERVICE SERVICE SERVICE	5 g 211 mg 255 mg 247 mg 248 mg 204 mg 179 mg 170 mg 77 mg	0
0	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 SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION	0	0	SEHNIL THROSINE ACETATE ACETATE CHLORIDE BALANCED DEVIONS FROM A PH ADJUSTED WITH GLACIA STIFRILE SINGLE DOSE CONTAINER SINGLE DOSE CONTAINER SINGLE DOSE CONTAINER AVOID EXCESSIVE HEAT PROTECT FROM FREEZING SEE PRESCRIBING INFORMA	17 mg 37 17 MINO ACIDS L ACETIC ACID 77°F)	0
	AFTER MIXING THE PRODUCT REPRESENTS 1000 mL REFRIGENATED STORAGE IS LIMITED TO DAYS A SLIGHT YELLOW COLOR DOES NOT ALTER THE OUALITY AND EFFICACY OF THIS PRODUCT ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY			BAXTER HEALTMCARE CORPO DATE HEALTMCARE CORPO DATE NUSA	DRATION	_
0		0	O Container L	abel		0

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 Logo

BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA

			LOT	EXP
	2B7704 NDC 0338-1089-04		CONTENTS OF EACH 100 mL OF ADMIXED INJECTION	THE
			DEXTROSE HYDROUS USP	
	CLINIMIX		ESSENTIAL AMINO ACIDS LEUCINE ISOLEUCINE	
0	4.25/5	0 0	VALINE	2
	SULFITE-FREE		LYSINE (ADDED AS THE HYDROCHLORIDE SALT) PHENYLALANINE	2
	(4.25% Amino Acids in 5% Dextrose)		HISTIDINE THREONINE METHIONINE TRYPTOPHAN	2
	Injection		NONESSENTIAL AMINO ACIE ALANINE ARGININE GLYCINE PROLINE SERINE	05 8 4 2 2
	1000 mL INJECTION PORT CHAMBER		TYROSINE	
	10% Dextrose Injection USP 1000 mL OUTLET PORT CHAMBER		mEq/L ACETATE 37 CHLORIDE 17	
0	8.5% Amino Acid Injection	0 0	BALANCED BY IONS FROM AMIN pH ADJUSTED WITH GLACIAL AV STERILE SINGLE DOSE CONTAINER	
	Rx Only		ROOM TEMPERATURE (25°C/77°	E)
	ACTIVATE SEAL AND MIX THOROUGHLY BEFORE USE		AVOID EXCESSIVE HEAT PROTECT FROM FREEZING SEE PRESCRIBING INFORMATIO	
	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			
0		0 0	BAXTER HEALTHCARE CORPORATIO DEERFELD 4 60016 USA MADE N USA	M

5 g 311 mg 255 mg 247 mg 0 247 mg 238 mg 204 mg 179 mg 170 mg 77 mg 880 mg 489 mg 438 mg 289 mg 213 mg 17 mg NO ACIDS 0 AL ACETIC ACID C/77°F) ATION

0

Container Label

LOT EXP

2B7704 NDC 0338-1089-04

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

1000 mL INJECTION PORT CHAMBER 10% 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 INJECTIONDEXTROSE 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

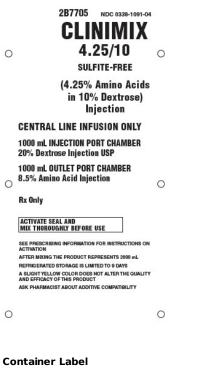
ROOM TEMPERATURE (25°C/77°F)

AVOID EXCESSIVE HEAT

PROTECT FROM FREEZING

SEE PRESCRIBING INFORMATION

Baxter Logo BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA



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

	LOT	EXP	
	CONTENTS OF EACH 100 mL ADMIXED INJECTION		
0	DEXTROSE HYDROUS USP ESSENTIAL AMINO ACIDA LEUCINE ISOLEUCINE VALINE LYSINE (ADDED AS THE HYDROCHLORIDE SALT) PHENYLALANINE HISTIDINE THREONINE METHIONINE	10 g 311 mg 255 mg 247 mg 248 mg 204 mg 179 mg 179 mg	<u> </u>
	TRYPTOPHAN NONESSENTIAL AMINO A ALANINE ARGININE GLYCINE PROLINE SERINE TYROSINE	77 mg 880 mg 489 mg 438 mg 289 mg 213 mg 17 mg	_
0	MEG/L ACETATE 32 CHLORIDE 12 BALANCED BY IONS FROM / PH ADJUSTED WITH GLACIA STERILE SINGLE DOSE CONTAINER	MINO ACIDS	0
	ROOM TEMPERATURE (25°C) AVOID EXCESSIVE HEAT PROTECT FROM FREEZING SEE PRESCRIBING INFORMA		_

BAXTER HEALTHCABE CORPORATION DEERFELD & 60015 USA MADE N USA

0

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 Logo BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA

287730 DOC 0338-1137-03 CLEANING ACCOUNT AND ACCOUNT					LOT	EXP	
SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON SEE PRESCRIBING INFORMATION ACTIVATION AFTER INSUNG THE PRODUCT REPRESENTS 1000 mL REFRIGERATED STORAGE IS LIMITED TO 9 DAYS A SUGHTY ELLOW COLOR DOES NOTALTER THE QUALITY AND EFFACTOR OF THIS PRODUCT ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY	0	CLINING 5/15 SULFITE-FREE (5% Amino Acids in 15% Dextrose) Injection CENTRAL LINE INFUSION ONLY 500 mL INJECTION PORT CHAMBER 30% Dextrose Injection USP 500 mL OUTLET PORT CHAMBER 10% Amino Acid Injection Rx Only		0	CONTENTS OF EACH 100 mL OF T INLECTON DEXTROSE HUDROUS USP ESSE ITTAL AMINO ACIDS ESCIENCE USINE USINE USINE USINE HUDROUS AND HUDROSINE	HE ADMIXED 15 g 300 mg 290 mg 290 mg 290 mg 290 mg 200 mg 200 mg 200 mg 90 ADDS 80 mg 200 mg	
	0	ACTIVATION AFTER MIXING THE PRODUCT REPRESENTS 1000 mL REFRIGERATED STORAGE IS LIMITED TO 9 DAYS A SUGHT YELLOW COLOR DOES NOT ALTER THE QUALITY AND EFFICACY OF THIS PRODUCT	0	0	SEE PRESCRIBING INFORMATION		•

Container Label

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

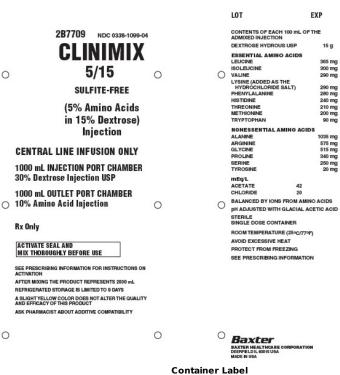
ROOM TEMPERATURE (25°C/77°F)

AVOID EXCESSIVE HEAT

PROTECT FROM FREEZING

SEE PRESCRIBING INFORMATION

Baxter Logo **BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA** MADE IN USA



15 g

365 mg 300 mg 290 mg

575 mg 515 mg 340 mg 250 mg 20 mg

0

0

0

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

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

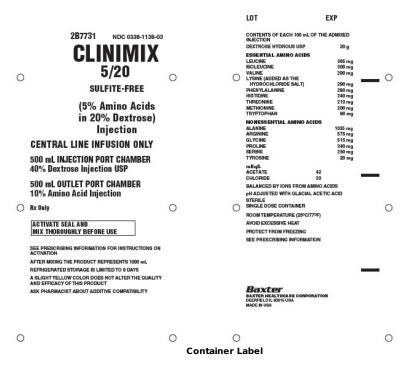
ROOM TEMPERATURE (25°C/77°F)

AVOID EXCESSIVE HEAT

PROTECT FROM FREEZING

SEE PRESCRIBING INFORMATION

Baxter Logo BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA



LOT EXP

2B7731 NDC 0338-1138-03

CLINIMIX 5/ SULFITE-FREE (5% Amino Acid 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

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 Logo BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA

		LOT	EXP
287710 DC 0338-1101-04 CLININALS 5/20 SULFITE-FREE (5% Amino Acids in 20% Dextrose) Injection CENTRAL LINE INFUSION ONLY 1000 mL INJECTION PORT CHAMBER 40% Dextrose Injection USP 1000 mL OUTLET PORT CHAMBER 10% Amino Acid Injection	o o o o	CONTENTS OF EACH 100 mL OI ADMIXED INJECTION DEXTROSE HYDROUS USP ESSENTIAL AMINO ACIDS LEUCINE VALINE LISULEUCINE VALINE LISULEUCINE VALINE HYDROCHLORIDE SALT) PHENYTALANINE HISTIDINE THREONINE METHIONINE TRYFTOPHAN NOMESSENTIAL AMINO ACI ALANINE ACRININE GLYCINE PROLINE SERINE TRYFTOPHAN NOMESSENTIAL AMINO ACI ALANINE CHLORIDE 200 BEALANCED BY IONS FROM AMI PA ADUSTED WITH GLACIAL A STERILE SINGLE DOSE CONTAINER ROOM TEMPERATURE (25°C/771 ANOID EXCESSIVE HEAT PROTECT FROM FREEZING SEE PRESCRIEING INFORMATIK	20 g 365 mg 280 mg 290 mg 200 mg
SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION AFTER MIXING THE PRODUCT REPRESENTS 2000 mL REFRIGERATED STORAGE IS LIMITED TO 9 DAYS A SLIGHT VELLOW COLOR DOES NOT ALTER THE QUALITY AND EFFICACY OF THIS PRODUCT ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY	0 0	Baxter	0



Container Label

BAXTER HEALTHCARE

ORATION

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 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 Logo BAXTER HEALTHCARE CORPORATION **DEERFIELD IL 60015 USA** MADE IN USA

FADB9913 NDC 0338-0198-01 1000 mL

CLINIMIX 6/5 SULFITE-FREE (6% Amino Acids in 5% Dextrose) Injection 400 mL INJECTION PORT CHAMBER 12.5% Dextrose Injection USP 600 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 ONCE OVERWRAP IS OPENED A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY AND EFFICACY OF THIS PRODUCT ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY

EXP

Container Label

EADB9913 NDC 0338-0198-01

1000 mL

CLINIMIX 6/5 SULFITE-FREE (6% Amino Acid in 5% Dextrose) Injection

400 mL INJECTION PORT CHAMBER 12.5% Dextrose Injection USP 600 mL OUTLET PORT CHAMBER 10% Amino Acid Injection Rx Only

ACTIVATE SEAL AND MIX THOROUGHTLY BEFORE USE

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

CONTENTS OF EACH 100 mL OF TH	E ADMIXED
INJECTION	
DEXTROSE HYDROUS USP	5 g
ESSENTIAL AMINO ACIDS	
LEUCINE	438 mg
ISOLEUCINE	360 mg
VALINE	348 mg
LYSINE (ADDED AS THE	
HYDROCHLORIDE SALT)	348 mg
PHENYLALANINE	336 mg
HISTIDINE	288 mg
THREONINE	252 mg
METHIONINE	240 mg
TRYPTOPHAN	108 mg
NONESSENTIAL AMINO ACIDS	
ALANINE	1242 mg
ARGININE	690 mg
GLYCINE	618 mg
PROLINE	408 mg
SERINE	300 mg _
TYROSINE	24 mg
mEq/L	
ACETATE	53
CHLORIDE	24
BALANCED BY IONS FROM AMINO	ACIDS
pH ADJUSTED WITH GLACIAL ACET	IC ACID AND
HYDROCHLORIC ACID	
STERILE	
SINGLE DOSE CONTAINER	
STORE AT ROOM TEMPERATURE (2	5°C/77°E)
IN UNOPENED OVERWRAP	o arriy
AVOID EXCESSIVE HEAT	
PROTECT FROM FREEZING	
SEE PRESCRIBING INFORMATION	
SEE PRESCRIBING INFORMATION	
	40
Baxter	2
BAXTER HEALTHCARE CORPORAT	ION 2
DEERFIELD IL 60015 USA	
MADE IN BELGIUM	8
107	

LOT

ESSENTIAL AMINO ACIDS

LEUCINE 438 mg ISOLEUCINE 360 mg VALINE 348 mg LYSINE (ADDED AS THE HYDROCHLORIDE SALT) 348 mg PHENYLALANINE 336 mg HISTIDINE 288 mg THREONINE 252 mg METHIONINE 240 mg TRYPTOPHAN 108 mg

NONESSENTIAL AMINO ACIDS

ALANINE 1242 mg ARGININE 690 mg GLYCINE 618 mg PROLINE 408 mg SERINE 300 mg TYROSINE 24 mg

mEq/L

ACETATE 53 CHLORIDE 24

BALANCED BY IONS FROM AMINO ACIDS

pH ADJUSTED WITH GLACIAL ACETIC ACID AND HYDROCHLORIC ACID

STERILE

SINGLE DOSE CONTAINER

STORE AT ROOM TEMPERATURE (25°C/77°F) IN UNOPENED OVERWRAP

AVOID EXCESSIVE HEAT

PROTECT FROM FREEZING

SEE PRESCRIBING INFORMATION

Baxter Logo

BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA

MADE IN BELGIUM

EXP LOT

BE-35-04-040

EADB9933 1000 mL NDC 0338-0188-01 CLINIMIX **8/10** T SULFITE-FREE (8% Amino Acids in 10% Dextrose) Injection **CENTRAL LINE INFUSION ONLY** 360 mL INJECTION PORT CHAMBER 28% Dextrose Injection USP 640 mL OUTLET PORT CHAMBER 12.5% 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 ONCE OVERWRAP IS OPENED A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY AND EFFICACY OF THIS PRODUCT ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY

EXP

CONTENTS OF EACH 100 mL OF THE ADMIXED INJECTION DEXTROSE HYDROUS USP 10 g ESSENTIAL AMINO ACIDS ESSENTIAL AMINO ACIU LEUCINE ISOLEUCINE VALINE LYSINE (ADDED AS THE HYDROCHLORIDE SALT) PHENYLALANINE HISTOINE THREONINE METHIONINE TRYPTOPHAN 584 mg 480 mg 464 mg 464 mg 448 mg 384 mg 336 mg 320 mg 144 mg NONESSENTIAL AMINO ACIDS 1656 mg 920 mg 824 mg 544 mg 400 mg _____ 32 mg ALANINE ALANINE ARGININE GLYCINE PROLINE SERINE TYROSINE mEa/L ACETATE 71 CHI ORIDE 32 BALANCED BY IONS FROM AMINO ACIDS pH ADJUSTED WITH GLACIAL ACETIC ACID AND HYDROCHLORIC ACID STERILE SINGLE DOSE CONTAINER STORE AT ROOM TEMPERATURE (25°C/77°F) IN UNOPENED OVERWRAP AVOID EXCESSIVE HEAT PROTECT FROM FREEZING SEE PRESCRIBING INFORMATION Baxter BE-35-04-041 BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA

MADE IN BELGIUM

Container Label EADP9933 NDC 0338-0188-01 1000 mL CLINIMIX 8/10 SULFITE-FREE (8% Amino Acid in 10% Dextrose) Injection

360 mL INJECTION PORT CHAMBER 28% Dextrose Injection USP 640 mL OUTLET PORT CHAMBER 12.5% Amino Acid Injection Rx Only

ACTIVATE SEAL AND MIX THOROUGHTLY BEFORE USE

SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION AFTER MIXING THE PRODUCT REPRESENTS 1000 mL REFRIGERATED STORAGE IS LIMITED TO 9 DAYS ONCE OVERWRAP IS OPENED 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 584 mg ISOLEUCINE 480 mg VALINE 464 mg LYSINE (ADDED AS THE HYDROCHLORIDE SALT) 464 mg PHENYLALANINE 448 mg HISTIDINE 384 mg THREONINE 336 mg METHIONINE 320 mg TRYPTOPHAN 144 mg

NONESSENTIAL AMINO ACIDS

ALANINE 1656 mg ARGININE 920 mg GLYCINE 824 mg PROLINE 544 mg SERINE 400 mg TYROSINE 32 mg

mEq/L

ACETATE 71 CHLORIDE 32

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

STERILE

SINGLE DOSE CONTAINER

STORE AT ROOM TEMPERATURE (25°C/77°F) IN UNOPENED OVERWRAP

AVOID EXCESSIVE HEAT

PROTECT FROM FREEZING

SEE PRESCRIBING INFORMATION

Baxter Logo

BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN BELGIUM

EXP LOT

BE-35-04-041



SULFITE-FREE (8% Amino Acids in 10% Dextrose) Injection

CENTRAL LINE INFUSION ONLY

720 mL INJECTION PORT CHAMBER 28% Dextrose Injection USP 1280 mL OUTLET PORT CHAMBER 12.5% 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 ONCE OVERWRAP IS OPENED A SLIGHT VELLOW COLOR DOES NOT ALTER THE QUALITY AND EFFICACY OF THIS PRODUCT ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY

Exp

ADMIXED INJECTION	
DEXTROSE HYDROUS USP	10 g
ESSENTIAL AMINO ACIDS	
LEUCINE	584 mg
ISOLEUCINE VALINE	480 mg
LYSINE (ADDED AS THE	464 mg
HYDROCHLORIDE SALT)	464 mg
PHENYLALANINE	448 mg
HISTIDINE	384 mg
THREONINE	336 mg
METHIONINE	320 mg
TRYPTOPHAN	144 mg
NONESSENTIAL AMINO AC	ins
ALANINE	1656 mg
ARGININE	920 mg
GLYCINE	824 mg
PROLINE	544 mg
SERINE	400 mg
TYROSINE	32 mg
mEq/L	
ACETATE	71
CHLORIDE	32
BALANCED BY IONS FROM	AMINO ACIDS
PH ADJUSTED WITH GLACIA AND HYDROCHLORIC ACID	LACETIC ACID
STERILE Single dose container	
STORE AT ROOM TEMPERAT	TURE (25°C/77°F)
AVOID EXCESSIVE HEAT	
PROTECT FROM FREEZING	
PRUTEUT FRUM FREEZING	

Baxter

BAXTER HEALTHCARE CORPORATION Deerfield IL 60015 USA Made in Belgium	35-04-045
Lot	BF

Container Label

EADB9935 NDC 0338-0194-01

2000 mL

CLINIMIX 8/10 SULFITE-FREE (8% Amino Acid in 10% Dextrose) Injection

720 mL INJECTION PORT CHAMBER 28% Dextrose Injection USP 1280 mL OUTLET PORT CHAMBER 12.5% Amino Acid Injection Rx Only

ACTIVATE SEAL AND MIX THOROUGHTLY BEFORE USE

SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION AFTER MIXING THE PRODUCT REPRESENTS 2000 mL REFRIGERATED STORAGE IS LIMITED TO 9 DAYS ONCE OVERWRAP IS OPENED 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 584 mg ISOLEUCINE 480 mg VALINE 464 mg LYSINE (ADDED AS THE HYDROCHLORIDE SALT) 464 mg PHENYLALANINE 448 mg HISTIDINE 384 mg THREONINE 336 mg METHIONINE 320 mg TRYPTOPHAN 144 mg

NONESSENTIAL AMINO ACIDS

ALANINE 1656 mg ARGININE 920 mg GLYCINE 824 mg PROLINE 544 mg SERINE 400 mg TYROSINE 32 mg

mEq/L ACETATE 71

CHLORIDE 32

BALANCED BY IONS FROM AMINO ACIDS

pH ADJUSTED WITH GLACIAL ACETIC ACID AND HYDROCHLORIC ACID

STERILE SINGLE DOSE CONTAINER

STORE AT ROOM TEMPERATURE (25°C/77°F) IN UNOPENED OVERWRAP

AVOID EXCESSIVE HEAT

PROTECT FROM FREEZING

SEE PRESCRIBING INFORMATION

Baxter Logo BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN BELGIUM

Exp Lot

BE-35-04-045

EADB9953 NDC 0338-0180 1000 mL

NDC 0338-0180-01 CLINIMIX 8/14 I SULFITE-FREE (8% Amino Acids in 14% Dextrose) Injection **CENTRAL LINE INFUSION ONLY** 360 mL INJECTION PORT CHAMBER 39% Dextrose Injection USP 640 mL OUTLET PORT CHAMBER 12.5% 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 ONCE OVERWRAP IS OPENED A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY AND EFFICACY OF THIS PRODUCT ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY

FXP

Container Label

EADB9953 NDC 0338-0180-01

1000 mL

CLINIMIX 8/14 SULFITE-FREE (8% Amino Acid in 14% Dextrose) Injection

360 mL INJECTION PORT CHAMBER 39% Dextrose Injection USP 640 mL OUTLET PORT CHAMBER

DEXTROSE HYDROUS USP	14 g
ESSENTIAL AMINO ACIDS	
LEUCINE	584 mg
ISOLEUCINE	480 mg
VALINE	464 mg
LYSINE (ADDED AS THE	
HYDROCHLORIDE SALT)	464 mg
PHENYLALANINE	448 mg
HISTIDINE	384 mg
THREONINE	336 mg
METHIONINE	320 mg
TRYPTOPHAN	144 mg
NONESSENTIAL AMINO ACI	
ALANINE	1656 mg 920 mg
ARGININE GLYCINE	920 mg 824 mg
PROLINE	544 mg
SEBINE	400 mg
TYROSINE	32 mg
mEq/L	
ACETATE	71
CHLORIDE	32
BALANCED BY IONS FROM A	MINO ACIDS
PH ADJUSTED WITH GLACIAL	ACETIC ACID
AND HYDROCHLORIC ACID	
STERILE	
SINGLE DOSE CONTAINER	
STORE AT ROOM TEMPERATI	JRE (25°C/77°F)
IN UNOPENED OVERWRAP	
AVOID EXCESSIVE HEAT	
PROTECT FROM FREEZING	
SEE PRESCRIBING INFORMAT	TON

Baxter Healthcare Corporation DEERFIELD IL 60015 USA MADE IN BELGIUM LOT

BE-35-04-

12.5% Amino Acid Injection Rx Only

ACTIVATE SEAL AND MIX THOROUGHTLY BEFORE USE

SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION AFTER MIXING THE PRODUCT REPRESENTS 1000 mL REFRIGERATED STORAGE IS LIMITED TO 9 DAYS ONCE OVERWRAP IS OPENED 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 14 g

ESSENTIAL AMINO ACIDS

LEUCINE 584 mg ISOLEUCINE 480 mg VALINE 464 mg LYSINE (ADDED AS THE HYDROCHLORIDE SALT) 464 mg PHENYLALANINE 448 mg HISTIDINE 384 mg THREONINE 336 mg METHIONINE 320 mg TRYPTOPHAN 144 mg

NONESSENTIAL AMINO ACIDS

ALANINE 1656 mg ARGININE 920 mg GLYCINE 824 mg PROLINE 544 mg SERINE 400 mg TYROSINE 32 mg

mEq/L

ACETATE 71 CHLORIDE 32

BALANCED BY IONS FROM AMINO ACIDS

PH ADJUSTED WITH GLACIAL ACETIC ACID AND HYDROCHLORIC ACID

STERILE SINGLE DOSE CONTAINER

STORE AT ROOM TEMPERATURE (25°C/77°F) IN UNOPENED OVERWRAP

AVOID EXCESSIVE HEAT

PROTECT FROM FREEZING

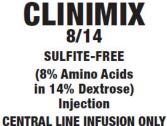
SEE PRESCRIBING INFORMATION

Baxter Logo

BAXTER HEALTHCARE CORPORATION

DEERFIELD IL 60015 USA MADE IN BELGIUM

EXP LOT BE-35-04-043



720 mL INJECTION PORT CHAMBER

39% Dextrose Injection USP 1280 mL OUTLET PORT CHAMBER 12.5% 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 ONCE OVERWRAP IS OPENED A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY AND EFFICACY OF THIS PRODUCT ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY

Ехр

CONTENTS OF EACH 100 ml	OF THE	
ADMIXED INJECTION		
DEXTROSE HYDROUS USP	14 g	
ESSENTIAL AMINO ACIDS		
LEUCINE	584 mg	
ISOLEUCINE	480 mg	
VALINE	464 mg	
LYSINE (ADDED AS THE HYDROCHLORIDE SALT)	101	
PHENYLALANINE	464 mg 448 mg	
HISTIDINE	384 mg	
THREONINE	336 mg	
METHIONINE	320 mg	
TRYPTOPHAN	144 mg	
NONESSENTIAL AMINO ACI	nc	
ALANINE	1656 mg	
ABGININE	920 mg	
GLYCINE	824 mg	
PROLINE	544 mg	
SERINE	400 mg	
TYROSINE	32 mg	
mEq/L		
ACETATE	71	
CHLORIDE	32	
BALANCED BY IONS FROM A	MINO ACIDS	
PHADJUSTED WITH GLACIA AND HYDROCHLORIC ACID	LACETIC ACI)
STERILE		
SINGLE DOSE CONTAINER		
STORE AT ROOM TEMPERAT IN UNOPENED OVERWRAP	URE (25°C/77	7 ⁰F)
AVOID EXCESSIVE HEAT		
PROTECT FROM FREEZING		
SEE PRESCRIBING INFORMA	TION	

Baxter

BAXTER HEALTHCARE CORPORATION Deerfield IL 60015 USA Made in Belgium	20000
Lot	ä

Container Label

EADB9955 NDC 0338-0184-01

2000 mL

- .

CLINIMIX 8/14 SULFITE-FREE (8% Amino Acid in 14% Dextrose) Injection

720 mL INJECTION PORT CHAMBER 39% Dextrose Injection USP 1280 mL OUTLET PORT CHAMBER 12.5% Amino Acid Injection Rx Only

ACTIVATE SEAL AND MIX THOROUGHTLY BEFORE USE

SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION AFTER MIXING THE PRODUCT REPRESENTS 2000 mL REFRIGERATED STORAGE IS LIMITED TO 9 DAYS ONCE OVERWRAP IS OPENED 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 14 g

ESSENTIAL AMINO ACIDS

LEUCINE 584 mg ISOLEUCINE 480 mg VALINE 464 mg LYSINE (ADDED AS THE HYDROCHLORIDE SALT) 464 mg PHENYLALANINE 448 mg HISTIDINE 384 mg THREONINE 336 mg METHIONINE 320 mg **TRYPTOPHAN 144 mg**

NONESSENTIAL AMINO ACIDS

ALANINE 1656 mg ARGININE 920 mg GLYCINE 824 mg PROLINE 544 mg SERINE 400 mg TYROSINE 32 mg

mEq/L ACETATE 71

CHLORIDE 32

BALANCED BY IONS FROM AMINO ACIDS

pH ADJUSTED WITH GLACIAL ACETIC ACID AND HYDROCHLORIC ACID

STERILE SINGLE DOSE CONTAINER

STORE AT ROOM TEMPERATURE (25°C/77°F) IN UNOPENED OVERWRAP

AVOID EXCESSIVE HEAT

PROTECT FROM FREEZING

SEE PRESCRIBING INFORMATION

Baxter Logo BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN BELGIUM

Exp Lot

BE-35-04-047

2B7726L	1000 mL	CONTENTS OF EACH 100 ml DEXTROSE HYDROUS USP	. OF THE ADMIXED INJE 5 a
NDC 0338-7001-01		DEXTRUSE HTDRUUS USP	эg
		ESSENTIAL AMINO ACIDS	
		LEUCINE	311 mg
		ISOLEUCINE	255 mg
(01)003	0 3 3 8 7 0 0 1 0 1 2	VALINE	247 mg
		LYSINE (ADDED AS THE	
	INIMIX	HYDROCHLORIDE SALT)	247 mg
		PHENYLALANINE	238 mg 204 mg
		THREONINE	204 mg 179 mg
	1.25/5	METHIONINE	170 mg
	t.ZJ/J	TRYPTOPHAN	77 mg
CII	LFITE-FREE	Inter For Base	77 mg
		NONESSENTIAL A MINO A CI	DS
(4.25% Amin	Acids in 5% Dextrose)	ALANINE	880 mg
-	Injection	ARGININE	489 mg
		GLYCINE	438 mg
500 mL INJ	ECTION PORT CHAMBER	PROLINE	289 mg
10% Dex	trose Injection USP	SERINE	213 mg
	•	TYROSINE	17 mg
500 mL OU	TLET PORT CHAMBER	-5-0	
0 5% Ar	nino Acid Injection	mEq/L ACETATE	37
0.0 /0 AI	nno Acia injection	CHLORIDE	17
D Datamatrix (GS1):		CHLUNIDE	11
DC, EXP, LOT	ACTIVATE SEAL AND	BALANCED BY IONS FROM A	
	MIX THOROUGHLY BEFORE USE	PH ADJUSTED WITH GLACIA	
	SEE PRESCRIBING INFORMATION FOR	AND HYDROCHLORIDIC ACI	0
	INSTRUCTIONS ON A CTNATION	STERILE	
	AFTER MIXING THE PRODUCT REPRESENTS 1000 mL	SINGLE DOSE CONTAINER	
	REPRESENTS 1000 mL		
	REFRIGERATED STORAGE IS LIMITED TO 9 DAYS ONCE OVERWRAP IS OPENED	STORE AT ROOM TEMPERATURE (25°C/77°F) In Unopened Overwrap Avoid Excessive heat	
2D Datamatrix	A SLIGHT YELLOW COLOR DOES NOT Alter the quality and efficacy of This product		
Barcode		PROTECT FROM FREEZING	
	ASK PHARMACIST ABOUT ADDITIVE Compatibility	SEE PRESCRIBING INFORMA	TION
1	Rx Only		
		Baxter	
		BAXTER HEALTHCARE COR	PORATION
		DEERFIELD IL 60015 USA	
		MADE IN BELGIUM	
	EXP	LOT	
	EAP	LUI	

Container Label

2B7726L

NDC0338-7001-01

1000 mL

Barcode (01) 00303387001012

CLINIMIX 4.25/10 SULFITE-FREE (4.25% Amino Acids in 5% Dextrose) Injection

500 mL INJECTION PORT CHAMBER

CONTENTS OF EACH 100 mL DEXTROSE HYDROUS USP	OF THE ADMIXED INJECTION 5 a	1600
	59	
ESSENTIAL AMINO ACIDS		
LEUCINE	311 mg	
ISOLEUCINE	255 mg	
LYSINE (ADDED AS THE	247 mg	
HYDROCHLORIDE SALT)	247 mg	
PHENYLALANINE	238 mg	
HISTIDINE	204 mg	
THREONINE	179 mg	
METHIONINE	170 mg	
TRYPTOPHAN	77 mg	1000
		1000
NONESSENTIAL A MINO A CID		
ALANINE	880 mg	
ARGININE	489 mg	
GLYCINE	438 mg	800
PROLINE	289 mg	
TYROSINE	213 mg	
TTHUSINE	17 mg	
mEq/L		
	37	600
CHLORIDE	17	000
BALANCED BY IONS FROM AI ph adjusted with glacial and hydrochloridic acid	ACETIC ACID	
STERILE SINGLE DOSE CONTAINER		
STORE AT ROOM TEMPERATU IN UNOPENED OVERWRAP	JRE (25°G/77°F)	400
AVOID EXCESSIVE HEAT		
PROTECT FROM FREEZING		110
SEE PRESCRIBING INFORMAT	TION	5-05-1
Baxter		BE-3
BAXTER HEALTHCARE CORP DEERFIELD IL 60015 USA MADE IN BELGIUM	ORATION	200

10% Dextrose Injection USP

500 mL OUTLET PORT CHAMBER

8.5% Amino Acid Injection Rx Only

2D Datamatrix (GS1): NDC, LOT, EXP

2D Datamatrix Barcode

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 ONCE OVERWRAP IS OPENED

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

m**Eq/L**

ACETATE 37 CHLORIDE 17

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

STERILE SINGLE DOSE CONTAINER

STORE AT ROOM TEMPERATURE (25°C/77°F) IN UNOPENED OVERWRAP

AVOID EXCESSIVE HEAT

PROTECT FROM FREEZING

SEE PRESCRIBING INFORMATION

Baxter Logo

BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA

MADE IN BELGIUM

<u>1000</u> <u>800</u> <u>600</u> <u>400</u>

<u>200</u>

BE-35-05-077

EXP LOT

2B7704L	2000 mL	CONTENTS OF EACH 100	mL OF THE ADMIXED
NDC 0338-7003-01		INJECTION DEXTROSE HYDROUS US	P 5 g
(01)0030	3 3 8 7 0 0 3 0 1 6	ESSENTIAL AMINO ACID Leucine Isoleucine Valine	
4.	25/5	LYSINE (ADDED AS THE HYDROCHLORIDE SALT PHENYLALANINE HISTIDINE THREONINE METHIONINE) 247 mg 238 mg 204 mg 179 mg 170 mg
SULF	ITE-FREE	TRYPTOPHAN	77 mg
in 5%	Amino Acids Dextrose) jection	NONESSENTIAL AMINO A Alanine Arginine Glycine Proline Serine Tyrosine	CODS 880 mg 489 mg 438 mg 289 mg 213 mg 17 mg
1000 mL INJECTIO 10% Dextrose Injec		mEq/L ACETATE 3 CHLORIDE 1	
1000 mL OUTLET P 8.5% Amino Acid Ir		BALANCED BY IONS FRO ph adjusted with GLA and hydrochloridic A	CIAL ACETIC ACID
ACTIVATE SEALAND MIX THOROUGHLY BEFO	REUSE	STERILE SINGLE DOSE CONTAINED	1
SEE PRESCRIBING INFO	RMATION FOR INSTRUCTIONS	STORE AT ROOM TEMPEI IN UNOPENED OVERWRA AVOID EXCESSIVE HEAT	
AFTER MIXING THE PRO	DUCT REPRESENTS 2000 mL	PROTECT FROM FREEZIN	c .
REFRIGERATED STORAG 9 Days once overwra		SEE PRESCRIBING INFOR	
A SLIGHT YELLOW COLO QUALITY AND EFFICACY	R DOES NOT ALTER THE OF THIS PRODUCT		
ASK PHARMACIST ABOU	JT ADDITIVE COMPATIBILITY		
Rx Only			
2D Datamatrix (GS1): NDC, EXP, LOT			
2D Datamatrix Barcode		Baxter	

BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN BELGIUM

LOT

2000

1600

1000

800

600

400

BE-35-05-073

200

Container Label

2B7704L NDC0338-7003-01

2000mL

Barcode (01) 00303387003016 **CLINIMIX**

4.25/5

SULFITE-FREE

(4.25% Amino Acids in 5% Dextrose) Injection

1000 mL INJECTION PORT CHAMBER 10% Dextrose Injection USP

EXP

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 ONCE OVERWRAP IS OPENED

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

ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY

2D Datamatrix (GS1): NDC, LOT, EXP

2D Datamatrix Barcode

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

m**Eq/L**

ACETATE 37 CHLORIDE 17

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

STERILE SINGLE DOSE CONTAINER

STORE AT ROOM TEMPERATURE (25°C/77°F) IN UNOPENED OVERWRAP

AVOID EXCESSIVE HEAT

PROTECT FROM FREEZING

SEE PRESCRIBING INFORMATION

Baxter Logo

BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA

MADE IN BELGIUM

<u>1600</u>

<u>1000</u>

<u>800</u>

<u>600</u>

<u>400</u>

<u>200</u>

BE-35-05-073

EXP LOT

2B7727L NDC 0338-7005-01	1000 mL	CONTENTS OF EACH 100 r DEXTROSE HYDROUS USP	mL OF THE ADMIXED INJECTION 10 g	1600
		ESSENTIAL AMINO ACIDS		
		LEUCINE	311 mg	
		ISOLEUCINE	255 mg	
(01)003	303387005010	VALINE	247 mg	
		LYSINE (ADDED AS THE		
	INIMIX	HYDROCHLORIDE SALT)		
		PHENYLALANINE	238 mg 204 mg	
	0.00	THREONINE	179 mg	
4	.25/10	METHIONINE	170 mg	
		TRYPTOPHAN	77 mg	4000
SU	LFITE-FREE			1000
	Acids in 10% Dextrose)	NONESSENTIAL A MINO A		
(4.20 /0 MIIIIIO		ALANINE	880 mg	
	Injection	ARGININE	489 mg	
CENTRAL I	INE INFUSION ONLY	GLYCINE	438 mg	800
		PROLINE	289 mg	
	ECTION PORT CHAMBER	SERINE	213 mg	
20% Dex	trose Injection USP	TYROSINE	17 mg	
	TLET PORT CHAMBER	mEo/L		
	nino Acid Injection	ACETATE	37	600
0.070 Pi	nno Acia injection	CHLOBIDE	17	000
2D Datamatrix (GS1):	ACTIVATE SEAL AND			
NDC, EXP, LOT	MIX THOROUGHLY BEFORE USE	BALANCED BY IONS FROM		
		PH ADJUSTED WITH GLAC AND HYDROCHLORIC ACID		
	SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION	AND HYDRUCHLORIC AGIL STERILE	U Contraction of the second seco	
	AFTER MIXING THE PRODUCT	SI ERILE SINGLE DOSE CONTAINER		
	REPRESENTS 1000 mL			
	REFRIGERATED STORAGE IS LIMITED TO 9 DAYS ONCE OVERWRAP IS OPENED	STORE AT ROOM TEMPER		400
2D Datamatrix	A SLIGHT YELLOW COLOR DOES NOT	AVOID EXCESSIVE HEAT		
2D Datamatrix Barcode	THIS PRODUCT	PROTECT FROM FREEZING		00
Barcode	ASK PHARMACIST ABOUT ADDITIVE			3E-35-05-078
	COMPATIBILITY	SEE PRESCRIBING INFORM	MATION	8
	Rx Only			35
		Baxter		ä
		BAXTER HEALTHCARE CO	RPORATION	
		DEERFIELD IL 60015 USA		200
		MADE IN BELGIUM		
	EXP	LOT		
	Letter .			

DEXTROSE HYDROUS USP	10 g	1600
ESSENTIAL A MINO A CIDS		
LEUCINE	311 mg	
ISOLEUCINE	255 mg	
VALINE	247 mg	
LYSINE (ADDED AS THE	3	
HYDROCHLORIDE SALT)	247 mg	
PHENYLALANINE	238 mg	
HISTIDINE	204 mg	
THREONINE	179 mg	
METHIONINE	170 mg	
TRYPTOPHAN	77 mg	1000
		1000
NONESSENTIAL AMINO A		
ALANINE	880 mg	
ARGININE	489 mg	
PROLINE	438 mg 289 mg	800
SERINE	289 mg 213 mg	
TYROSINE	17 mg	
TTRUSINE	17 ling	
mEg/L		
ACETATE	37	600
CHLORIDE	17	000
BALANCED BY IONS FROM PH ADJUSTED WITH GLAC AND HYDROCHLORIC ACII	CIAL ACETIC ACID	
STERILE Single dose container	U.	
STORE AT ROOM TEMPER		400
AVOID EXCESSIVE HEAT		
PROTECT FROM FREEZING	G	18
SEE PRESCRIBING INFOR	MATION	3
SEET RESONDING INFORM		20
		2
Baxter		
BAXTER HEALTHCARE CO		200
DEERFIELD IL 60015 USA		200
MADE IN BELGIUM		
LOT		

Container Label

2B7727L NDC0338-7005-01

1000mL Barcode

(01) 00303387005010

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**

2D Datamatrix (GS1): NDC, LOT, EXP

2D Datamatrix Barcode

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 ONCE OVERWRAP IS OPENED

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

m**Eq/L**

ACETATE 37 CHLORIDE 17

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

STERILE SINGLE DOSE CONTAINER

STORE AT ROOM TEMPERATURE (25°C/77°F) IN UNOPENED OVERWRAP

AVOID EXCESSIVE HEAT

PROTECT FROM FREEZING

SEE PRESCRIBING INFORMATION

Baxter Logo

BAXTER HEALTHCARE CORPORATION

DEERFIELD IL 60015 USA MADE IN BELGIUM

<u>400</u>

<u>200</u>

BE-35-05-078

EXP LOT

2B7705L NDC 0338-7007-01	2000 mL	CONTENTS OF EACH 100 m INJECTION	65572	
		DEXTROSE HYDROUS USP	10 g	
		ESSENTIAL AMINO ACIDS		
(01)003		LEUCINE	311 mg 255 mg	
15.35519355		VALINE	247 mg	
	NIMIX	LYSINE (ADDED AS THE		
ULI		HYDROCHLORIDE SALT)	247 mg	
Λ	25/10	PHENYLALANINE	238 mg 204 mg	2000
	23/10	THREONINE	204 mg 179 mg	
CIII	FITE-FREE	METHIONINE	170 mg	
501	FIIE-FREE	TRYPTOPHAN	77 mg	
(4.25%	Amino Acids	NONESSENTIAL AMINO ACI		
	% Dextrose)	ALANINE	880 mg	
		ARGININE	489 mg 438 mg	
1	njection	PROLINE	289 mg	
		SERINE	213 mg	1600
CENTRAL L	NE INFUSION ONLY	TYROSINE	17 mg	
		mEq/L		
1000 mL IN JECTIC	ON PORT CHAMBER	ACETATE 37		
20% Dextrose Inj		CHLORIDE 17		
		BALANCED BY IONS FROM		1005
1000 mL OUTLET		pH ADJUSTED WITH GLACK AND HYDROCHLORIC ACID	IL ACETIC ACID	1000
8.5% Amino Acid	Injection			
ACTIVATE SEALAND		STERILE SINGLE DOSE CONTAINER		
MIX THOROUGHLY BE	FORE USE	STORE AT ROOM TEMPERAT		
		IN UNOPENED OVERWRAP	URE (25"6/77"F)	
	ORMATION FOR INSTRUCTIONS	AVOID EXCESSIVE HEAT		
ON ACTIVATION		PROTECT FROM FREEZING		
	ODUCT REPRESENTS 2000 mL	SEE PRESCRIBING INFORM	TION	800
REFRIGERATED STOR				
A SLIGHT YELLOW COL QUALITY AND EFFICAD	OR DOES NOT ALTER THE Y OF THIS PRODUCT			
ASK PHARMACIST AB	DUT ADDITIVE COMPATIBILITY			
Rx Only				600
2D Datamatrix (GS1): NDC, EXP, LOT				
NOO, EAP, LOI				400
2D Datamatrix Barcode		Baxter Baxter Healthcare Cor Deerfield IL 60015 USA Made in Belgium	PORATION	BE-35-05-074
				200
	EXP	LOT		

Container Label

2B7705L NDC0338-7007-01

2000mL

Barcode (01) 00303387007014

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 ONCE OVERWRAP IS OPENED

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

ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY

2D Datamatrix (GS1):

NDC, LOT, EXP

2D Datamatrix Barcode

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

m**Eq/L**

ACETATE 37 CHLORIDE 17

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

STERILE

SINGLE DOSE CONTAINER

STORE AT ROOM TEMPERATURE (25°C/77°F) IN UNOPENED OVERWRAP

AVOID EXCESSIVE HEAT

PROTECT FROM FREEZING

SEE PRESCRIBING INFORMATION

Baxter Logo

BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN BELGIUM

<u>2000</u>

EXP LOT

2B7730L NDC 0338-7009-01	1000 mL
	3 0 3 3 8 7 0 0 9 0 1 8
UL	
(5%	5/15 LFITE-FREE Amino Acids 5% Dextrose)
CENTRAL	Injection
500 mL INJI 30% Dex 500 mL OU	ECTION PORT CHAMBER trose injection USP ITLET PORT CHAMBER nino Acid injection
2D Datamatrix (GS1): NDC, EXP, LOT	ACTIVATE SEAL AND
2D Datamatrix Barcode	MX THOROUGHLY DEFORE USE SEE PRESCRIBING INFORMATION FOR INSTRUCTIONS ON ACTIVATION AFTER MIXING THE PRODUCT REPRESENTS 1000 mL REFRIGERATED STORAGE IS LIMITED TO 0 DAYS ONCE ONEWWARP IS DOPHED A SLIGHT YELLOW COLOR DOES NOT ALTER THE QUALITY AND EFTEACY OF THIS PRODUCT ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY Rx Only

EXP

ESSENTIAL A MINO A CIDS Leucine Isoleucine		
LEUCINE		
	205 mm	
	365 mg 300 mg	
VALINE	290 mg	
LYSINE (ADDED AS THE	290 mg	
	000-	
HYDROCHLORIDE SALT) PHENYLALANINE	290 mg	
HISTIDINE	280 mg 240 mg	
THREONINE	240 mg 210 mg	
METHIONINE		
TRYPTOPHAN	200 mg	
INTPIOPHAN	90 mg	100
NONESSENTIAL & MINO & CID	c	
ALANINE	1035 mc	
ARGININE	575 mg	
GIYCINE	515 mg	000
PROLINE	340 mg	800
SERINE	250 mg	
TYROSINE	20 mg	
- THOUSE	Long	
mEq/L		
	42	600
CHLORIDE	20	
BALANCED BY IONS FROM A	MINO ACIDS	
pH ADJUSTED WITH GLACIAL		
AND HYDROCHLORIC ACID	HOLITOHOL	
STERILE		
SINGLE DOSE CONTAINER		
STORE AT ROOM TEMPERATU	JRE (25°C/77°F)	400
IN UNOPENED OVERWRAP		
AVOID EXCESSIVE HEAT		52
PROTECT FROM FREEZING		BE-35-079
SEE PRESCRIBING INFORMAT	ION	the second se
		4
Baxter		8
	an an an	
BAXTER HEALTHCARE CORP	UKAIIUN	200
DEERFIELD IL 60015 USA Made in Bei Gium		200
MADE IN BELGIUM		

Container Label

2B7730L NDC0338-7009-01

1000mL

Barcode (01) 00303387009018

CLINIMIX 5/15 SULFITE-FREE (5% Amino Acids in 15% Dextrose) Injection

CENTRAL LINE INFUSION ONLY

500 mL INJECTION PORT CHAMBER 30% Dextrose Injection USP 500 mL OUTLET PORT CHAMBER **10% Amino Acid Injection Rx Only**

2D Datamatrix (GS1): NDC, LOT, EXP

2D Datamatrix Barcode

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 ONCE OVERWRAP IS OPENED

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

m**Eq/L**

ACETATE 42 CHLORIDE 20

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

STERILE SINGLE DOSE CONTAINER

STORE AT ROOM TEMPERATURE (25°C/77°F) IN UNOPENED OVERWRAP

AVOID EXCESSIVE HEAT

PROTECT FROM FREEZING

SEE PRESCRIBING INFORMATION

Baxter Logo BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA

MADE IN BELGIUM

<u>1600</u>

<u>1000</u> <u>800</u>

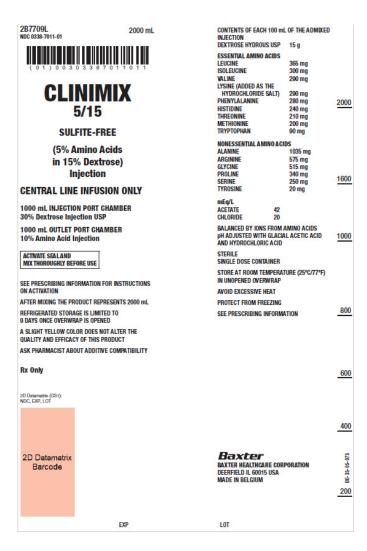
<u>600</u>

<u>400</u>

<u>200</u>

BE-35-05-079

EXP LOT



Container Label

2B7709L

NDC0338-7011-01

2000mL

Barcode (01) 00303387011011 CLINIMIX

5/15

SULFITE-FREE

(5% Amino Acids in 15% Dextrose) Injection

CENTRAL LINE INFUSION ONLY

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 ONCE OVERWRAP IS OPENED

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

ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY

2D Datamatrix (GS1):

NDC, LOT, EXP

2D Datamatrix Barcode

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

m**Eq/L**

ACETATE 42 CHLORIDE 20

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

STERILE

SINGLE DOSE CONTAINER

STORE AT ROOM TEMPERATURE (25°C/77°F) IN UNOPENED OVERWRAP

AVOID EXCESSIVE HEAT

PROTECT FROM FREEZING

SEE PRESCRIBING INFORMATION

Baxter Logo

BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN BELGIUM

<u>2000</u>

EXP LOT

2B7731L NDC 0338-7013-01	1000 mL
(01)003	3 0 3 3 8 7 0 1 3 0 1 5
CL	INIMIX
	5/20
(5%	LFITE-FREE 5 Amino Acids 0% Dextrose) Injection
	LINE INFUSION ONLY
	ECTION PORT CHAMBER trose injection USP
500 mL OU 10% An	ITLET PORT CHAMBER nino Acid Injection
2D Datamatrix (GS1): NDC, EXP, LOT	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 ONCE OVERWYRAP IS OPENED
2D Datamatrix Barcode	A SLIGHT YELLOW COLOR DOES NOT Alter the quality and efficacy of this product Ask pharmacist about additive compatibility
	Rx Only
	EXP

LEUCINE 365 mg ISICILECINE 300 mg VALINE 200 mg VALINE 200 mg IVALINE 200 mg HYDROLLOBIDE SALT) 200 mg HYDROLLOBIDE SALT) 200 mg HYDROLLOBIDE SALT) 200 mg HISTIONNE 240 mg HISTIONNE 240 mg MCHIONNE 210 mg MCHIONNE 210 mg ALANINE 1035 mg ALANINE 1035 mg ALANINE 575 mg GUCGNE 515 mg BOO SERNE 250 mg mfg/L AGEATE 42 600 GLORIDE 20 GO BLANCED BY IONS FROM ANNIO ACIDS PHADUSTED WITH GLACIL ACENTE ACID AND HYDROHUME ACIDS PHADUSTED WITH GLACIAL ACENTE ACID AND HYDROHUME ACIDS SERNE 200 mg mfg/L AGEATE 42 600 SEGNEE 20 600 STORE AT BOOM TEMPERATURE (25°077°F) 4000 STORE AT BOOM TEMPERATURE (25°07	DEXTROSE HYDROUS USP	L OF THE ADMIXED INJECTION 20 g	1600
ISOLEUCINE 300 mg ISOLEUCINE 300 mg VISINE (ADDED AS THE 290 mg IVESINE (ADDED AS THE 290 mg IVESINE (ADDED AS THE 290 mg INTRODENDES GALT) 290 mg INTODNE 240 mg INTODNE 240 mg INTODNE 200 mg INTODNE 200 mg INTODNE 200 mg INTERONNE 200 mg ADDINNE 200 mg ADDINNE 200 mg ADDINNE 200 mg ADDINNE 200 mg SERINE 575 mg GICVINE 340 mg SERINE 20 mg METAJ 200 mg METAJ 200 mg METAJ 200 mg SERINE 20 mg SERINE 20 mg METAJ 42 CHLORIDE 20 STERLE SIGNEL ALCALL ACET CALD ANOT DOCHLORIC ACID STERLE STERLE SIGNEL ADOSE CONTAINER	ESSENTIAL A MINO A CIDS		
VALUNE 200 mg VALUNE 200 mg VALUNE 200 mg HYDRORLORDE SALT) 200 mg HYDRORLORDE SALT) 200 mg HYSTIONNE 240 mg HISTIONNE 240 mg HISTIONNE 240 mg MCTHIONNE 210 mg MCTHIONNE 210 mg MCTHIONNE 210 mg MCTHIONNE 200 mg HISTIONE 200 mg MCTHIE 340 mg SERNE 250 mg MCTHIE 340 mg SERNE 250 mg MCTHIE 340 mg SERNE 200 mg MCTHIE 420 MG SERNE 200 mg MCTHIE 420 MG STORL AT ROOM TEMPERATURE (25°077°F) MCTHIE MCTHIE MCTHIE MCTHIE (25°077°F) MCTHIE			
UTSINE QUDED AS THE LATING AND ACTION AND ACTION AND ACTION AND ACTION AND ACTION AND ACTION			
HYDBROCHLORIDE SALT) 200 mg HYDBROCHLORIDE SALT) 200 mg HISTIDINIE 240 mg HISTIDINIE 240 mg HISTIDINIE 210 mg METHIONNE 200 mg HISTIDINIE 200 mg HISTIDINIE 200 mg HISTIDINIE 200 mg HORESSENTAL AMINO ACIDS 1035 mg ALANNE 1035 mg ALANNE 515 mg BOULE 515 mg BOULE 200 mg mfrij 1000 SERNE 250 mg mfrij AGEATE AGEATE 42 AGEATE 42 AGEATE 42 AGEATE 42 MONOCHLORIC ACID SERNE STORE AT ROOM TEMERATURE (25°077°F) 400 ANOID EXCESSIVE HEAT PROTECT FROM FREEZING SEE PRESCRIBING INFORMATION 40 SECTECT 400 MADE IN BELGIUM 200		290 mg	
PHENTLANINE 280 mg INTONNE 240 mg INTONNE 210 mg MERTIONNE 200 mg TRYPTOPHAN 90 mg NONESSENTAL AMING ACIDS ALANINE 1035 mg ARGININE 575 mg GICVANE 535 mg ARGININE 525 mg SICVANE 340 mg SERINE 20 mg mEdy L 20 mg ACETATE 42 CHLORIDE 20 mg mEdy L ACETATE ACETATE 42 CHLORIDE 20 mg MEDU LALGEL DY INS FROM AMINO ACIDS PALAUSED BY INS FROM AMINO ACIDS STERLE SINGLE DOSC CONTAINER STORE AT ROOM TEMPERATURE (25'077'F) ADOID EXCESSIVE HEAT PROJECT FROM FREEZING SEE PRESCRIBING INFORMATION SECENTECT MADE IN BELGIUM			
HISTIDINE 240 mg HISTIDINE 240 mg MCTHIONNE 210 mg MCTHIONNE 200 mg 1000 NORSSERTAL AMINO ACIDS ALANINE 1035 mg ALANINE 1055 mg GUCGNE 515 mg 800 SERNE 250 mg MEGYLE 340 mg SERNE 200 mg MEGYLE 340 mg SERNE 200 mg MEGYLE 422 6000 MCI DI STROM ANNIO ACIDS PH AUJISTED WITH GLACKL ACETIC ACID AND HYDOCHLORIC ACID STERLE 500 GONTAINER STORE AT ROOM TEMPERATURE (25'077'F) MOUTO EXCESSIVE HEAT PROTECT FROM FHEZING 36 SEE PRESCRIBING INFORMATION 36 SEE PRESCRIBING INFORMATION 36 SEE PRESCRIBING INFORMATION 36 SECTEP MADETED LALINGARE CORPORATION 200 MADE IN BELGIUM			
THREENINE 210 mg MERTHONNE 200 mg TRYPTOPHAN 90 mg NONESSENTAL AMINO ACIDS ALANINE 1035 mg ARGININE 575 mg GICYDNE 340 mg SERINE 20 mg MEGY L 220 mg ARGININE 20 mg MERY L 42 GOOD ACETATE 42 GOOD CHLORIDE 20 mg MERY L ACETATE ACETATE 42 GOOD PADUSTED WITH GLACAL ACETIC ACID AND HONOCHLORIC ACID STERLE STERLE STERLE<			
METHIONNE 200 mg 1000 TRYPTOPHAN 90 mg 1000 NORSSERTTAL AMINO ACIDS ALANINE 1035 mg ARON ALANINE 1035 mg ARON ALANINE 575 mg 800 GUCGNE 515 mg 800 SERNE 250 mg 100 mEryl ACETATE 20 mg 100 MERYL 42 600 BALANECE BY IONS FROM AMINO ACIDS PHADUSTE UNIT INCLACELL ACETIC ACID AND HYDORCHLORIC ACID STERLE 500 STERLE 500 STERLE 500 STERLE 500 STERLE 500 STERLE 500 STERLE 600 SERNE 200 STERLE 500 STERLE 500 STERLE 500 SERNE 200 STERLE 500 STERLE 500 SERNE 200 STERLE 500 STERLE 500 STE			
TRYPTOPHAN 90 mg 1000 NONESSENTAL AMINO ACIDS ALANINE 1035 mg ARGININE 575 mg 1035 mg ARGININE 515 mg 800 SERINE 250 mg 800 SERINE 20 mg 800 ARGININE 20 mg 600 BALANCED BY IONS FROM AMINO ACIDS PH ADUSTED WITH GLACAL ACETIC ACID AND HYDOCHLORIC ACID 800 STERLE STERLE STERLE SINGLE DOSE CONTAINER STERLE STERLE SINGLE DOSE CONTAINER STERLE STERLE STERLE			
Interview Interview ALANINE 1035 mg ALANINE 1035 mg ALANINE 1035 mg ALANINE 515 mg BOUNE 515 mg BOUNE 340 mg SERNE 250 mg Integrit 42 ACEATE 42 ChORDe 20 mg Integrit 42 ACEATE 20 mg Integrit 20 mg Integrit 20 mg Integrit 42 ACEATE 20 mg Integrit 42 mg ACEATE 20 mg Integrit 42 mg Integrit 42 mg Integrit 40 mg Integrit 42 mg Integrit 42 mg Integrit 42 mg Integrit 40 mg Integrit 10 mg			
ALAMINE 1005 mg ALAMINE 175 mg GUYCINE 515 mg 800 SERNE 250 mg TYROSINE 200 mg mg/L ACEDATE 42 600 GRUCHE 20 mg MG/L ACEDATE 42 600 GRUCHE 20 600 STERUE 20 600 MUNOPERED VIONS FROM AMINO ACIDS PH ADJUSTED WITH GLACALL ACETIC ACID AND MYROROHLORIC ACID STERULE SINGLE DOSC CONTAINER STERULE SINGLE TO DOSC CONTAINER STERULE SINGLE TO DOSC CONTAINER STERULE SINGLE TO DOSC CONTAINER SINGLE TO DOSC CONTAINER SINGLE TO DOSC CONTAINER SINGLE TO DOSC CONTAINER SINGLE TO DOSC CONTAINER SEE PRESCRIBING INFORMATION SECONCEPTION FREEZING SEE PRESCRIBING INFORMATION SECONCEPTION FREEZING SECONCEPTION FREEZING SCH TO DOSC SINGLE ACID SINGLE ACID SINGLE ACID AND TO DOSC SINGLE ACID SIN	TRYPTOPHAN	90 mg	1000
ARGININE 975 mg GICYORE 515 mg PROLINE 540 mg 800 SERINE 250 mg TYROSINE 20 mg mtg/L ACETATE 42 600 BALANCED BY IONS FROM AMINO ACIDS PLADUSTED WTH GLACALL ACETIC ACID AND HYDORCHLORIC ACID STERLE SINGLE DOSE CONTAINER STORE AT BOOM TEMPERATURE (25°C77°F) 400 IN UNOPEND OLYNWRAP AVOID EXCESSIVE HEAT PROTECT FROM FREEZING 85 SEE PRESCRIBING INFORMATION 85 BEXCEP BATER HEATINGARE CORPORATION 200 BETHELL 2005 USA 200	NONESSENTIAL A MINO A C	IDS	
GUYCHRE 515 mg 800 GUYCHRE 340 mg 800 SERNE 250 mg 90 mg SERNE 20 mg 600 SERNE 20 mg 600 GALDREDE 20 600 SALANCED BY IONS FROM AMINO ACIDS pH ADJUSTED WITH GLACIAL ACETIC ACID AND MYOROCHLORIC ACID 400 STERLE SINGLE DOSC CONTAINER STERLE STORAL TO BUY CONSCINATION 400 NUNOPERED OVERWRAP 400 AVOID EXCESSIVE HEAT PROTECT FROM FREEZING SEE PRESCRIBING INFORMATION 400 BEXCECE 400 BUTTER HEALTINGARE CORPORATION 400 BENCECE 400 MADE IN BELGIUM 200	ALANINE	1035 mg	
PROLINE 340 mg 000 PROLINE 250 mg 000 TYROSINE 20 mg 000 mtg/L ACETATE 42 600 BALANCED BY IONS FROM AMINO ACIDS PH ADJUSTED WITH GLACAL ACETIC ACID AND HYDORCHLORIC ACID STIGULE 1000 TEMPERATURE (25'077'F) 400 NUMOPEND 002WWARP AVOID EXCESSIVE HEAT PROTECT FROM FREEZING 9 SEE PRESCRIBING INFORMATION 9 BEXCEP BATTER HEATINGARE CORPORATION 200 MADE IN BELGIUM	ARGININE	575 mg	
PROLINE 340 mg PROLINE 250 mg TYROSINE 20 mg mEq/L Actatt Actatt 42 GRUNCE 20 PH ADJUSTED WITH GLACAL AGETIC ACID AND HYDROHLORIC ACID STORE AT ROOM TEMPONATING ACIDS STORE AT ROOM TEMPERATURE (25°077°F) AVOID EXCESSIVE HEAT PROJECT FROM FREEZING SEE PRESCRIBING INFORMATION SECRECE BACKTEER BACTER HEALTIVAGE CORPORATION CEFFRIED IL, GOSTI SLA MADE IN BELGIUM	GLYCINE	515 mg	800
TYHOSINE 20 mg mfcyl Actaite 42 600 Balanced by Ions from Amino Acids balanced by Ions from Amino Acids and Hodosted with Glackal Actiet Acid And Hodosted with Glackal Actiet Acid And Hodosted With Glackal Actiet Acid And Hodosted Kingles Strene La Strene Acids Strene Acids Actiet Acids Strene Acids Acids Acids Acids Strene Acids Acids Acids Acids Strene Acids Acids Acids Acids Strene Acids Acids Acids Acids Acids Acids Acids Acids Acids Strene Acids Acid	PROLINE	340 mg	000
megyl Actente 42 600 Actente 20 600 QHORIDE 20 600 BALANCED BY IONS FROM AMINO ACIDS ph ADJUSTED WITH GLACALL ACETIC ACID AND MYOBOCHLORIC ACID 600 Sterile Single Dose Container 400 Store at Room transpersatione 20 400 IN UNOFENED OVERWRAP 400 AVDID EXCESSIVE HEAT PROTECT FROM FREEZING BEXCEPE 400 DETRIED L GOST SAA 200 MADE IN BELGIUM 200	SERINE	250 mg	
ACÉTATE 42 600 CHLORIDE 20 600 BALANCED BY IONS FROM AMINO ACIDS ph ADJUSTED WITH GLACALL ACETIC ACID AND HYDROCHLORIC ACID STERILE SINGLE DOSE CONTAINER STORE AT ROOM TREMEYEATURE (25°C77°F) 400 IN UNOFENED OVERWRAP AVOID EXCESSIVE HEAT PROTECT FROM FREEZING SEE PRESCRIBING INFORMATION BEXCEPT BATTER HEALTICARE CORPORATION BETRIELL I. ACID SUSA MADE IN BELGIUM	TYROSINE	20 mg	
CHLORIDE 20 COUCH CHARACTER 20 COUCH CHARACTER 20 COUCH CHARACTER 20 COUCH CHARACTER 20 CHARACTE	mEo/L		
CHLORIDE 20 EALARCED BY IONS FROM AMINO ACIDS EALARCED BY IONS FROM AMINO ACIDS PH ADJUSTED WITH GLACALL ACENT ACID AND HYDOCHLORIC ACID STORE AT ROOM TEMPERITURE (25°077°F) 400 NO ID EXCESSIVE HEAT PROTECT FROM FREEZING SEE PRESCRIBING INFORMATION BECEVEE MATTER HEATINGARE CORPORATION ECHTELEIL ACIDS USA 200 MADE IN BELGIUM	ACETATE	42	600
pH ADJESTED WITH GLACAL AGETIC AGID AND HYDROCHLORIG AGID STORLE DOSE CONTAINER STORLE DOSE CONTAINER STORE AT ROOM TEMPERATURE (25°C77°F) 400 IN NOOPENG OLYNWARAP AVOID EXCESSIVE HEAT PROTECT FROM FREEZING SEE PRESCRIBING INFORMATION BEXELET BAXTER HEALTICARE CORPORATION EDETRIELI L GAOTO IS USA 200	CHLORIDE	20	000
STORE AT ROOM TEMPERATURE (25°G77°F) 400 IN UNOPENED OVERWRAP AVOID EXCESSIVE HEAT PROTECT FROM FREEZING SEE PRESCRIBING INFORMATION BEXEEP BATER HEALTINGARE CORPORATION DEFINED IL GOTO SUSA 200	PH ADJUSTED WITH GLACK AND HYDROCHLORIC ACID STERILE	AL ACETIC ACID	
IN UNOPENED OVERWIRAP AVVIDE VCESSAVE HEAT PROTECT FROM FREEZING SEE PRESCRIBING INFORMATION BEXCEP BATER HEALTINGARE CORPORATION DEFINED IL GOIS USA MADE IN BELGIUM			
ROTECT FROM FREEZING SEE PRESCRIBING INFORMATION SEE PRESCRIBING INFORMATION SEE PRESCRIBING INFORMATION SEE PRESCRIBING INFORMATION SEE PRESCRIBING SEE PRESCRIBING INFORMATION SEE PRESCRIBING SEE PRESCRIBING INFORMATION SEE PRESCRIBING SEE PRESCRIBULT SEE PRESCRIBING SEE PRESCRIBING SEE PRESCRIBING SEE PRESC	STORE AT ROOM TEMPERA In Unopened overwrap	TURE (25°G/77°F)	400
SEE PRESCRIBING INFORMATION S Baxter Heatmcare corporation Defined II. Good State Made IN Belgium	AVOID EXCESSIVE HEAT		
BAXTER HEALTHCARE CORPORATION DEFINELD IL GOOTS USA 200 MADE IN BELGIUM	PROTECT FROM FREEZING		8
BAXTER HEALTHCARE CORPORATION DEFINELD IL GOOTS USA 200 MADE IN BELGIUM	SEE PRESCRIBING INFORM	ATION	35-05-0
BAXTER HEALTHCARE CORPORATION DEERFIELD IL GOOTS USA 200 MADE IN BELGIUM	Daytor		出
DEERFIELD IL 60015 USA 200 MADE IN BELGIUM			
MADE IN BELGIUM		IPUKATION	200
			200
101	MADE IN BELGIUM		
	LOT		

Container Label

2B7731L NDC0338-7013-01

1000mL

Barcode (01) 00303387013015

CLINIMIX 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

2D Datamatrix (GS1): NDC, LOT, EXP

2D Datamatrix Barcode

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 ONCE OVERWRAP IS OPENED

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

NONESSENTIAL AMINO ACIDS

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

m**Eq/L**

ACETATE 42 CHLORIDE 20

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

STERILE SINGLE DOSE CONTAINER

STORE AT ROOM TEMPERATURE (25°C/77°F) IN UNOPENED OVERWRAP

AVOID EXCESSIVE HEAT

PROTECT FROM FREEZING

SEE PRESCRIBING INFORMATION

Baxter Logo

BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA

MADE IN BELGIUM

<u>1600</u>

1000

<u>800</u>

<u>600</u>

<u>400</u>

<u>200</u>

BE-35-04-996

EXP LOT

SUL	2000 mL	CONTENTS OF EACH 100 mL OF THE ADMIXED INJECTION DEXTROSE HYDROUS USP 20 g ESSENTAL AMINO ACIDS LEUCINE 365 mg ISOLEUCINE 300 mg VALINE 280 mg LYSINE (ADDED AS THE HYDROCHLORIDE SALT) 290 mg PHENYLALANINE 280 mg HISTIDINE 240 mg THREONINE 210 mg THREONINE 210 mg THREONINE 210 mg THREONINE 210 mg	<u>2000</u>
in 20 ⁰ Ir	Amino Acids % Dextrose) njection E INFUSION ONLY	NONESSENTIAL AMINO ACIDS ALANINE 1035 mg ARGININE 575 mg GLYCINE 615 mg PROLINE 340 mg SERINE 250 mg TYROSINE 20 mg	<u>1600</u>
1000 mL INJECTIC 40% Dextrose Inje 1000 mL OUTLET 10% Amino Acid I Activate sealand MIX Thoroughly Ber	PORT CHAMBER njection	mEq/L ACETATE 42 CHLORIDE 20 BALANCED BY IONS FROM AMINO ACIDS pH ADJUSTED WITH GLACHLACETIC ACID AND HYDROCHLORIC ACID STERILE SINGLE DOSE CONTAINER	<u>1000</u>
ON ACTIVATION AFTER MIXING THE PR Refrigerated Stora 9 Days once overwe A slight yellow col Quality and Efficac	AP IS OPENED .or does not alter the	STORE AT ROOM TEMPERATURE (25°C/77°F) In Unopened overwrap Avoid excessive heat Protect from freezing See prescribing information	800
Rx Only 2D Datamatrix (GS1): NDC, EXP, LOT			600
			400
2D Datamatrix Barcode		Baxter Baxter Halthcare Corporation Deferield 16 60015 USA Made in Belgium	9/0-90-92 -38 200
	EXP	LOT	

Container Label

2B7710L NDC0338-7015-01

2000mL

Barcode (01) 00303387015019 **CLINIMIX**

5/20

SULFITE-FREE

(5% Amino Acids in 20% Dextrose) Injection

CENTRAL LINE INFUSION ONLY

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 ONCE OVERWRAP IS OPENED

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

ASK PHARMACIST ABOUT ADDITIVE COMPATIBILITY

2D Datamatrix (GS1):

NDC, LOT, EXP

2D Datamatrix Barcode

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

NONESSENTIAL AMINO ACIDS

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

m**Eq/L**

ACETATE 42 CHLORIDE 20

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

STERILE

SINGLE DOSE CONTAINER

STORE AT ROOM TEMPERATURE (25°C/77°F) IN UNOPENED OVERWRAP

AVOID EXCESSIVE HEAT

PROTECT FROM FREEZING

SEE PRESCRIBING INFORMATION

Baxter Logo

BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN BELGIUM

2000

1600
1000
<u>800</u>
<u>600</u>
<u>400</u>
<u>200</u>
BE-35-04-988

EXP LOT

CLINIMIX

leucine, phenylalanine, lysine, methionine, isoleucine, valine, histidine, threonine, tryptophan, alanine, glycine, arginine, proline, serine, tyrosine, dextrose injection **Product Information** HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:0338-1133 Product Type INTRAVENOUS Route of Administration Active Ingredient/Active Moiety Basis of Ingredient Name Strength Strength 311 mg in 100 mL LEUCINE (UNII: GMW67QNF9C) (LEUCINE - UNII:GMW67QNF9C) LEUCINE 238 mg in 100 mL PHENYLALANINE (UNII: 47E5017Y3R) (PHENYLALANINE - UNII:47E5017Y3R) PHENYLALANINE 247 mg in 100 mL LYSINE (UNII: K3Z4F929H6) (LYSINE - UNII:K3Z4F929H6) LYSINE 170 mg in 100 mL METHIONINE (UNII: AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL) METHIONINE 255 mg

Marketing	Application Number or Monograph	Marketing S	tart Marketing End
Marketing	Information		
1 NDC:0338-1133- 03	1000 mL in 1 BAG; Type 0: Not a Combination Product	09/29/1997	
# Item Code	Package Description	Date	Date
		Marketing St	art Marketing End
Packaging			
NITROGEN (UNII: N			
ACETIC ACID (UNI WATER (UNII: 0590			
	Ingredient Name		Strength
Inactive Ingre			
DEXTROSE (UNII: I UNII:5SL0G7R0OK)	Y9XDZ 35W2) (ANHYDROUS DEXTROSE -	DEXTROSE	5 g in 100 mL
TYROSINE (UNII: 4	2HK56048U) (TYROSINE - UNII:42HK56048U)	TYROSINE	17 mg in 100 mL
SERINE (UNII: 452)	'LY9402) (SERINE - UNII:452VLY9402)	SERINE	213 mg in 100 mL
PROLINE (UNII: 9D	Q4CIU6V) (PROLINE - UNII:9DLQ4CIU6V)	PROLINE	289 mg in 100 mL
ARGININE (UNII: 94	ZLA3W45F) (ARGININE - UNII:94ZLA3W45F)	ARGININE	489 mg in 100 mL
GLYCINE (UNII: TE	660X01C) (GLYCINE - UNII:TE7660X01C)	GLYCINE	438 mg in 100 mL
ALANINE (UNII: OF	P57N2ZX) (ALANINE - UNII:OF5P57N2ZX)	ALANINE	880 mg in 100 mL
TRYPTOPHAN (UN	I: 8DUH1N11BX) (TRYPTOPHAN - UNII:8DUH1N11B)	K) TRYPTOPHA	N 77 mg in 100 mL
THREONINE (UNII:	2ZD004190S) (THREONINE - UNII:2ZD004190S)	THREONINE	179 mg in 100 mL
HISTIDINE (UNII: 4	QD397987E) (HISTIDINE - UNII:4QD397987E)	HISTIDINE	204 mg in 100 mL
VALINE (UNII: HG18	BB9YRS7) (VALINE - UNII:HG18B9YRS7)	VALINE	247 mg in 100 mL
	041/3900//) (ISOLEOCINE - 0141.041/3900//)	IJULEUCINE	in 100 mL

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:0338-1089
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEUCINE (UNII: GMW67QNF9C) (LEUCINE - UNII:GMW67QNF9C)	LEUCINE	311 mg in 100 mL
PHENYLALANINE (UNII: 47E5017Y3R) (PHENYLALANINE - UNII:47E5017Y3R)	PHENYLALANINE	238 mg in 100 mL
LYSINE (UNII: K3Z4F929H6) (LYSINE - UNII:K3Z4F929H6)	LYSINE	247 mg in 100 mL
METHIONINE (UNII: AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL)	METHIONINE	170 mg in 100 mL
ISOLEUCINE (UNII: 04Y7590D77) (ISOLEUCINE - UNII:04Y7590D77)	ISOLEUCINE	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: TE7660X01C) (GLYCINE - UNII:TE7660X01C)	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: IY9XDZ 35W2) (ANHYDROUS DEXTROSE - UNII:55L0G7R0OK)	DEXTROSE	5 g in 100 mL
Inactive Ingredients		

٩C	ETIC ACID (UNII:		ngredient Name			Strength
NA	TER (UNII: 059Q	F0KO0R)				
דוע	ROGEN (UNII: N	762921K75)				
Pa	ckaging					
#	ltem Code	Pa	ackage Description	Ма	rketing Start Date	Marketing End Date
			BAG; Type 0: Not a Combination	09/29/		Date
•	04	Product		03/23/	1557	
М	arketing	Informat	tion			
	Marketing Category	Applica	ation Number or Monograph Citation	м	arketing Start Date	Marketing End Date
ND		NDA020734	4	09/2	9/1997	
eu			e, methionine, isoleucine, valir line, serine, tyrosine, dextros			ne, tryptophan,
Pr	oduct Infor	mation				
	oduct Type		HUMAN PRESCRIPTION DRUG	ltem	Code (Source)	NDC:0338-1134
Ro	ute of Admini	stration	INTRAVENOUS			
Ac	tive Ingredi	ent/Active	Moiety			
		Ingre	dient Name		Basis of Strength	Strength
LEI	JCINE (UNII: GM	N67QNF9C) (LE	EUCINE - UNII:GMW67QNF9C)		LEUCINE	311 mg in 100 mL
РН	ENYLALANINE (JNII: 47E5017	Y3R) (PHENYLALANINE - UNII:47E5O)	.7Y3R)	PHENYLALANINE	238 mg in 100 mL
LYS	SINE (UNII: K3Z4	F929H6) (LYSII	NE - UNII:K3Z4F929H6)		LYSINE	247 mg in 100 mL
ме	THIONINE (UNII:	AE28F7PNPL)	(METHIONINE - UNII:AE28F7PNPL)		METHIONINE	170 mg in 100 mL
ISC	DLEUCINE (UNII:	04Y7590D77)	(ISOLEUCINE - UNII:04Y7590D77)		ISOLEUCINE	255 mg
VA	LINE (UNII: HG18	B9YRS7) (VALI	NE - UNII:HG18B9YRS7)		VALINE	in 100 mL 247 mg
			IISTIDINE - UNII:4QD397987E)		HISTIDINE	in 100 mL 204 mg
			(THREONINE - UNII:2Z D004190S)		THREONINE	in 100 mL 179 mg
			(TRYPTOPHAN - UNII:8DUH1N11B)	<)	TRYPTOPHAN	in 100 mL 77 mg in 100 ml
			ANINE - UNII:OF5P57N2ZX)		ALANINE	880 mg in 100 mL
GL	YCINE (UNII: TE7	660X01C) (GL	YCINE - UNII:TE7660XO1C)		GLYCINE	438 mg
			RGININE - UNII:94ZLA3W45F)		ARGININE	in 100 mL 489 mg
						in 100 mL 289 mg
			DLINE - UNII:9DLQ4CIU6V)		PROLINE	in 100 mL
			NE - UNII:452VLY9402)		SERINE	213 mg in 100 mL
DE	XTROSE (UNII: IY		YROSINE - UNII:42HK56048U) NHYDROUS DEXTROSE -		DEXTROSE	17 mg in 100 ml
UNI	I:5SL0G7R0OK)				SEATION	
in	active Ingre		ngredient Name			Strength
AC	ETIC ACID (UNII:		•			····g-··
	TER (UNII: 059Q					
-	ckaging			Ma	rketing Start	Marketing End
	Item Code		ackage Description		Date	Date
#			BAG; Type 0: Not a Combination	03/20/	/2012	
#	NDC:0338-1134- 03	Product				
#	03		tion			
#		Informat	t ion ation Number or Monograph Citation	м	arketing Start Date	Marketing End Date

Product Inforr Product Type	nation	HUMAN PRESCRIPTION DRUG	ltom	Code (Source)	NDC:0338-1091
Route of Adminis	stration	INTRAVENOUS	iten	coue (source)	NDC.0550-1051
Active Ingredie	ent/Active	Moiety			
	Ingred	lient Name		Basis of Strength	Strength
EUCINE (UNII: GMV	V67QNF9C) (LE	UCINE - UNII:GMW67QNF9C)		LEUCINE	311 mg in 100 mL
HENYLALANINE (U	INII: 47E5O17Y	3R) (PHENYLALANINE - UNII:47E5C	17Y3R)	PHENYLALANINE	238 mg in 100 mL
YSINE (UNII: K3Z4F	929H6) (LYSIN	E - UNII:K3Z4F929H6)		LYSINE	247 mg in 100 mL
IETHIONINE (UNII:	AE28F7PNPL)	(METHIONINE - UNII:AE28F7PNPL)		METHIONINE	170 mg in 100 mL
OLEUCINE (UNII: (04Y7590D77) (ISOLEUCINE - UNII:04Y7590D77)		ISOLEUCINE	255 mg in 100 mL
ALINE (UNII: HG18E	39YRS7) (VALIN	IE - UNII:HG18B9YRS7)		VALINE	247 mg in 100 mL
ISTIDINE (UNII: 4Q	D397987E) (HI	STIDINE - UNII:4QD397987E)		HISTIDINE	204 mg
		THREONINE - UNII:2Z D004190S)		THREONINE	in 100 mL 179 mg
) (TRYPTOPHAN - UNII:8DUH1N11E	3X)	TRYPTOPHAN	in 100 mL 77 mg in 100 r
LANINE (UNII: OF5F	P57N2ZX) (ALA	NINE - UNII:OF5P57N2ZX)		ALANINE	880 mg in 100 mL
LYCINE (UNII: TE76	560XO1C) (GL)	CINE - UNII:TE7660XO1C)		GLYCINE	438 mg in 100 mL
RGININE (UNII: 94Z	(AR	GININE - UNII:94ZLA3W45F)		ARGININE	489 mg in 100 mL
ROLINE (UNII: 9DLC	Q4CIU6V) (PRO	LINE - UNII:9DLQ4CIU6V)		PROLINE	289 mg in 100 mL
ERINE (UNII: 452VL	Y9402) (SERIN	E - UNII:452VLY9402)		SERINE	213 mg
YROSINE (UNII: 42	HK56048U) (TY	ROSINE - UNII:42HK56048U)		TYROSINE	in 100 mL 17 mg in 100 r
EXTROSE (UNII: IY NII:55L0G7R00K)	9XDZ 35W2) (A	NHYDROUS DEXTROSE -		DEXTROSE	10 g in 100 ml
CETIC ACID (UNII: IATER (UNII: 059QF	lr Q40Q9N063P) =0KO0R)	ngredient Name			Strength
CETIC ACID (UNII: /ATER (UNII: 059QF ITROGEN (UNII: N7	lr Q40Q9N063P) =0KO0R)	-			Strength
CETIC ACID (UNII: VATER (UNII: 059QF ITROGEN (UNII: N7 Packaging	Ir Q40Q9N063P) 50KO0R) 762921K75)	-	Ма	rketing Start	Marketing En
CETIC ACID (UNII: VATER (UNII: 059QF ITROGEN (UNII: N7 Packaging Item Code NDC:0338-1091-	ii Q40Q9N063P) OKOOR) (62921K75) (62921K75) Pa 2000 mL in 1		Ma 09/29,	Date	Strength Marketing End Date
CETIC ACID (UNII: /ATER (UNII: 059QF ITROGEN (UNII: N7 Packaging : Item Code NDC:0338-1091-	Ir Q40Q9N063P) F0KOOR) F62921K75) Pa	ckage Description		Date	Marketing End
CETIC ACID (UNII: VATER (UNII: 059QF ITROGEN (UNII: N7 Packaging Item Code NDC:0338-1091- 04	li Q40Q9N063P) F0K00R) 762921K75) 762921K75) Pa 2000 mL in 1 1 Product	ckage Description BAG; Type 0: Not a Combination		Date	Marketing En
CETIC ACID (UNII: VATER (UNII: 059QF ITROGEN (UNII: N7 Packaging Item Code NDC:0338-1091- 04 Marketing I Marketing	II Q40Q9N063P) F0K00R) F0E2921K75) Pa 2000 mL in 1 Product	ckage Description BAG; Type 0: Not a Combination ion tion Number or Monograph	09/29	Date /1997 arketing Start	Marketing En Date Marketing En
CETIC ACID (UNII: VATER (UNII: 059QF ITROGEN (UNII: N7 Packaging Item Code NDC:0338-1091- 04 Marketing I Marketing Category	II Q40Q9N063P) F0K00R) F0E2921K75) Pa 2000 mL in 1 Product	ckage Description BAG; Type 0: Not a Combination iON tion Number or Monograph Citation	09/29	Date /1997	Marketing End Date
CETIC ACID (UNII: VATER (UNII: 059QF ITROGEN (UNII: N7 Packaging t Item Code NDC:0338-1091- 04 Marketing I Marketing Category IDA CLINIMIX ucine, phenylala anine, glycine, a	II Q40Q9N063P) FOKOOR) FOEQ21K75) Pa 2000 mL in 1 Product NDA020734 Applica NDA020734	ckage Description BAG; Type 0: Not a Combination iON tion Number or Monograph Citation	09/29 M 09/2 09/2 ine, his se inje	Date (1997 arketing Start Date (9)(1997 stidine, threonin	Marketing End Date Marketing End Date
CETIC ACID (UNII: VATER (UNII: 059QF ITROGEN (UNII: N7 Packaging i Item Code NDC:0338-1091- 04 Arketing I Marketing Category DA LINIMIX ucine, phenylala anine, glycine, a Product Inform Product Inform Product Type Route of Adminis	II Q40Q9N063P) FOKOOR) FOKOOR) FOE FOE Pa 2000 mL in 1 Product Product Applica NDA020734 Applica NDA020734 Applica Stration	ckage Description BAG; Type 0: Not a Combination iON tion Number or Monograph Citation , methionine, isoleucine, va ine, serine, tyrosine, dextro HUMAN PRESCRIPTION DRUG INTRAVENOUS	09/29 M 09/2 09/2 ine, his se inje	Date (1997 arketing Start Date (9/1997 stidine, threonin ction	Marketing End Date Marketing End Date e, tryptophan,
CETIC ACID (UNII: ATER (UNII: 0590F ITROGEN (UNII: N7 Packaging Item Code NDC:0338-1091- 04 Arketing I Marketing Category DA LINIMIX ucine, phenylala anine, glycine, a Product Inforr troduct Type soute of Adminis	II Q40Q9N063P) FOKOOR) FOKOOR) FOKOOR) FOKOOR FOKOOR Pa 2000 mL in 1 Product Applica NDA020734 Applica NDA020734 Applica Stration Stration	ckage Description BAG; Type 0: Not a Combination ion tion Number or Monograph Citation , methionine, isoleucine, va ine, serine, tyrosine, dextro HUMAN PRESCRIPTION DRUG INTRAVENOUS Moiety	09/29 M 09/2 09/2 ine, his se inje	Date (1997 arketing Start Date (9/1997 stidine, threonin ction	Marketing End Date Marketing End Date e, tryptophan, NDC:0338-1137
CETIC ACID (UNII: ATER (UNII: 059QF ITROGEN (UNII: N7 Packaging Item Code NDC:0338-1091- 04 Aarketing I Marketing I Marketing Category DA LINIMIX ucine, phenylaka anine, glycine, a Product Inform roduct Type soute of Adminis	II Q40Q9N063P) FOKOOR) FOKOOR) FOKOOR) FOKOOR INDERITY INDE	ckage Description BAG; Type 0: Not a Combination ion tion Number or Monograph Citation , methionine, isoleucine, va ine, serine, tyrosine, dextro HUMAN PRESCRIPTION DRUG INTRAVENOUS Moiety ient Name	09/29 M 09/2 09/2 ine, his se inje	Date (1997 arketing Start Date (1997)	Marketing End Date Marketing End Date e, tryptophan, NDC:0338-1137
CETIC ACID (UNII: VATER (UNII: 059QF ITROGEN (UNII: N7 Packaging titem Code NDC:0338-1091- 04 NDC:0338-1091- 04 Arketing I Marketing Category DA CLINIMIX ucine, phenylala anine, glycine, a Product Inform Product Sala	II Q40Q9N063P) FOKOOR) FOKOOR) FOKOOR) FOKOOR) FOKOOR FOKOOR FOKOOR Pa 2000 mL in 1 Product Pa 2000 mL in 1 Product NDA020734 Applica NDA020734 Applica NDA020734 Applica NDA020734 Stration Stra	ckage Description 3AG; Type 0: Not a Combination iON tion Number or Monograph Citation , methionine, isoleucine, va ine, serine, tyrosine, dextro HUMAN PRESCRIPTION DRUG INTRAVENOUS Moiety ient Name UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E5CE E - UNII:SZ4F929H6) METHIONINE - UNII:AE28F7PNPL) ISOLEUCINE - UNII:AE28F7PNPL)	ine, his se inje	Date (1997 arketing Start Date (9)1997 stidine, threonin ction ction ction ction ction b code (Source) Basis of Strength LEUCINE PHENYLALANINE LEUCINE METHIONINE ISOLEUCINE	Marketing End Date Marketing End Date e, tryptophan, NDC:0338-1137 NDC:0338-1137
NDC:0338-1091- 04 Marketing Category IDA CLINIMIX ucine, phenylala anine, glycine, a Product Inforr Product Inforr Product Type Route of Adminis Active Ingredie EUCINE (UNII: GMW HENYLALANINE (UNII: GMW HENYLALANINE (UNII: SoleUCINE (UNII: GMW	II Q40Q9N063P) FOKOOR) FOKOOR) FOKOOR) FOKOOR) FOKOOR FOKOOR FOKOOR Pa 2000 mL in 1 Product I Product I Applica Applica NDA020734 Applica NDA020734 Applica NDA020734 Applica Applica NDA020734 Comparison Applica Applica Stration Comparison Applica Applica Applica Applica Applica (ING Applica Applica (ING (ING	ckage Description BAG; Type 0: Not a Combination ion tion Number or Monograph Citation , methionine, isoleucine, va ine, serine, tyrosine, dextro HUMAN PRESCRIPTION DRUG INTRAVENOUS Moiety ient Name UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E5C E - UNII:K3Z4F929H6) (METHIONINE - UNII:AE28F7PNPL)	ine, his se inje	Date (1997 arketing Start Date (9/1997 stidine, threonin ction Code (Source) Basis of Strength LEUCINE PHENYLALANINE LYSINE METHIONINE	Marketing End Date Marketing End Date e, tryptophan, NDC:0338-1137 Strength 365 mg in 100 r 280 mg in 100 r 290 mg in 100 r

	3711227) (ALA	NINE - UNII:OF5P57N2ZX)	AL	ANINE	1035 mg in 100 mL
SLYCINE (UNII: TE76	560XO1C) (GLY	CINE - UNII:TE7660XO1C)	G	LYCINE	515 mg in 100 mL
ARGININE (UNII: 94Z	LA3W45F) (AR	GININE - UNII:94ZLA3W45F)	AF	RGININE	575 mg in 100 mL
PROLINE (UNII: 9DLC	Q4CIU6V) (PRO	LINE - UNII:9DLQ4CIU6V)	PF	ROLINE	340 mg in 100 mL
SERINE (UNII: 452VL	Y9402) (SERIN	E - UNII:452VLY9402)	SI	ERINE	250 mg in 100 mL
YROSINE (UNII: 421	HK56048U) (TY	ROSINE - UNII:42HK56048U)	T	ROSINE	20 mg in 100 mL
DEXTROSE (UNII: IY JNII:5SL0G7R0OK)	9XDZ 35W2) (Al	NHYDROUS DEXTROSE -	D	EXTROSE	15 g in 100 mL
nactive Ingree		ngredient Name			Strength
ACETIC ACID (UNII:					Strength
VATER (UNII: 059QF	OKOOR)				
Packaging					
# Item Code	Pa	ckage Description	Mark	eting Start Date	Marketing End Date
	1000 mL in 1 I Product	BAG; Type 0: Not a Combination	09/29/19	997	
Marketing I				duality of	Mart
Marketing Category		tion Number or Monograph Citation		Date	Marketing End Date
NDA	NDA020734		09/29/	1997	
Product Type Route of Adminis	stration	HUMAN PRESCRIPTION DRUG	item C	ode (Source)	NDC:0338-1099
Active Ingredie	ent/Active	Moiety			
	Ingred	ient Name		Basis of	
				Strength	Strength
EUCINE (UNII: GMW	/67QNF9C) (LE	UCINE - UNII:GMW67QNF9C)	LE		
				Strength UCINE	365 mg in 100 mL
HENYLALANINE (U	NII: 47E5O17Y	UCINE - UNII:GMW67QNF9C)	17Y3R) PH	Strength UCINE	365 mg in 100 ml 280 mg in 100 ml
HENYLALANINE (U YSINE (UNII: K3Z4F	NII: 47E5O17Y 929H6) (LYSIN	ucine - Unii:gmw67qnf9c) '3r) (phenylalanine - Unii:47e50	17Y3R) PH	Strength UCINE HENYLALANINE	365 mg in 100 ml 280 mg in 100 ml 290 mg in 100 ml
HENYLALANINE (U YSINE (UNII: K3Z4F IETHIONINE (UNII:	INII: 47E5O17Y 929H6) (LYSIN AE28F7PNPL) (UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E5O E - UNII:K3Z4F929H6)	17Y3R) PH LY M	Strength UCINE HENYLALANINE SINE	365 mg in 100 ml 280 mg in 100 ml 290 mg in 100 ml 200 mg in 100 ml
YHENYLALANINE (U YSINE (UNII: K3Z4F METHIONINE (UNII: SOLEUCINE (UNII: (YALINE (UNII: HG18E	INII: 47E5O17Y 929H6) (LYSIN AE28F7PNPL) (04Y7590D77) (89YRS7) (VALIN	UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E5O E - UNII:X3Z4F929H6) METHIONINE - UNII:AE28F7PNPL) ISOLEUCINE - UNII:04Y7590D77) IE - UNII:HG18B9YRS7)	17Y3R) PH LY Mi IS	Strength UCINE HENYLALANINE SINE ETHIONINE	365 mg in 100 ml 280 mg in 100 ml 290 mg in 100 ml 200 mg in 100 ml 300 mg in 100 ml
HENYLALANINE (U YSINE (UNII: K3Z4F METHIONINE (UNII: SOLEUCINE (UNII: (YALINE (UNII: HG18E MISTIDINE (UNII: 4Q	NII: 47E5O17Y 929H6) (LYSIN AE28F7PNPL) (04Y7590D77) (39YRS7) (VALIN D397987E) (HI	UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E5O E - UNII:X3Z4F929H6) (METHIONINE - UNII:AE28F7PNPL) ISOLEUCINE - UNII:04Y7590D77) IE - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E)	17Y3R) PH LY MI IS V/	Strength EUCINE HENYLALANINE 'SINE ETHIONINE OLEUCINE	365 mg in 100 ml 280 mg in 100 ml 290 mg in 100 ml 200 mg in 100 ml 300 mg in 100 ml 290 mg in 100 ml
PHENYLALANINE (U YSINE (UNII: K3Z 4F METHIONINE (UNII: SOLEUCINE (UNII: 6 MALINE (UNII: HG18E MISTIDINE (UNII: 4Q "HREONINE (UNII: 2	NII: 47E5O17Y 929H6) (LYSIN AE28F7PNPL) (04Y7590D77) (39YRS7) (VALIN D397987E) (HI ZD004190S) (UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E5O E - UNII:X3Z4F929H6) (METHIONINE - UNII:AE28F7PNPL) ISOLEUCINE - UNII:04Y7590D77) IE - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD004190S)	17Y3R) PH LY MI IS V/ HI TH	Strength EUCINE HENYLALANINE 'SINE ETHIONINE OLEUCINE ALINE STIDINE HREONINE	365 mg in 100 ml 280 mg in 100 ml 290 mg in 100 ml 200 mg in 100 ml 300 mg in 100 ml 290 mg in 100 ml 240 mg in 100 ml 210 mg in 100 ml
HENYLALANINE (U YSINE (UNII: K3Z 4F METHIONINE (UNII: SOLEUCINE (UNII: 6 MLINE (UNII: HG18E MISTIDINE (UNII: 4Q HREONINE (UNII: 2	NII: 47E5O17Y 929H6) (LYSIN AE28F7PNPL) (04Y7590D77) (39YRS7) (VALIN D397987E) (HI ZD004190S) (UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E5O E - UNII:X3Z4F929H6) (METHIONINE - UNII:AE28F7PNPL) ISOLEUCINE - UNII:04Y7590D77) IE - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E)	17Y3R) PH LY MI IS V/ HI TH	Strength EUCINE HENYLALANINE SINE ETHIONINE OLEUCINE ALINE STIDINE	365 mg in 100 ml 280 mg in 100 ml 290 mg in 100 ml 200 mg in 100 ml 300 mg in 100 ml 290 mg in 100 ml 240 mg in 100 ml 210 mg in 100 mL
YHENYLALANINE (U YSINE (UNII: K324F METHIONINE (UNII: SOLEUCINE (UNII: G MLINE (UNII: HG18E HISTIDINE (UNII: 4Q HREONINE (UNII: 2 RYPTOPHAN (UNII:	NII: 47E5O17Y 929H6) (LYSIN AE28F7PNPL) (04Y7590D77) (39YRS 7) (VALIN D397987E) (HI Z D004190S) (8DUH1N11BX	UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E5O E - UNII:X3Z4F929H6) (METHIONINE - UNII:AE28F7PNPL) ISOLEUCINE - UNII:04Y7590D77) IE - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD004190S)	17Y3R) PH LY MI IS V/ V/ HI TH X) TF	Strength EUCINE HENYLALANINE 'SINE ETHIONINE OLEUCINE ALINE STIDINE HREONINE	365 mg in 100 ml 280 mg in 100 ml 290 mg in 100 ml 200 mg in 100 ml 300 mg in 100 ml 290 mg in 100 ml 240 mg in 100 ml 210 mg in 100 ml
HENYLALANINE (U YSINE (UNII: K324F METHIONINE (UNII: SOLEUCINE (UNII: GOLEUCINE (UNII: H618E IIISTIDINE (UNII: 4Q HREONINE (UNII: 2 RYPTOPHAN (UNII: LLANINE (UNII: 055F	NII: 47E5017Y 929H6) (LYSIN AE28F7PNPL) (04Y7590D77) (39YRS7) (VALIN D397987E) (HI Z D0041905) (8DUH1N11BX 257N2ZX) (ALA	UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E5O E - UNII:X3Z4F929H6) METHIONINE - UNII:AE28F7PNPL) ISOLEUCINE - UNII:04Y7590D77) IE - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD004190S)) (TRYPTOPHAN - UNII:8DUH1N11B	17Y3R) PH LY MI IS IS V/ HI TF X) TF AL	Strength UCINE HENYLALANINE TSINE ETHIONINE OLEUCINE ALINE STIDINE HREONINE RYPTOPHAN	365 mg in 100 ml 280 mg in 100 ml 290 mg in 100 ml 200 mg in 100 ml 300 mg in 100 ml 290 mg in 100 ml 240 mg in 100 ml 90 mg in 100 mL 1035 mg in 100 mL
YHENYLALANINE (U YSINE (UNII: K324F METHIONINE (UNII: SOLEUCINE (UNII: G MLINE (UNII: H618F MISTIDINE (UNII: 4Q "HREONINE (UNII: 2 "RYPTOPHAN (UNII: ALANINE (UNII: 075F SLYCINE (UNII: TE76	NII: 47E5017Y 929H6) (LYSIN AE28F7PNPL) (04Y7590D77) (93YRS7) (VALIN D397987E) (HI Z D004190S) (8DUH1N11BX p57N2ZX) (ALA 560X01C) (GLY	UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E5O E - UNII:K324F929H6) METHIONINE - UNII:AE28F7PNPL) ISOLEUCINE - UNII:04Y7590D77) IE - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD004190S)) (TRYPTOPHAN - UNII:8DUH1N11B NINE - UNII:0F5P57N2ZX)	17Y3R) PH LY MI IS V/ HI TH X) TH X) AL	Strength UCINE UCINE ETHIONINE ETHIONINE OLEUCINE OLEUCINE STIDINE REPONINE RYPTOPHAN ANINE	365 mg in 100 ml 280 mg in 100 ml 290 mg in 100 ml 200 mg in 100 ml 300 mg in 100 ml 290 mg in 100 ml 240 mg in 100 ml 210 mg in 100 mL 1035 mg in 100 mL 515 mg in 100 ml
YHENYLALANINE (U YSINE (UNII: K324F METHIONINE (UNII: SOLEUCINE (UNII: G MILINE (UNII: HG18E MISTIDINE (UNII: 4Q "HREONINE (UNII: 2 "RYPTOPHAN (UNII: ALANINE (UNII: 0F5F SLYCINE (UNII: 1942 RGININE (UNII: 942	NII: 47E5017Y 929H6) (LYSIN AE28F7PNPL) (04Y7590D77) (39YRS7) (VALIN D397987E) (HI Z D004190S) (8DUH1N11BX p57N2ZX) (ALA 560X01C) (GLY :LA3W45F) (AR4	UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E5O E - UNII:K324F929H6) METHIONINE - UNII:A228F7PNPL) ISOLEUCINE - UNII:04Y7590D77) IE - UNII:HG18B9YRS7) STIDINE - UNII:2D037987E) THREONINE - UNII:2ZD004190S)) (TRYPTOPHAN - UNII:8DUH1N11B NINE - UNII:0F5P57N2ZX) 'CINE - UNII:TE7660X01C)	17Y3R) PH 17 17 17 17 17 17 17 17 17 17	Strength UCINE ENYLALANINE ETHIONINE OLEUCINE ALINE STIDINE RECONINE RYPTOPHAN ANINE LYCINE	365 mg in 100 ml 280 mg in 100 ml 290 mg in 100 ml 200 mg in 100 ml 200 mg in 100 ml 290 mg in 100 ml 240 mg in 100 ml 210 mg in 100 mL 1035 mg in 100 mL 515 mg in 100 ml
PHENYLALANINE (U YSINE (UNII: K3Z4F METHIONINE (UNII: SOLEUCINE (UNII: C MALINE (UNII: H018E IISTIDINE (UNII: 4Q HREONINE (UNII: 4Q HREONINE (UNII: 5F5F SLYCINE (UNII: 5F5F SLYCINE (UNII: 5F2F REGININE (UNII: 9427 PROLINE (UNII: 9427	NII: 47E5017Y 929H6) (LYSIN AE28F7PNPL) (94Y7590D77) (89YRS7) (VALIN 2D041905) (8DUH1N11BX P57N2Z X) (ALA 560X01C) (GLY (LA3W45F) (ARR Q4CIU6V) (PRO	UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E5O E - UNII:X3Z4F929H6) (METHIONINE - UNII:AE28F7PNPL) ISOLEUCINE - UNII:04Y7590D77) IE - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD004190S)) (TRYPTOPHAN - UNII:8DUH1N11B NINE - UNII:0F5P57N2ZX) (CINE - UNII:TE7660X01C) GININE - UNII:9ZLA3W45F)	17Y3R) PH LY M IS IS V/ H H T T X) T F X) T F AL G I AF	Strength UCINE ENYLALANINE ETHIONINE CHIONINE OLEUCINE ALINE STIDINE HREONINE ANINE LYCINE RGININE	365 mg in 100 ml 280 mg in 100 ml 290 mg in 100 ml 200 mg in 100 ml 300 mg in 100 ml 290 mg in 100 ml 240 mg in 100 ml 210 mg in 100 mL 1035 mg in 100 mL 515 mg in 100 ml 575 mg in 100 ml
YHENYLALANINE (U YSINE (UNII: K3Z4F METHIONINE (UNII: SOLEUCINE (UNII: G IISTIDINE (UNII: HG18E IISTIDINE (UNII: 4011: 42 RYPTOPHAN (UNII: 47 RYPTOPHAN (UNII: 452VL YROSINE (UNII: 421	NII: 47E5017Y 929H6) (LYSIN AE28F7PNPL) (39YR57) (VALIN D397987E) (HI ZD0041905) (8DUH1N11BX 557NZZ X) (ALA 560X01C) (GLY (LA3W45F) (ARI 24CIU6V) (PRO Y9402) (SERIN HK56048U) (TY	UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E50 E - UNII:K3Z4F929H6) (METHIONINE - UNII:A228F7PNPL) ISOLEUCINE - UNII:A228F7PNPL) ISOLEUCINE - UNII:A20397987E) TIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD004190S)) (TRYPTOPHAN - UNII:8DUH1N11B NINE - UNII:0F5P57NZZX) (CINE - UNII:7F7660X01C) GININE - UNII:94ZLA3W45F) LINE - UNII:94ZLA3W45F) LINE - UNII:94ZVLY9402) (ROSINE - UNII:42HK56048U)	17Y3R) PH LY M IS IS V/ H H T T X) T F X) T F A A A A S S S	Strength EUCINE ETHIONINE ETHIONINE ETHIONINE OLEUCINE ALINE STIDINE ETIDINE AREONINE ANINE LYCINE REGININE ROLINE	365 mg in 100 ml 280 mg in 100 ml 290 mg in 100 ml 200 mg in 100 ml 300 mg in 100 ml 290 mg in 100 ml 240 mg in 100 ml 210 mg in 100 mL 1035 mg in 100 mL 515 mg in 100 ml 575 mg in 100 ml
HENYLALANINE (U YSINE (UNII: K324F METHIONINE (UNII: SOLEUCINE (UNII: G ALINE (UNII: HG1BE IIISTIDINE (UNII: 4Q "RECONINE (UNII: 4Q "RECONINE (UNII: 505F SLYCINE (UNII: 505F SLYCINE (UNII: 504Z "ROLINE (UNII: 94Z "ROLINE (UNII: 942Z "ROLINE (UNII: 422VL "YROSINE (UNII: 422VL "YROSINE (UNII: 421)	NII: 47E5017Y 929H6) (LYSIN AE28F7PNPL) (39YR57) (VALIN D397987E) (HI ZD0041905) (8DUH1N11BX 557NZZ X) (ALA 560X01C) (GLY (LA3W45F) (ARI 24CIU6V) (PRO Y9402) (SERIN HK56048U) (TY	UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E50 E - UNII:K3Z4F929H6) (METHIONINE - UNII:A228F7PNPL) ISOLEUCINE - UNII:A228F7PNPL) ISOLEUCINE - UNII:A20397987E) THIENOINE - UNII:2ZD004190S)) (TRYPTOPHAN - UNII:SDUH1N11B NINE - UNII:0F5P57N2ZX) 'CINE - UNII:7F7660X01C) GININE - UNII:9DLQ4CIU6V) E - UNII:452VLY9402)	17Y3R) PH LY MI IS V/ HI TH X) TF AL GI GI AF SI SI	Strength EUCINE ETHIONINE ETHIONINE ETHIONINE STIDINE STIDINE EREONINE ANINE ANINE CUCINE REGININE CUCINE COLINE ERINE	365 mg in 100 ml 280 mg in 100 ml 290 mg in 100 ml 200 mg in 100 ml 300 mg in 100 ml 290 mg in 100 ml 240 mg in 100 ml 210 mg in 100 mL 1035 mg in 100 mL 515 mg in 100 ml 340 mg in 100 ml 250 mg in 100 ml
PHENYLALANINE (U YSINE (UNII: K3Z4F METHIONINE (UNII: SOLEUCINE (UNII: 5 ALLINE (UNII: 40 HISTIDINE (UNII: 40 HIREONINE (UNII: 20 FRYPTOPHAN (UNII: 20 ALLININE (UNII: 1976 SLYCINE (UNII: 1977 SERINE (UNII: 422VL YROSINE (UNII: 422VL YROSINE (UNII: 422VL YROSINE (UNII: 421) DEXTROSE (UNII: 1917) NIII: SSLOG7ROOK)	NII: 47E5017Y 929H6) (LYSIN AE28F7PNPL) (04Y7590D77) (89YRS7) (VALIN 2D0397987E) (HI Z D0041905) (8DUH1N11BX P57N2Z X) (ALA 560X01C) (GLY LA3W45F) (ARI Q4CIU6V) (PRO Y9402) (SERIN HK56048U) (TY 9XDZ 35W2) (AI	UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E50 E - UNII:K3Z4F929H6) (METHIONINE - UNII:A228F7PNPL) ISOLEUCINE - UNII:A228F7PNPL) ISOLEUCINE - UNII:A20397987E) TIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD004190S)) (TRYPTOPHAN - UNII:8DUH1N11B NINE - UNII:0F5P57NZZX) (CINE - UNII:7F7660X01C) GININE - UNII:94ZLA3W45F) LINE - UNII:94ZLA3W45F) LINE - UNII:94ZVLY9402) (ROSINE - UNII:42HK56048U)	17Y3R) PH LY MI IS V/ HI TH X) TF AL GI AL SI SI	Strength UCINE EVILALANINE ETHIONINE ETHIONINE STIDINE STIDINE AREONINE ANINE ANINE CLYCINE ROLINE ROLINE ROLINE ROLINE ROLINE ROLINE ROLINE ROLINE	365 mg in 100 mL 280 mg in 100 mL 290 mg in 100 mL 200 mg in 100 mL 200 mg in 100 mL 200 mg in 100 mL 200 mg in 100 mL 90 mg in 100 mL 1035 mg in 100 mL 515 mg in 100 mL 340 mg in 100 mL 250 mg in 100 mL
PHENYLALANINE (U YSINE (UNII: K3Z4F METHIONINE (UNII: SOLEUCINE (UNII: GUNII: 5 ALLINE (UNII: 401 HISTIDINE (UNII: 401 TRYPTOPHAN (UNII: 401 ALANINE (UNII: 675F SLYCINE (UNII: 675F SLYCINE (UNII: 675F SLYCINE (UNII: 41 PROLINE (UNII: 942 PROLINE (UNII: 942 PROLINE (UNII: 942 PROLINE (UNII: 452VL "YROSINE (UNII: 421 DEXTROSE (UNII: 141 MINI: SSLOG7ROOK)	NII: 47E5017Y 929H6) (LYSIN AE28F7PNPL) (04Y7590D77) (89YRS7) (VALIM 2 D004190S) (8DUH1N11BX P57N2Z X) (ALA 560X01C) (GLY (LA3W45F) (ARR 04ClU6V) (PRO Y9402) (SERIN HK56048U) (TY 9XDZ 35W2) (AI	UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E50 E - UNII:K3Z4F929H6) (METHIONINE - UNII:A228F7PNPL) ISOLEUCINE - UNII:A228F7PNPL) ISOLEUCINE - UNII:A20397987E) TIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD004190S)) (TRYPTOPHAN - UNII:8DUH1N11B NINE - UNII:0F5P57NZZX) (CINE - UNII:7F7660X01C) GININE - UNII:94ZLA3W45F) LINE - UNII:94ZLA3W45F) LINE - UNII:94ZVLY9402) (ROSINE - UNII:42HK56048U)	17Y3R) PH LY MI IS V/ HI TH X) TF AL GI AL SI SI	Strength UCINE EVILALANINE ETHIONINE ETHIONINE STIDINE STIDINE AREONINE ANINE ANINE CLYCINE ROLINE ROLINE ROLINE ROLINE ROLINE ROLINE ROLINE ROLINE	365 mg in 100 ml 280 mg in 100 ml 290 mg in 100 ml 200 mg in 100 ml 300 mg in 100 ml 240 mg in 100 ml 240 mg in 100 ml 210 mg in 100 mL 1035 mg in 100 mL 515 mg in 100 ml 340 mg in 100 ml 250 mg in 100 ml
HENYLALANINE (U YSINE (UNII: K3Z4F METHIONINE (UNII: SOLEUCINE (UNII: G MILLINE (UNII: G18E IISTIDINE (UNII: G	NII: 47E5017Y 929H6) (LYSIN AE28F7PNPL) (44Y7590D77) (939YR57) (VALIN D397987E) (HI ZD0041905) (8DUH1N1BX 257N2Z X) (ALA 560X01C) (GLY LA3W45F) (ARd 42CIU6V) (PRO Y9402) (SERIN HK56048U) (TY 9XDZ 35W2) (AI Clients Ir Q40Q9N063P)	UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E50 E - UNII:K3Z4F929H6) (METHIONINE - UNII:A228F7PNPL) ISOLEUCINE - UNII:A228F7PNPL) ISOLEUCINE - UNII:A20397987E) THREONINE - UNII:2D004190S)) (TRYPTOPHAN - UNII:8DUH1N11B NINE - UNII:0F5P57NZZX) (CINE - UNII:94ZLA3W45F) LINE - UN	17Y3R) PH LY MI IS V/ HI TH X) TF AL GI AL SI SI	Strength UCINE EVILALANINE ETHIONINE ETHIONINE STIDINE STIDINE AREONINE ANINE ANINE CLYCINE ROLINE ROLINE ROLINE ROLINE ROLINE ROLINE ROLINE ROLINE	365 mg in 100 mL 280 mg in 100 mL 290 mg in 100 mL 200 mg in 100 mL 200 mg in 100 mL 290 mg in 100 mL 240 mg in 100 mL 1035 mg in 100 mL 515 mg in 100 mL 340 mg in 100 mL 250 mg in 100 mL 250 mg in 100 mL 20 mg in 100 mL
HENYLALANINE (U YSINE (UNII: K3Z4F METHIONINE (UNII: SOLEUCINE (UNII: G MILLINE (UNII: HG18E IISTIDINE (UNII: HG18E IISTIDINE (UNII: HG18E IISTIDINE (UNII: OF5F SILYCINE (UNII: OF5F SILYCINE (UNII: OF5F REGININE (UNII: OF5F REGININE (UNII: 92L REGININE (UNII: 92L REGININE (UNII: 92L REGININE (UNII: 42L VEXTROSE (UNII: 42L VE	NII: 47E5017Y 929H6) (LYSIN AE28F7PNPL) (14Y7590D77) (39YR57) (VALIN D397987E) (HI D397987E) (HI 2D0041905) (8DUH1N11BX 957N2Z X) (ALA 560X01C) (GLY 14X3445F) (ARG 44CUG6V) (PRO Y9402) (SERIN HK56048U) (TY 9XDZ 35W2) (AI CHIENTS I Q40Q9N063P) 50K00R)	UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E50 E - UNII:K3Z4F929H6) (METHIONINE - UNII:A228F7PNPL) ISOLEUCINE - UNII:A228F7PNPL) ISOLEUCINE - UNII:A20397987E) THREONINE - UNII:2D004190S)) (TRYPTOPHAN - UNII:8DUH1N11B NINE - UNII:0F5P57NZZX) (CINE - UNII:94ZLA3W45F) LINE - UN	17Y3R) PH LY MI IS V/ HI TH X) TF AL GI AL SI SI	Strength UCINE EVILALANINE ETHIONINE ETHIONINE STIDINE STIDINE AREONINE ANINE ANINE CLYCINE ROLINE ROLINE ROLINE ROLINE ROLINE ROLINE ROLINE ROLINE	365 mg in 100 ml 280 mg in 100 ml 290 mg in 100 ml 200 mg in 100 ml 200 mg in 100 ml 290 mg in 100 ml 240 mg in 100 ml 1035 mg in 100 mL 515 mg in 100 ml 340 mg in 100 ml 250 mg in 100 ml 250 mg in 100 ml 250 mg in 100 ml
PHENYLALANINE (U YSINE (UNII: K3Z4F METHIONINE (UNII: SOLEUCINE (UNII: SOLEUCINE (UNII: 40 INIE (UNII: 40] INIE (UNII: 40] INIE (UNII: 40] INIE (UNII: 40] INIE (UNII: 40] INIE (UNII: 40] INIE (UNII: 41) INIE (UNII: 42] INIE (UNIE (UNII: 42] INIE (UNIE (UNII: 42] INIE (UNIE (UNII: 42] INIE (UNIE (UNIE (UNIE 42] INIE (UNIE 42] INIE (UNIE (UNIE 42] INIE (UNIE 42] INIE (UNIE (UNIE 42] INIE	NII: 47E5017Y 929H6) (LYSIN AE28F7PNPL) (14Y7590D77) (39YR57) (VALIN D397987E) (HI D397987E) (HI 2D0041905) (8DUH1N11BX 957N2Z X) (ALA 560X01C) (GLY 14X3445F) (ARG 44CUG6V) (PRO Y9402) (SERIN HK56048U) (TY 9XDZ 35W2) (AI CHIENTS I Q40Q9N063P) 50K00R)	UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E50 E - UNII:K3Z4F929H6) (METHIONINE - UNII:A228F7PNPL) ISOLEUCINE - UNII:A228F7PNPL) ISOLEUCINE - UNII:A20397987E) THREONINE - UNII:2D004190S)) (TRYPTOPHAN - UNII:8DUH1N11B NINE - UNII:0F5P57NZZX) (CINE - UNII:94ZLA3W45F) LINE - UN	17Y3R) PH LY MI IS V/ HI TH X) TF AL GI AL SI SI	Strength UCINE EVILALANINE ETHIONINE ETHIONINE STIDINE STIDINE AREONINE ANINE ANINE CLYCINE ROLINE ROLINE ROLINE ROLINE ROLINE ROLINE ROLINE ROLINE	365 mg in 100 mL 280 mg in 100 mL 290 mg in 100 mL 200 mg in 100 mL 200 mg in 100 mL 290 mg in 100 mL 240 mg in 100 mL 1035 mg in 100 mL 515 mg in 100 mL 340 mg in 100 mL 250 mg in 100 mL 250 mg in 100 mL 20 mg in 100 mL
PHENYLALANINE (U YSINE (UNII: K3Z4F METHIONINE (UNII: SOLEUCINE (UNII: G ALINE (UNII: 4Q HISTIDINE (UNII: 4Q HISTIDINE (UNII: 4Q TRYPTOPHAN (UNII: 42 TRYPTOPHAN (UNII: 42 SERINE (UNII: 9DLC SERINE (UNII: 422 SERINE (UNII: 422 SER	NII: 47E5017Y 929H6) (LYSIN AE28F7PNPL) (04Y7590D77) (39YRS7) (VALIN D397987E) (HI 2D0041905) (8DUH1N11BX P57N2Z X) (ALA 560X01C) (GLY LA3V45F) (ARA 04CUG6V) (PRO Y9402) (SERIN HK56048U) (TY 9XDZ 35W2) (AI Clients Ir Q40Q9N063P) 0KO0R) 162921K75)	UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E50 E - UNII:K3Z4F929H6) (METHIONINE - UNII:AE28F7PNPL) ISOLEUCINE - UNII:AE28F7PNPL) ISOLEUCINE - UNII:AE28F7PNPL) TISOLEUCINE - UNII:220041905) THREONINE - UNII:22D041905) (TRYPTOPHAN - UNII:8DUH1N11B NINE - UNII:0F5P57NZZX) (CINE - UNII:94ZLA3W45F) LINE	17Y3R) PH LY MI IS V/ HI TH X) TH AL GI GI SI TN DI	Strength UCINE UCI	365 mg in 100 mL 280 mg in 100 mL 290 mg in 100 mL 200 mg in 100 mL 200 mg in 100 mL 290 mg in 100 mL 290 mg in 100 mL 200 mg in 100 mL 210 mg in 100 mL 1035 mg in 100 mL 1035 mg in 100 mL 515 mg in 100 mL 340 mg in 100 mL 250 mg in 100 mL 20 mg in 100 mL 15 g in 100 mL 15 g in 100 mL Strength
PHENYLALANINE (U YSINE (UNII: K3Z 4F METHIONINE (UNII: SOLEUCINE (UNII: G) ALLINE (UNII: G) ALLINE (UNII: G) METHIODINE (UNII: G) ALLINE (UNII: G) A	NII: 47E5017Y 929H6) (LYSIN AE28F7PNPL) (44Y7590D77) (939YR57) (VALIN D397987E) (HI 2D0041905) (8DUH1N1BX P57N2Z X) (ALA 560X01C) (GLY 1.LA3W45F) (ARA 24CIU6V) (PRO Y9402) (SERIN HK56048U) (TY 9XDZ 35W2) (AI Clients I Q40Q9N063P) 0K00R) 62921K75) Pa 2000 mL in 1	UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E50 E - UNII:K3Z4F929H6) (METHIONINE - UNII:A228F7PNPL) ISOLEUCINE - UNII:A228F7PNPL) ISOLEUCINE - UNII:A20397987E) THREONINE - UNII:2D004190S)) (TRYPTOPHAN - UNII:8DUH1N11B NINE - UNII:0F5P57NZZX) (CINE - UNII:94ZLA3W45F) LINE - UN	17Y3R) PH LY MI IS V/ HI TH X) TH AL GI GI SI TN DI	Strength UCINE UCI	365 mg in 100 mL 280 mg in 100 mL 290 mg in 100 mL 200 mg in 100 mL 200 mg in 100 mL 200 mg in 100 mL 240 mg in 100 mL 210 mg in 100 mL 1035 mg in 100 mL 515 mg in 100 mL 575 mg in 100 mL 250 mg in 100 mL 250 mg in 100 mL 250 mg in 100 mL 250 mg in 100 mL
PHENYLALANINE (U YSINE (UNII: K3Z 4F METHIONINE (UNII: SOLEUCINE (UNII: G) ALLINE (UNII: G) ALLINE (UNII: G) METHIODINE (UNII: G) ALLINE (UNII: G) A	NII: 47E5017Y 929H6) (LYSIN AE28F7PNPL) (04Y7590D77) (89YRS7) (VALIM 2D041905) (8DUH1N11BX 050X01C) (GLY 2LA3W45F) (AR 04CUG6V) (PRO Y9402) (SERIN HK56048U) (TY 9XDZ35W2) (AI Clients I Q40Q9N063P) 50K00R) 62921K75)	UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E50 E - UNII:K3Z 4F929H6) (METHIONINE - UNII:A228F7PNPL) ISOLEUCINE - UNII:A228F7PNPL) STIDINE - UNII:40D397987E) THREONINE - UNII:2Z D004190S)) (TRYPTOPHAN - UNII:2Z D004190S)) (TRYPTOPHAN - UNII:2Z D004190S)) (TRYPTOPHAN - UNII:8DUH1N11B NINE - UNII:0F5P57N2Z X) (CINE - UNII:7F7660X01C) GININE - UNII:9DLQ4CIU6V) E - UNII:452VLY9402) (ROSINE - UNII:42HX56048U) VHYDROUS DEXTROSE - NGRENENNENNENNENNENNENNENNENNENNENNENNENNE	17Y3R) PH LY MI IS V/ HI TH X) TF AL GI AF PF SI DI DI Mark	Strength UCINE UCI	365 mg in 100 mL 280 mg in 100 mL 290 mg in 100 mL 200 mg in 100 mL 200 mg in 100 mL 290 mg in 100 mL 290 mg in 100 mL 200 mg in 100 mL 210 mg in 100 mL 1035 mg in 100 mL 1035 mg in 100 mL 515 mg in 100 mL 340 mg in 100 mL 250 mg in 100 mL 20 mg in 100 mL 15 g in 100 mL 15 g in 100 mL Strength
PHENYLALANINE (U YSINE (UNII: K324F AETHIONINE (UNII: SOLEUCINE (UNII: SOLEUCINE (UNII: 504F AISTIDINE (UNII: 4018E AISTIDINE (UNII: 4018E AISTIDINE (UNII: 4075F SLYCINE (UNII: 942 PROLINE (UNII: 942 PROLINE (UNII: 942 PROLINE (UNII: 950C ARGININE (UNII: 950C ARGININE (UNII: 950C ARGININE (UNII: 950C ARGININE (UNII: 452UC PROSINE (UNII: 452UC AISTICE ACID (UNII: 422UC AISTICE ACID (UNII: 422UC AISTICE ACID (UNII: 472UC AISTICE ACID (UNII: 472UC AISTICE ACID (UNII: 472UC AISTICE ACID (UNII: 472UC AISTICE ACID (UNII: 177 PACKAGING # Item Code NDC:0338-1099- 04	NII: 47E5017Y 929H6) (LYSIN AE28F7PNPL) (39YR57) (VALIN 39YR57) (VALIN 20041905) (8DUH1N11BX 257N2Z X) (ALA 560X01C) (GLY 2LA3W45F) (ARG 24CIU6V) (PRO 24CIU6V) (PRO 24CIU6V	UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E50 E - UNII:K3Z4F929H6) IMETHIONINE - UNII:AE28F7PNPL) ISOLEUCINE - UNII:04Y7590D77) IE - UNII:HG18B9YRS7) STIDIRE - UNII:22D004190S)) (TRYPTOPHAN - UNII:8DUH1N11B NINE - UNII:0F5P57N2ZX) ICINE - UNII:97560X01C) GININE - UNII:94ZLA3W45F) LINE - UNII:94ZLA3W45F) LINE - UNII:94ZLA3W45F) LINE - UNII:94ZLA3W45F) ILNE - UNII:94ZLA3W45F) COSINE - UNII:94ZLA3W45F) ILNE - UNII:94ZLA3W45F) GOSINE - UNII:94ZLA3W45F) COSINE - UNII:94ZLA3W45F) COSINE - UNII:94ZLA3W45F) SAGSI - UNII:94ZLA3W45F) COSINE - UNII:94ZLA3W5F) COSINE	17Y3R) PH LY MI IS V/ HI TH X) TF AL GI AF PF SI DI DI Mark	Strength UCINE UCI	365 mg in 100 mL 280 mg in 100 mL 290 mg in 100 mL 200 mg in 100 mL 300 mg in 100 mL 290 mg in 100 mL 200 mg in 100 mL 210 mg in 100 mL 210 mg in 100 mL 1035 mg in 100 mL 515 mg in 100 mL 575 mg in 100 mL 200 mg in 100 mL 15 g in 100 mL 55 mg in 100 mL 55 mg in 100 mL 56 mg in 100 mL 57 mg in 100 mL 58 rength
PHENYLALANINE (U YSINE (UNII: K3Z 4F METHIONINE (UNII: SOLEUCINE (UNII: G) ALLINE (UNII: G) ALLINE (UNII: G) METHIODINE (UNII: G) ALLINE (UNII: G) A	NII: 47E5017Y 929H6) (LYSIN AE28F7PNPL) (J4Y7590D77) (39YRS7) (VALIN D397987E) (HI 2D0041905) (8DUH1N1BX P57N2Z X) (ALA 560X01C) (GLY LA3W45F) (ARA 24CIU6V) (PRO Y9402) (SERIN HK56048U) (TY 9XDZ 35W2) (AI Glients Ir Q40Q9N063P) 0K00R) 62921K75) Pa 2000 mL in 1 I Product	UCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E50 E - UNII:K3Z4F929H6) IMETHIONINE - UNII:AE28F7PNPL) ISOLEUCINE - UNII:04Y7590D77) IE - UNII:HG18B9YRS7) STIDIRE - UNII:22D004190S)) (TRYPTOPHAN - UNII:8DUH1N11B NINE - UNII:0F5P57N2ZX) ICINE - UNII:97560X01C) GININE - UNII:94ZLA3W45F) LINE - UNII:94ZLA3W45F) LINE - UNII:94ZLA3W45F) LINE - UNII:94ZLA3W45F) ILNE - UNII:94ZLA3W45F) COSINE - UNII:94ZLA3W45F) ILNE - UNII:94ZLA3W45F) GOSINE - UNII:94ZLA3W45F) COSINE - UNII:94ZLA3W45F) COSINE - UNII:94ZLA3W45F) SAGSI - UNII:94ZLA3W45F) COSINE - UNII:94ZLA3W5F) COSINE	17Y3R) PH LY M IS V/ HI TT X) TF AL GI SI SI TT DI 09/29/15	Strength UCINE UCI	365 mg in 100 mL 280 mg in 100 mL 290 mg in 100 mL 200 mg in 100 mL 300 mg in 100 mL 290 mg in 100 mL 200 mg in 100 mL 210 mg in 100 mL 210 mg in 100 mL 1035 mg in 100 mL 515 mg in 100 mL 575 mg in 100 mL 200 mg in 100 mL 15 g in 100 mL 55 mg in 100 mL 55 mg in 100 mL 56 mg in 100 mL 57 mg in 100 mL 58 rength

alanine, glycine, a	arginine, prol	ne, serine, tyrosine, dextros	e inje	ection		
Product Infor	mation					
Product Type	mation	HUMAN PRESCRIPTION DRUG	Iten	n Code (Sou	rce)	NDC:0338-1138
Route of Admini	stration	INTRAVENOUS	nen	li couc (sou	,	110010000 1100
Active Ingredi	ent/Active	Moiety				
	Ingred	ient Name		Basis (Streng		Strength
LEUCINE (UNII: GMV	N67QNF9C) (LEU	JCINE - UNII:GMW67QNF9C)		LEUCINE		365 mg in 100 m
PHENYLALANINE (U	JNII: 47E5017Y	BR) (PHENYLALANINE - UNII:47E5O)	L7Y3R)	PHENYLALANI	ΝE	280 mg in 100 m
LYSINE (UNII: K3Z4I	F929H6) (LYSIN	E - UNII:K3Z4F929H6)		LYSINE		290 mg in 100 m
METHIONINE (UNII:	AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL)		METHIONINE		200 mg in 100 m
ISOLEUCINE (UNII:	04Y7590D77) (I	SOLEUCINE - UNII:04Y7590D77)		ISOLEUCINE		300 mg in 100 m
VALINE (UNII: HG18	B9YRS7) (VALIN	E - UNII:HG18B9YRS7)		VALINE		290 mg in 100 m
HISTIDINE (UNII: 40	D397987E) (HI	STIDINE - UNII:4QD397987E)		HISTIDINE		240 mg in 100 m
THREONINE (UNII: 2	2ZD004190S)(THREONINE - UNII:2ZD004190S)		THREONINE		210 mg in 100 m
TRYPTOPHAN (UNII	: 8DUH1N11BX)	(TRYPTOPHAN - UNII:8DUH1N11B)	K)	TRYPTOPHAN		90 mg in 100 mL
ALANINE (UNII: OF5	P57N2ZX) (ALAI	NINE - UNII:OF5P57N2ZX)		ALANINE		1035 mg in 100 mL
GLYCINE (UNII: TE7	660XO1C) (GLY	CINE - UNII:TE7660XO1C)		GLYCINE		515 mg in 100 m
ARGININE (UNII: 942	ZLA3W45F) (ARC	GININE - UNII:94ZLA3W45F)		ARGININE		575 mg in 100 m
PROLINE (UNII: 9DL	Q4CIU6V) (PROI	LINE - UNII:9DLQ4CIU6V)		PROLINE		340 mg in 100 m
SERINE (UNII: 452VL	LY9402) (SERINI	E - UNII:452VLY9402)		SERINE		250 mg in 100 m
TYROSINE (UNII: 42	HK56048U) (TY	ROSINE - UNII:42HK56048U)		TYROSINE		20 mg in 100 mL
DEXTROSE (UNII: IY UNII:5SL0G7R0OK)	9XDZ 35W2) (AN	IHYDROUS DEXTROSE -		DEXTROSE		20 g in 100 mL
Inactive Ingre	dients					
	In	gredient Name				Strength
ACETIC ACID (UNII:	Q40Q9N063P)					
WATER (UNII: 059Q	F0KO0R)					
NITROGEN (UNII: N	762921K75)					
Packaging						
# Item Code	Pa	kage Description	Ma	rketing Sta Date	rt	Marketing End Date
1 NDC:0338-1138- 03	1000 mL in 1 E Product	AG; Type 0: Not a Combination	09/29	0/1997		
Marketing I	Informat	ion				

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
NDA	NDA020734	09/29/1997	

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	ltem Code (Source)	NDC:0338-1101
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEUCINE (UNII: GMW67QNF9C) (LEUCINE - UNII:GMW67QNF9C)	LEUCINE	365 mg in 100 mL
PHENYLALANINE (UNII: 47E5O17Y3R) (PHENYLALANINE - UNII:47E5O17Y3R)	PHENYLALANINE	280 mg in 100 mL
LYSINE (UNII: K3Z4F929H6) (LYSINE - UNII:K3Z4F929H6)	LYSINE	290 mg in 100 mL
METHIONINE (UNII: AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL)	METHIONINE	200 mg in 100 mL
ISOLEUCINE (UNII: 04Y7590D77) (ISOLEUCINE - UNII:04Y7590D77)	ISOLEUCINE	300 mg in 100 mL
VALINE (UNII: HG18B9YRS7) (VALINE - UNII:HG18B9YRS7)	VALINE	290 mg in 100 mL
HISTIDINE (UNII: 4QD397987E) (HISTIDINE - UNII:4QD397987E)	HISTIDINE	240 mg in 100 mL
THREONINE (UNII: 2ZD004190S) (THREONINE - UNII:2ZD004190S)	THREONINE	210 mg in 100 mL
TRYPTOPHAN (UNII: 8DUH1N11BX) (TRYPTOPHAN - UNII:8DUH1N11BX)	TRYPTOPHAN	90 mg in 100 mL
ALANINE (UNII: OF5P57N2ZX) (ALANINE - UNII:OF5P57N2ZX)	ALANINE	1035 mg in 100 mL
GLYCINE (UNII: TE7660XO1C) (GLYCINE - UNII:TE7660XO1C)	GLYCINE	515 mg in 100 mL
ARGININE (UNII: 94ZLA3W45F) (ARGININE - UNII:94ZLA3W45F)	ARGININE	575 mg in 100 mL
PROLINE (UNII: 9DLQ4CIU6V) (PROLINE - UNII:9DLQ4CIU6V)	PROLINE	340 mg in 100 mL

SE	ERINE (UNII: 452VLY	'9402) (SERINE - UNII:452VLY9402)	SERINE	250 mg in 100 mL
ТΥ	ROSINE (UNII: 42H	K56048U) (TYROSINE - UNII:42HK56048U)	TYROSINE	20 mg in 100 mL
	EXTROSE (UNII: IY9 NII:5SL0G7R0OK)	XDZ 35W2) (ANHYDROUS DEXTROSE -	DEXTROSE	20 g in 100 mL
In	nactive Ingred	lients		
		Ingredient Name		Strength
AC	CETIC ACID (UNII: C	Q40Q9N063P)		
w	ATER (UNII: 059QFC	DKOOR)		
ALC	ITROGEN (UNII: N76	52921K75)		
INI				
INI				
INI				
	ackaging			
		Package Description	Marketing Sta	art Marketing End Date
Pa	Item Code	Package Description 2000 mL in 1 BAG; Type 0: Not a Combination Product		
Pa #	Item Code	2000 mL in 1 BAG; Type 0: Not a Combination	Date	
Pa # 1	Item Code	2000 mL in 1 BAG; Type 0: Not a Combination roduct	Date	
Pa # 1	Item Code NDC:0338-1101- 2 04 P	2000 mL in 1 BAG; Type 0: Not a Combination roduct	Date	Date
Pa # 1	Item Code NDC:0338-1101- 2 04 Marketing Category	2000 mL in 1 BAG; Type 0: Not a Combination roduct	Date 09/29/1997 Marketing S	Date tart Marketing End

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:0338-0198
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEUCINE (UNII: GMW67QNF9C) (LEUCINE - UNII:GMW67QNF9C)	LEUCINE	438 mg in 100 mL
PHENYLALANINE (UNII: 47E5O17Y3R) (PHENYLALANINE - UNII:47E5O17Y3R)	PHENYLALANINE	336 mg in 100 mL
LYSINE (UNII: K3Z4F929H6) (LYSINE - UNII:K3Z4F929H6)	LYSINE	348 mg in 100 mL
METHIONINE (UNII: AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL)	METHIONINE	200 mg in 100 mL
ISOLEUCINE (UNII: 04Y7590D77) (ISOLEUCINE - UNII:04Y7590D77)	ISOLEUCINE	360 mg in 100 mL
VALINE (UNII: HG18B9YRS7) (VALINE - UNII:HG18B9YRS7)	VALINE	348 mg in 100 mL
HISTIDINE (UNII: 4QD397987E) (HISTIDINE - UNII:4QD397987E)	HISTIDINE	288 mg in 100 mL
THREONINE (UNII: 2ZD004190S) (THREONINE - UNII:2ZD004190S)	THREONINE	252 mg in 100 mL
TRYPTOPHAN (UNII: 8DUH1N11BX) (TRYPTOPHAN - UNII:8DUH1N11BX)	TRYPTOPHAN	108 mg in 100 mL
ALANINE (UNII: OF5P57N2ZX) (ALANINE - UNII:OF5P57N2ZX)	ALANINE	1242 mg in 100 mL
GLYCINE (UNII: TE7660XO1C) (GLYCINE - UNII:TE7660XO1C)	GLYCINE	618 mg in 100 mL
ARGININE (UNII: 94ZLA3W45F) (ARGININE - UNII:94ZLA3W45F)	ARGININE	690 mg in 100 mL
PROLINE (UNII: 9DLQ4CIU6V) (PROLINE - UNII:9DLQ4CIU6V)	PROLINE	408 mg in 100 mL
SERINE (UNII: 452VLY9402) (SERINE - UNII:452VLY9402)	SERINE	300 mg in 100 mL
TYROSINE (UNII: 42HK56048U) (TYROSINE - UNII:42HK56048U)	TYROSINE	24 mg in 100 mL
DEXTROSE (UNII: IY9XDZ 35W2) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE	5 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
ACETIC ACID (UNII: Q40Q9N063P)	
WATER (UNII: 059QF0KO0R)	
NITROGEN (UNII: N762921K75)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
Packaging	

			Marketing Start	Marketing End
#	Item Code	Package Description	Date	Date
1	NDC:0338-0198- 06	6 in 1 CARTON	09/21/2020	
1		1000 mL in 1 BAG; Type 0: Not a Combination Product		
M	larketing l	Information		
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NE	A	NDA020734	09/29/1997	

Product Infor	mation				
Product Type		HUMAN PRESCRIPTION DRUG	Iton	n Code (Source)	NDC:0338-0188
			iten	incode (Source)	NDC.0550-0100
Route of Admin	istration	INTRAVENOUS			
Active Ingred	ient/Active	Moiety			
	Ingred	ient Name		Basis of Strength	Strength
EUCINE (UNII: GM	W67QNF9C)(LEU	JCINE - UNII:GMW67QNF9C)		LEUCINE	584 mg in 100 r
HENYLALANINE	UNII: 47E5017Y	BR) (PHENYLALANINE - UNII:47E	5017Y3R)	PHENYLALANINE	448 mg in 100 r
		E - UNII:K3Z4F929H6)		LYSINE	464 mg in 100 r
		METHIONINE - UNII:AE28F7PNPL		METHIONINE	320 mg in 100 r
		SOLEUCINE - UNII:04Y7590D77)	ISOLEUCINE	480 mg in 100 r
		E - UNII:HG18B9YRS7)		VALINE	464 mg in 100 r
		TIDINE - UNII:4QD397987E)		HISTIDINE	384 mg in 100 r
		THREONINE - UNII:2Z D004190S		THREONINE	336 mg in 100 m
RTPTOPHAN (UNI	I: 8DUHINIIBA)	(TRYPTOPHAN - UNII:8DUH1N1	1BX)	TRYPTOPHAN	144 mg in 100 r
LANINE (UNII: OF	6P57N2ZX) (ALAI	NNE - UNII:OF5P57N2ZX)		ALANINE	1656 mg in 100 mL
GLYCINE (UNII: TE7	660X01C) (GLY	CINE - UNII:TE7660XO1C)		GLYCINE	515 mg in 100 r
ARGININE (UNII: 94	ZLA3W45F) (ARC	ININE - UNII:94ZLA3W45F)		ARGININE	920 mg in 100 r
ROLINE (UNII: 9DI	_Q4CIU6V) (PROI	INE - UNII:9DLQ4CIU6V)		PROLINE	544 mg in 100 r
SERINE (UNII: 452V	LY9402) (SERINI	- UNII:452VLY9402)		SERINE	400 mg in 100 r
YROSINE (UNII: 42	2HK56048U) (TY	ROSINE - UNII:42HK56048U)		TYROSINE	32 mg in 100 m
DEXTROSE (UNII: F JNII:5SLOG7ROOK)		HYDROUS DEXTROSE -		DEXTROSE	10 g in 100 mL
UNII:55LOG7ROOK)	dients	HYDROUS DEXTROSE -		DEXTROSE	10 g in 100 mL Strength
JNII:55L0G7R0OK)	e dients : Q40Q9N063P)			DEXTROSE	
INII:55L0G7ROOK) Inactive Ingre ACETIC ACID (UNII WATER (UNII: 059C NITROGEN (UNII: N	edients : Q40Q9N063P))F0KO0R) 762921K75)	Ingredient Name		DEXTROSE	
INII:55LOG7ROOK) nactive Ingre ACETIC ACID (UNII NATER (UNII: 059C	edients : Q40Q9N063P))F0KO0R) 762921K75)	Ingredient Name		DEXTROSE	
INII:55LOG7ROOK) nactive Ingre Ingre NATER (UNII: 059C INTROGEN (UNII: N INTROGEN (UNII: N INTROCHLORIC A Packaging	edients : Q40Q9N063P) 0F0KOOR) 762921K75) ICID (UNII: QTT1	Ingredient Name 7582CB)	Ма		Strength
INII:55L0G7ROOK) INII:55L0G7ROOK) INII:55L0G7ROOK) ICCETIC ACID (UNII VATER (UNII: 059C) ITTROGEN (UNII: N ITROGEN (UNII: N ITROCHLORIC A Packaging Item Code	edients : Q40Q9N063P) 0F0KOOR) 762921K75) ICID (UNII: QTT1	Ingredient Name	Ma	DEXTROSE	Strength
INII:55L0G7ROOK) INII:55L0G7ROOK) INII:55L0G7ROOK) INITROGEN (UNII: INITROGEN (UNII: N INTROGEN (UNII: N INTROCHLORIC A Packaging Item Code NDC:0338-0188- 06	edients : Q40Q9N063P) (F0KOOR) 762921K75) ICID (UNII: QTT1 Par 6 in 1 CARTON	Ingredient Name 7582CB) :kage Description	09/21	urketing Start	Strength Marketing End
INII:55LOG7ROOK) INII:55LOG7ROOK INII:55LOG7ROOK) INII:55LOG7ROOK INII:55LOG7ROOK) INII:55LOG7ROOK INII:55LOGROOK INII:55LO	edients : Q40Q9N063P) (F0KOOR) 762921K75) ICID (UNII: QTT1 Par 6 in 1 CARTON	Ingredient Name 7582CB)	09/21	rketing Start Date	Strength Marketing End
INII:55L0G7ROOK) INII:55L0G7ROOK INII:55L0G7ROOK) INII:55L0G7ROOK INII:5	edients : 04009N063P) F0KOOR) 762921K75) CID (UNII: QTT1 Part 6 in 1 CARTON 1000 mL in 1 E Product	Ingredient Name 7582CB) :kage Description AG; Type 0: Not a Combination	09/21	rketing Start Date	Strength Marketing End
INII:55L0G7ROOK) A CETIC ACID (UNII VATER (UNII: 059C INTROGEN (UNII: N IYDROCHLORIC A Packaging Item Code NDC:0338-0188- 01 Marketing	edients : Q40Q9N063P))F0KO0R) 762921K75) CID (UNII: QTT1 Part 6 in 1 CARTON 1000 mL in 1 E Product	Ingredient Name 7582CB) :kage Description AG; Type 0: Not a Combination	09/21	arketing Start Date /2020	Strength Marketing End Date
INII:55L0G7ROOK) A active Ingre CETIC ACID (UNII VATER (UNII: 059C INTROGEN (UNII: N IYDROCHLORIC A Packaging Item Code NDC:0338-0188- 06 NDC:0338-0188- 01 Marketing Marketing	edients : Q40Q9N063P))F0KO0R) 762921K75) CID (UNII: QTT1 Part 6 in 1 CARTON 1000 mL in 1 E Product	Ingredient Name 7582CB) :kage Description AG; Type 0: Not a Combination	09/21	rketing Start Date	Strength Marketing End
INII:55L0G7ROOK) A active Ingre CETIC ACID (UNII VATER (UNII: 059C INTROGEN (UNII: N IYDROCHLORIC A Packaging Item Code NDC:0338-0188- 06 NDC:0338-0188- 01 Marketing Category	edients : Q40Q9N063P))F0KO0R) 762921K75) CID (UNII: QTT1 Part 6 in 1 CARTON 1000 mL in 1 E Product	Ingredient Name 7582CB) :kage Description AG; Type 0: Not a Combination	09/21	rrketing Start Date /2020	Strength Marketing End Date
NII:5SLOG7ROOK)	edients : Q40Q9N063P) (F0KOOR) 762921K75) ICID (UNII: QTT1 Pau 6 in 1 CARTON 1000 mL in 1 E Product Informat Applicat	Ingredient Name 7582CB) :kage Description AG; Type 0: Not a Combination	09/21	arketing Start Date /2020	Strength Marketing En Date
INII:55L0G7ROOK) A active Ingre CETIC ACID (UNII VATER (UNII: 059C INTROGEN (UNII: N IYDROCHLORIC A Packaging Item Code NDC:0338-0188- 06 NDC:0338-0188- 01 Marketing Category	edients : Q40Q9N063P) (F0KOOR) 762921K75) ICID (UNII: QTT1 Pau 6 in 1 CARTON 1000 mL in 1 E Product Informat Applicat	Ingredient Name 7582CB) :kage Description AG; Type 0: Not a Combination	09/21	arketing Start Date /2020	Strength Marketing En Date
INII:55L0G7ROOK) INII:55L0G7ROOK	edients : Q40Q9N063P) (F0KOOR) 762921K75) ICID (UNII: QTT1 Pau 6 in 1 CARTON 1000 mL in 1 E Product Informat Applicat	Ingredient Name 7582CB) :kage Description AG; Type 0: Not a Combination	09/21	arketing Start Date /2020	Strength Marketing End Date

	Ingredient/Active	A
ΔΟΤΙΛΑ	Indredient/Active	MOIET\

Product Type

Route of Administration

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
LEUCINE (UNII: GMW67QNF9C) (LEUCINE - UNII:GMW67QNF9C)	LEUCINE	584 mg in 100 mL		
PHENYLALANINE (UNII: 47E5O17Y3R) (PHENYLALANINE - UNII:47E5O17Y3R)	PHENYLALANINE	448 mg in 100 mL		
LYSINE (UNII: K3Z4F929H6) (LYSINE - UNII:K3Z4F929H6)	LYSINE	464 mg in 100 mL		
METHIONINE (UNII: AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL)	METHIONINE	320 mg in 100 mL		
ISOLEUCINE (UNII: 04Y7590D77) (ISOLEUCINE - UNII:04Y7590D77)	ISOLEUCINE	480 mg in 100 mL		
VALINE (UNII: HG18B9YRS7) (VALINE - UNII:HG18B9YRS7)	VALINE	464 mg in 100 mL		
HISTIDINE (UNII: 4QD397987E) (HISTIDINE - UNII:4QD397987E)	HISTIDINE	384 mg in 100 mL		
THREONINE (UNII: 2ZD004190S) (THREONINE - UNII:2ZD004190S)	THREONINE	336 mg in 100 mL		
TRYPTOPHAN (UNII: 8DUH1N11BX) (TRYPTOPHAN - UNII:8DUH1N11BX)	TRYPTOPHAN	144 mg in 100 mL		
ALANINE (UNII: OF5P57N2ZX) (ALANINE - UNII:OF5P57N2ZX)	ALANINE	1656 mg in 100 mL		
GLYCINE (UNII: TE7660XO1C) (GLYCINE - UNII:TE7660XO1C)	GLYCINE	824 mg in 100 mL		
ARGININE (UNII: 94ZLA3W45F) (ARGININE - UNII:94ZLA3W45F)	ARGININE	920 mg in 100 mL		
PROLINE (UNII: 9DLQ4CIU6V) (PROLINE - UNII:9DLQ4CIU6V)	PROLINE	544 mg in 100 mL		

HUMAN PRESCRIPTION DRUG

INTRAVENOUS

Item Code (Source) NDC:0338-0194

	2HK56048U) (TY	E - UNII:452VLY9402) ROSINE - UNII:42HK56048U) HYDROUS DEXTROSE -		SERINE TYROSINE DEXTROSE	400 mg in 100 ml 32 mg in 100 mL 10 g in 100 mL
Inactive Ingre	dients	Ingredient Name			Strength
ACETIC ACID (UNII: WATER (UNII: 0590 NITROGEN (UNII: N' HYDROCHLORIC A	F0KO0R) 762921K75)				Strength
Packaging					
# Item Code	Pa	ckage Description	Ма	rketing Start Date	Marketing End Date
1 NDC:0338-0194- 04	4 in 1 CARTON		09/21	/2020	
1 NDC:0338-0194- 01	2000 mL in 1 E Product	BAG; Type 0: Not a Combination			
Marketing		ion tion Number or Monograph	M	larketing Start	Marketing End
Category NDA	ND4020724	Citation	00/	Date	Date
	NDA020734		09/2	29/1997	
Product Infor Product Type Route of Admini	mation	ine, serine, tyrosine, dextros HUMAN PRESCRIPTION DRUG INTRAVENOUS		n Code (Source)	NDC:0338-0180
Active Ingredi				Basis of	Charles with
	-	ient Name		Strength	Strength
		JCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E5O]	7Y3B)		584 mg in 100 m 448 mg in 100 m
		E - UNII:K3Z4F929H6)	.,	LYSINE	464 mg in 100 m
METHIONINE (UNII:	AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL)		METHIONINE	320 mg in 100 m
					-
ISOLEUCINE (UNII:	04Y7590D77) (SOLEUCINE - UNII:04Y7590D77)		ISOLEUCINE	-
ISOLEUCINE (UNII: VALINE (UNII: HG18	04Y7590D77) (B9YRS7) (VALIN	E - UNII:HG18B9YRS7)		VALINE	464 mg in 100 m
ISOLEUCINE (UNII: VALINE (UNII: HG18 HISTIDINE (UNII: 40	04Y7590D77) (B9YRS7) (VALIN QD397987E) (HI	E - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E)		VALINE HISTIDINE	464 mg in 100 m 384 mg in 100 m
ISOLEUCINE (UNII: VALINE (UNII: HG18 HISTIDINE (UNII: 40 THREONINE (UNII: 20	04Y7590D77) (B9YRS7) (VALIN QD397987E) (HI 2ZD004190S) (E - UNII:HG18B9YRS7)	K)	VALINE	464 mg in 100 m 384 mg in 100 m 336 mg in 100 m
ISOLEUCINE (UNII: VALINE (UNII: HG18 HISTIDINE (UNII: 40 THREONINE (UNII: TRYPTOPHAN (UNII	04Y7590D77) (B9YRS7) (VALIN QD397987E) (HI 2ZD004190S) (I: 8DUH1N11BX	E - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD004190S)	×)	VALINE HISTIDINE THREONINE	464 mg in 100 m 384 mg in 100 m 336 mg in 100 m 144 mg in 100 m 1656 mg
ISOLEUCINE (UNII: VALINE (UNII: HG18 HISTIDINE (UNII: 4C THREONINE (UNII: 1 TRYPTOPHAN (UNII ALANINE (UNII: OF5	04Y7590D77) (B9YRS7) (VALIN QD397987E) (HI 2ZD0041905) (I: 8DUH1N11BX P57N2ZX) (ALA	E - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2Z D004190S)) (TRYPTOPHAN - UNII:8DUH1N11B; NINE - UNII:0F5P57N2ZX)	K)	VALINE HISTIDINE THREONINE TRYPTOPHAN ALANINE	464 mg in 100 m 384 mg in 100 m 336 mg in 100 m 144 mg in 100 m 1656 mg in 100 mL
ISOLEUCINE (UNII: VALINE (UNII: HG18 HISTIDINE (UNII: 4C THREONINE (UNII: 1 TRYPTOPHAN (UNII ALANINE (UNII: OF5 GLYCINE (UNII: TE7	04Y7590D77) (B9YRS7) (VALIN QD397987E) (HI 2Z D0041905) (B 8DUH1N11BX P57N2ZX) (ALA 660X01C) (GLY	e - Unii:Hg18b9yrs7) Stidine - Unii:4QD397987E) THREONINE - UNII:2ZD004190S)) (TRYPTOPHAN - UNII:8DUH1N11B)	K)	VALINE HISTIDINE THREONINE TRYPTOPHAN	464 mg in 100 m 384 mg in 100 m 336 mg in 100 m 144 mg in 100 m 1656 mg in 100 mL 824 mg in 100 m
ISOLEUCINE (UNII: VALINE (UNII: HG18 HISTIDINE (UNII: 4C THREONINE (UNII: 4 TRYPTOPHAN (UNII ALANINE (UNII: 0F5 GLYCINE (UNII: 197 ARGININE (UNII: 947 PROLINE (UNII: 9DL	04Y7590D77) (B9YRS 7) (VALIN QD397987E) (HI 2Z D004190S) (I: 8DUH1N11BX P57N2Z X) (ALA 660X01C) (GLY Z LA3W45F) (ARG Q4CIU6V) (PRO	E - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD004190S) (TRYPTOPHAN - UNII:8DUH1N11B; NINE - UNII:0F5P57N2ZX) CINE - UNII:TE7660X01C) SININE - UNII:94ZLA3W45F) LINE - UNII:9DLQ4CIU6V)	K)	VALINE HISTIDINE THREONINE TRYPTOPHAN ALANINE GLYCINE ARGININE PROLINE	464 mg in 100 m 384 mg in 100 m 336 mg in 100 m 144 mg in 100 m 1656 mg in 100 mL 824 mg in 100 m 920 mg in 100 m
ISOLEUCINE (UNII: VALINE (UNII: HG18 HISTIDINE (UNII: 4C THREONINE (UNII: 4 TRYPTOPHAN (UNII ALANINE (UNII: 0F5 GLYCINE (UNII: 197 PROLINE (UNII: 92 SERINE (UNII: 92	04Y7590D77) (B9YRS7) (VALIA 2D397987E) (HI 2Z D004190S) (I: BDUH1N11BX P57N2ZX) (ALA 660X01C) (GLY ZLA3W45F) (ARC Q4CIU6V) (PRO LY9402) (SERIN	E - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD004190S)) (TRYPTOPHAN - UNII:8DUH1N11B; NINE - UNII:0F5P57N2ZX) CINE - UNII:7E7660X01C) GININE - UNII:9ZLA3W45F) LINE - UNII:9DLQ4CIU6V) E - UNII:4S2VLY9402)	×)	VALINE HISTIDINE THREONINE TRYPTOPHAN ALANINE GLYCINE ARGININE PROLINE SERINE	464 mg in 100 m 384 mg in 100 m 336 mg in 100 m 1656 mg in 100 mL 824 mg in 100 m 920 mg in 100 m 544 mg in 100 m
ISOLEUCINE (UNII: VALINE (UNII: HG18 HISTIDINE (UNII: 4C THREONINE (UNII: 4C TRYPTOPHAN (UNII ALANINE (UNII: 0F5 GLYCINE (UNII: 10F5 ARGININE (UNII: 10F SERINE (UNII: 92 SERINE (UNII: 92 TYROSINE (UNII: 422/ TYROSINE (UNII: 42	04Y7590D77) (B9YRS7) (VALIN 2D397987E) (HI 2Z D004190S) (I: 8DUH1N11BX P57N2Z X) (ALA 660X01C) (GLY Z LA3W45F) (ARR Q4CIU6V) (PRO LY9402) (SERIN 2HK56048U) (TY	E - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD004190S)) (TRYPTOPHAN - UNII:8DUH1N11B; NINE - UNII:0F5P57N2ZX) CINE - UNII:7E7660X01C) SININE - UNII:9ZLA3W45F) LINE - UNII:9DLQ4CIU6V) E - UNII:452VLY9402) ROSINE - UNII:42HK56048U)	×)	VALINE HISTIDINE THREONINE TRYPTOPHAN ALANINE GLYCINE ARGININE PROLINE SERINE TYROSINE	464 mg in 100 m 384 mg in 100 m 336 mg in 100 m 1656 mg in 100 mL 824 mg in 100 m 920 mg in 100 m 544 mg in 100 m 32 mg in 100 mL
ISOLEUCINE (UNII: VALINE (UNII: HG18 HISTIDINE (UNII: 4C THREONINE (UNII: 4C TRYPOPHAN (UNII ALANINE (UNII: 0F5 GLYCINE (UNII: 97 ARGININE (UNII: 94 PROLINE (UNII: 94 SERINE (UNII: 452VI TYROSINE (UNII: 42	04Y7590D77) (B9YRS7) (VALIN 2D397987E) (HI 2Z D004190S) (I: 8DUH1N11BX P57N2Z X) (ALA 660X01C) (GLY Z LA3W45F) (ARR Q4CIU6V) (PRO LY9402) (SERIN 2HK56048U) (TY	E - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD004190S)) (TRYPTOPHAN - UNII:8DUH1N11B; NINE - UNII:0F5P57N2ZX) CINE - UNII:7E7660X01C) GININE - UNII:9ZLA3W45F) LINE - UNII:9DLQ4CIU6V) E - UNII:4S2VLY9402)	×)	VALINE HISTIDINE THREONINE TRYPTOPHAN ALANINE GLYCINE ARGININE PROLINE SERINE	464 mg in 100 m 384 mg in 100 m 336 mg in 100 m 1656 mg in 100 mL 824 mg in 100 m 920 mg in 100 m 544 mg in 100 m
ISOLEUCINE (UNII: VALINE (UNII: HG18 HISTIDINE (UNII: 4C THREONINE (UNII: 4C TRYPTOPHAN (UNII ALANINE (UNII: 0F5 GLYCINE (UNII: 0F5 GLYCINE (UNII: 97 PROLINE (UNII: 97 TYROSINE (UNII: 42 DEXTROSE (UNII: 17 UNII: 55L0G7ROOK)	04Y7590D77) (B9YRS7) (VALIN 2D397987E) (HI 2Z D0041905) (I: 8DUH1N11BX P57NZZX) (ALA 660X01C) (GLY Z LA3W45F) (ARG Q4CIU6V) (PRO LY9402) (SERIN 2HK56048U) (TY (9XDZ 35W2) (AI	E - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD004190S) (TRYPTOPHAN - UNII:8DUH1N11B; NINE - UNII:0F5P57N2ZX) CINE - UNII:7E7660X01C) SININE - UNII:94ZLA3W45F) LINE - UNII:9DLQ4CIU6V) E - UNII:452VLY9402) ROSINE - UNII:42HK56048U) HYDROUS DEXTROSE -	×)	VALINE HISTIDINE THREONINE TRYPTOPHAN ALANINE GLYCINE ARGININE PROLINE SERINE TYROSINE	464 mg in 100 m 384 mg in 100 m 336 mg in 100 m 144 mg in 100 m 1656 mg in 100 mL 824 mg in 100 m 920 mg in 100 m 544 mg in 100 m 32 mg in 100 mL 14 g in 100 mL
ISOLEUCINE (UNII: VALINE (UNII: HG18 HISTIDINE (UNII: 4C THREONINE (UNII: 4C TRYPTOPHAN (UNII ALANINE (UNII: 0F5 GLYCINE (UNII: 0F5 GLYCINE (UNII: 97 PROLINE (UNII: 97 PROLINE (UNII: 97 TYROSINE (UNII: 42 DEXTROSE (UNII: 17 UNII:55L0G7ROOK)	04Y7590D77) (B9YRS7) (VALIA QD397987E) (HI 22 D0041905) (I: 8DUH1N11BX P57NZZX) (ALA 660X01C) (GLY ZLA3W45F) (ARG Q4CIU6V) (PRO LY9402) (SERIN QHK56048U) (TY (9XDZ 35W2) (AI dients	E - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD004190S)) (TRYPTOPHAN - UNII:8DUH1N11B; NINE - UNII:0F5P57N2ZX) CINE - UNII:7E7660X01C) SININE - UNII:9ZLA3W45F) LINE - UNII:9DLQ4CIU6V) E - UNII:452VLY9402) ROSINE - UNII:42HK56048U)	X)	VALINE HISTIDINE THREONINE TRYPTOPHAN ALANINE GLYCINE ARGININE PROLINE SERINE TYROSINE	464 mg in 100 m 384 mg in 100 m 336 mg in 100 m 144 mg in 100 m 1656 mg in 100 mL 824 mg in 100 m 920 mg in 100 m 544 mg in 100 m 32 mg in 100 mL
ISOLEUCINE (UNII: VALINE (UNII: HG18 HISTIDINE (UNII: 4G THREONINE (UNII: 4G TRYPTOPHAN (UNII ALANINE (UNII: 0F5 GLYCINE (UNII: 0F5 GLYCINE (UNII: 92 DEROLINE (UNII: 92 DESENINE (UNII: 4522/I TYROSINE (UNII: 422/I TYROSINE (UNII: 42/I TYROSINE (UNII: 42/I T	04Y7590D77) (B9YR57) (VALIA QD397987E) (HI ZZ D0041905) (I: 8DUH1N11BX P57N2Z X) (ALA 660X01C) (GLY ZLA3W45F) (AR Q4CIU6V) (PRO Q4CIU6V) (PRO Q4CIU6V) (SERIN 2HK56048U) (TY (9XDZ 35W2) (AI dients : Q40Q9N063P)	E - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD004190S) (TRYPTOPHAN - UNII:8DUH1N11B; NINE - UNII:0F5P57N2ZX) CINE - UNII:7E7660X01C) SININE - UNII:94ZLA3W45F) LINE - UNII:9DLQ4CIU6V) E - UNII:452VLY9402) ROSINE - UNII:42HK56048U) HYDROUS DEXTROSE -	×)	VALINE HISTIDINE THREONINE TRYPTOPHAN ALANINE GLYCINE ARGININE PROLINE SERINE TYROSINE	464 mg in 100 m 384 mg in 100 m 336 mg in 100 m 144 mg in 100 m 1656 mg in 100 mL 824 mg in 100 m 920 mg in 100 m 544 mg in 100 m 32 mg in 100 mL 14 g in 100 mL
ISOLEUCINE (UNII: VALINE (UNII: HG18 HISTIDINE (UNII: 4C THREONINE (UNII: 4C TRYPTOPHAN (UNII ALANINE (UNII: 0F5 GLYCINE (UNII: 942 PROLINE (UNII: 942 PROLINE (UNII: 942 PROLINE (UNII: 942 PROLINE (UNII: 942 DEXTROSE (UNII: 422VI TYROSINE (UNII: 422VI TYROSINE (UNII: 422VI DEXTROSE (UNII: 422VI INACTIVE INGRE ACETIC ACID (UNII: WATER (UNII: 059Q NITROGEN (UNII: NI	04Y7590D77) (B9YRS7) (VALIA QD397987E) (HI 22 D0041905) (I: 8DUH1N11BX P57N2ZX) (ALA 660X01C) (GLY Z LA3W45F) (AR Q4CIU6V) (PRO LY9402) (SERIN HKS6048U) (TY '9XDZ 35W2) (AI dients : Q40Q9N063P) F0KO0R) 762921K75)	E - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD0041905) (TRYPTOPHAN - UNII:8DUH1N11B) NINE - UNII:0F5P57N2ZX) CINE - UNII:9F560X01C) SININE - UNII:9DLQ4CI06V) E - UNII:9DLQ4CI06V) E - UNII:452VLY9402) ROSINE - UNII:42HK56048U) HYDROUS DEXTROSE - Ingredient Name	X)	VALINE HISTIDINE THREONINE TRYPTOPHAN ALANINE GLYCINE ARGININE PROLINE SERINE TYROSINE	464 mg in 100 m 384 mg in 100 m 386 mg in 100 m 144 mg in 100 m 1656 mg in 100 mL 824 mg in 100 m 920 mg in 100 m 544 mg in 100 m 32 mg in 100 mL 14 g in 100 mL
ISOLEUCINE (UNII: VALINE (UNII: HG18 HISTIDINE (UNII: 4C THREONINE (UNII: 4C TRYPTOPHAN (UNII ALANINE (UNII: 0F5 GLYCINE (UNII: 0F5 GLYCINE (UNII: 94) PROLINE (UNII: 452VI TYROSINE (UNII: 452VI TYROSINE (UNII: 452VI TYROSINE (UNII: 452VI UNII:55L0G7ROOK) INACTIVE INGRE ACETIC ACID (UNII: WATER (UNII: 59Q NITROGEN (UNII: N' HYDROCHLORIC A	04Y7590D77) (B9YRS7) (VALIA QD397987E) (HI 22 D0041905) (I: 8DUH1N11BX P57N2ZX) (ALA 660X01C) (GLY Z LA3W45F) (AR Q4CIU6V) (PRO LY9402) (SERIN HKS6048U) (TY '9XDZ 35W2) (AI dients : Q40Q9N063P) F0KO0R) 762921K75)	E - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD0041905) (TRYPTOPHAN - UNII:8DUH1N11B) NINE - UNII:0F5P57N2ZX) CINE - UNII:9F560X01C) SININE - UNII:9DLQ4CI06V) E - UNII:9DLQ4CI06V) E - UNII:452VLY9402) ROSINE - UNII:42HK56048U) HYDROUS DEXTROSE - Ingredient Name	×)	VALINE HISTIDINE THREONINE TRYPTOPHAN ALANINE GLYCINE ARGININE PROLINE SERINE TYROSINE	464 mg in 100 m 384 mg in 100 m 386 mg in 100 m 144 mg in 100 m 1656 mg in 100 mL 824 mg in 100 m 920 mg in 100 m 544 mg in 100 m 32 mg in 100 mL 14 g in 100 mL
ISOLEUCINE (UNII: VALINE (UNII: HG18 HISTIDINE (UNII: 4G THREONINE (UNII: 4G TRYPTOPHAN (UNII ALANINE (UNII: 0F5 GLYCINE (UNII: 0F5 GLYCINE (UNII: 0F5 GLYCINE (UNII: 4G PROLINE (UNII: 452VI TROSINE (UNII: 551C) ACETIC ACID (UNII: 472VI HYDROCHLORIC A	04Y7590D77) (B9YR57) (VALIN 2D397987E) (HI 2Z D0041905) (I: 8DUH1N11BX P57N2Z X) (ALA 660X01C) (GLY ZLA3W45F) (AR Q4CIU6V) (PRO Q4CIU6V) (PRO Q4CIU6V) (PRO (J4X040) (TA (1) (9XDZ 35W2) (AI (9XDZ	E - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD0041905) (TRYPTOPHAN - UNII:8DUH1N11B) NINE - UNII:0F5P57N2ZX) CINE - UNII:9F560X01C) SININE - UNII:9DLQ4CI06V) E - UNII:9DLQ4CI06V) E - UNII:452VLY9402) ROSINE - UNII:42HK56048U) HYDROUS DEXTROSE - Ingredient Name		VALINE HISTIDINE THREONINE TRYPTOPHAN ALANINE GLYCINE ARGININE PROLINE SERINE TYROSINE	464 mg in 100 m 384 mg in 100 m 386 mg in 100 m 144 mg in 100 m 1656 mg in 100 mL 824 mg in 100 m 920 mg in 100 m 544 mg in 100 m 32 mg in 100 mL 14 g in 100 mL
ISOLEUCINE (UNII: VALINE (UNII: HG18 HISTIDINE (UNII: 4G THREONINE (UNII: 4G TRYPTOPHAN (UNII ALANINE (UNII: 0F5 GLYCINE (UNII: 94) PROLINE (UNII: 94) INACTOR (UNII: 555007800K) INACTOR (UNI	04Y7590D77) (B9YR57) (VALIN 2D397987E) (HI 2Z D0041905) (I: 8DUH1N11BX P57N2Z X) (ALA 660X01C) (GLY ZLA3W45F) (AR Q4CIU6V) (PRO Q4CIU6V) (PRO Q4CIU6V) (PRO (J4X040) (TA (1) (9XDZ 35W2) (AI (9XDZ	E - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD0041905) (TRYPTOPHAN - UNII:BDUH1N11B2) NINE - UNII:0F5P57N2ZX) CINE - UNII:7E7660X01C) SININE - UNII:9DL04CIU6V) E - UNII:452VLY9402) ROSINE - UNII:42HK56048U) IHYDROUS DEXTROSE - Ingredient Name L7582CB)		VALINE HISTIDINE TREONINE TRYPTOPHAN ALANINE GLYCINE ARGININE PROLINE SERINE TYROSINE DEXTROSE	in 100 mL 824 mg in 100 ml 920 mg in 100 ml 544 mg in 100 ml 400 mg in 100 mL 14 g in 100 mL Strength
ISOLEUCINE (UNII: VALINE (UNII: HG18 HISTIDINE (UNII: 4G THREONINE (UNII: 4G TRYPTOPHAN (UNII ALANINE (UNII: 0F5 GLYCINE (UNII: 0F5 GLYCINE (UNII: 94) PROLINE (UNII: 94) DESTROSE (UNII: 42) DESTROSE (UNII: 42) DESTROSE (UNII: 42) DESTROSE (UNII: 55) DESTROSE (UNIII: 55) DESTROSE (UNII: 55) DESTROSE (UNII: 55) DEST	04Y7590D77) (B9YRS7) (VALIN 2D397987E) (HI 2Z D0041905) (I: BDUH1N11BX P57N2ZX) (ALA 660X01C) (GLY Z LA3W45F) (AR Q4CIU6V) (PRO LY9402) (SERIN WHK56048U) (TY 9XDZ 35W2) (AI dients : Q40Q9N063P) F0KOGR 762921K75) CID (UNII: QTT: Pa 6 in 1 CARTON	E - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD0041905) (TRYPTOPHAN - UNII:BDUH1N11B2) NINE - UNII:0F5P57N2ZX) CINE - UNII:7E7660X01C) SININE - UNII:9DL04CIU6V) E - UNII:452VLY9402) ROSINE - UNII:42HK56048U) IHYDROUS DEXTROSE - Ingredient Name L7582CB)	Ма	VALINE HISTIDINE THREONINE TRYPTOPHAN ALANINE GLYCINE ARGININE PROLINE SERINE TYROSINE DEXTROSE	464 mg in 100 m 384 mg in 100 m 386 mg in 100 m 144 mg in 100 m 1656 mg in 100 mL 824 mg in 100 m 920 mg in 100 m 544 mg in 100 m 400 mg in 100 mL 14 g in 100 mL Strength Marketing End
ISOLEUCINE (UNII: VALINE (UNII: HG18 HISTIDINE (UNII: 4G18 HISTIDINE (UNII: 4G18 HISTIDINE (UNII: 4G18 HISTIDINE (UNII: 4G18 HISTIDINE (UNII: 4G18 ALANINE (UNII: 9G1 GLYCINE (UNII: 9G1 PROLINE (UNII: 9G1 PROLINE (UNII: 9G1 PROLINE (UNII: 4G2VI TYROSINE (UNII: 4G2V	04Y7590D77) (B9YRS7) (VALIN D397987E) (HI 2Z D0041905) (I: 8DUH1N11BX P57N2Z X) (ALA 660X01C) (GLY ZLA3W45F) (AR Q4CIU6V) (PRO LY9402) (SERIN 2HK56048U) (TY (9XDZ 35W2) (AI CID (UNII: QTT: CID (UNII: QTT: Pa 6 in 1 CARTON 1000 mL in 1 f	E - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD004190S) (TRYPTOPHAN - UNII:BDUH1N11B2) NINE - UNII:0F5P57N2ZX) CINE - UNII:9F2660X01C) SININE - UNII:9DLQ4CU6V) E - UNII:9DLQ4CU6V) E - UNII:452VLY9402) ROSINE - UNII:42HK56048U) IHYDROUS DEXTROSE - Ingredient Name I7582CB) Ckage Description	Ма	VALINE HISTIDINE THREONINE TRYPTOPHAN ALANINE GLYCINE ARGININE PROLINE SERINE TYROSINE DEXTROSE	464 mg in 100 m 384 mg in 100 m 386 mg in 100 m 144 mg in 100 m 1656 mg in 100 mL 824 mg in 100 m 920 mg in 100 m 544 mg in 100 m 400 mg in 100 mL 14 g in 100 mL Strength Marketing End
ISOLEUCINE (UNII: VALINE (UNII: HG18 HISTIDINE (UNII: 4G18 HISTIDINE (UNII: 4G18 HISTIDINE (UNII: 4G18 HISTIDINE (UNII: 4G18 HISTIDINE (UNII: 4G18 ALANINE (UNII: 9G1 GLYCINE (UNII: 9G1 PROLINE (UNII: 9G1 PROLINE (UNII: 9G1 PROLINE (UNII: 4G2VI TYROSINE (UNII: 4G2V	04Y7590D77) (B9YR57) (VALIN 2D397987E) (HI 2Z D0041905) (I: 8DUH1N11BX P57N2Z X) (ALA 660X01C) (GLY Z LA3W45F) (AR Q4CIU6V) (PRO LY9402) (SERIN 2HK56048U) (TY (9XDZ 35W2) (AI CID (UNII: QTT: Pa 6 in 1 CARTON 1000 mL in 1 Product Informat	E - UNII:HG18B9YRS7) STIDINE - UNII:4QD397987E) THREONINE - UNII:2ZD0041905) (TRYPTOPHAN - UNII:8DUH1N11B; NINE - UNII:0F5P57N2ZX) CINE - UNII:94ZLA3W45F) LINE - UNII:94ZLA3W45F) E - UNII:94ZLA3W45F) ROSINE - UNII:94ZLA3W45F) HYDROUS DEXTROSE - Ingredient Name L7582CB) Ckage Description BAG; Type 0: Not a Combination	Ma	VALINE HISTIDINE THREONINE TRYPTOPHAN ALANINE GLYCINE ARGININE PROLINE SERINE TYROSINE DEXTROSE	464 mg in 100 m 384 mg in 100 m 386 mg in 100 m 144 mg in 100 m 1656 mg in 100 mL 824 mg in 100 m 920 mg in 100 m 544 mg in 100 m 400 mg in 100 mL 14 g in 100 mL Strength Marketing End

NDC:0338-0184

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)
Route of Administration	INTRAVENOUS	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength			
LEUCINE (UNII: GMW67QNF9C) (LEUCINE - UNII:GMW67QNF9C)	LEUCINE	584 mg in 100 mL			
PHENYLALANINE (UNII: 47E5O17Y3R) (PHENYLALANINE - UNII:47E5O17Y3R)	PHENYLALANINE	448 mg in 100 mL			
LYSINE (UNII: K3Z4F929H6) (LYSINE - UNII:K3Z4F929H6)	LYSINE	464 mg in 100 mL			
METHIONINE (UNII: AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL)	METHIONINE	320 mg in 100 mL			
ISOLEUCINE (UNII: 04Y7590D77) (ISOLEUCINE - UNII:04Y7590D77)	ISOLEUCINE	480 mg in 100 mL			
VALINE (UNII: HG18B9YRS7) (VALINE - UNII:HG18B9YRS7)	VALINE	464 mg in 100 mL			
HISTIDINE (UNII: 4QD397987E) (HISTIDINE - UNII:4QD397987E)	HISTIDINE	384 mg in 100 mL			
THREONINE (UNII: 2Z D004190S) (THREONINE - UNII:2Z D004190S)	THREONINE	336 mg in 100 mL			
TRYPTOPHAN (UNII: 8DUH1N11BX) (TRYPTOPHAN - UNII:8DUH1N11BX)	TRYPTOPHAN	144 mg in 100 mL			
ALANINE (UNII: OF5P57N2ZX) (ALANINE - UNII:OF5P57N2ZX)	ALANINE	1656 mg in 100 mL			
GLYCINE (UNII: TE7660XO1C) (GLYCINE - UNII:TE7660XO1C)	GLYCINE	824 mg in 100 mL			
ARGININE (UNII: 94ZLA3W45F) (ARGININE - UNII:94ZLA3W45F)	ARGININE	920 mg in 100 mL			
PROLINE (UNII: 9DLQ4CIU6V) (PROLINE - UNII:9DLQ4CIU6V)	PROLINE	544 mg in 100 mL			
SERINE (UNII: 452VLY9402) (SERINE - UNII:452VLY9402)	SERINE	400 mg in 100 mL			
TYROSINE (UNII: 42HK56048U) (TYROSINE - UNII:42HK56048U)	TYROSINE	32 mg in 100 mL			
DEXTROSE (UNII: IY9XDZ35W2) (ANHYDROUS DEXTROSE - UNII:55L0G7R0OK)	DEXTROSE	14 g in 100 mL			

Inactive Ingredients				
Ingredient Name	Strength			
ACETIC ACID (UNII: Q40Q9N063P)				
WATER (UNII: 059QF0KO0R)				
NITROGEN (UNII: N762921K75)				
HYDROCHLORIC ACID (UNII: QTT17582CB)				

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 ^N C	NDC:0338-0184- 04	4 in 1 CARTON	09/21/2020	
	NDC:0338-0184- 01	2000 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
NDA	NDA020734	09/29/1997			

CLINIMIA						
leucine, phenylalanine, lysine, methionine, isoleucine, valine, histidine, threonine, tryptophan,						
alanine, glycine, arginine, proline, serine, tyrosine, dextrose injection						
Product Information						
Product Type	HUMAN PRESCRIPTION DRUG	ltem	Code (Source)	NDC:0338-7001		
Route of Administration	INTRAVENOUS					
Active Ingredient/Active Moiety						
Ingred	lient Name		Basis of Strength	Strength		
Ingred	lient Name			Strength 311 mg in 100 mL		
LEUCINE (UNII: GMW67QNF9C) (LEI	lient Name		Strength	311 mg		
LEUCINE (UNII: GMW67QNF9C) (LEI	i ent Name JCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E5O17	Y3R)	Strength	311 mg in 100 mL 238 mg		
LEUCINE (UNII: GMW67QNF9C) (LEU PHENYLALANINE (UNII: 47E5017Y	l ient Name JCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E5O17 E - UNII:K3Z4F929H6)	Y3R)	Strength LEUCINE PHENYLALANINE	311 mg in 100 mL 238 mg in 100 mL 247 mg		
LEUCINE (UNII: GMW67QNF9C) (LEU PHENYLALANINE (UNII: 47E5017Y LYSINE (UNII: K3Z4F929H6) (LYSIN	ient Name JCINE - UNII:GMW67QNF9C) 3R) (PHENYLALANINE - UNII:47E5O17 E - UNII:K3Z4F929H6) METHIONINE - UNII:AE28F7PNPL)	Y3R)	Strength LEUCINE PHENYLALANINE LYSINE	311 mg in 100 mL 238 mg in 100 mL 247 mg in 100 mL 170 mg		

VALINE

247 mg in 100 mL

VALINE (UNII: HG18B9YRS7) (VALINE - UNII:HG18B9YRS7)

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: 94Z LA3W45F) (ARGININE - UNII:94Z LA3W45F)	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: IY9XDZ 35W2) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ACETIC ACID (UNII: Q40Q9N063P)	
WATER (UNII: 059QF0KO0R)	
NITROGEN (UNII: N762921K75)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Ρ	Packaging					
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:0338-7001- 06	6 in 1 CARTON	07/15/2024			
1	NDC:0338-7001- 01	1000 mL in 1 BAG; Type 0: Not a Combination Product				

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020734	07/15/2024	

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:0338-7003
	Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEUCINE (UNII: GMW67QNF9C) (LEUCINE - UNII:GMW67QNF9C)	LEUCINE	311 mg in 100 mL
PHENYLALANINE (UNII: 47E5017Y3R) (PHENYLALANINE - UNII:47E5017Y3R)	PHENYLALANINE	238 mg in 100 mL
LYSINE (UNII: K3Z4F929H6) (LYSINE - UNII:K3Z4F929H6)	LYSINE	247 mg in 100 mL
METHIONINE (UNII: AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL)	METHIONINE	170 mg in 100 mL
ISOLEUCINE (UNII: 04Y7590D77) (ISOLEUCINE - UNII:04Y7590D77)	ISOLEUCINE	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: TE7660X01C) (GLYCINE - UNII:TE7660X01C)	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: IY9XDZ 35W2) (ANHYDROUS DEXTROSE - UNII:55L0G7R0OK)	DEXTROSE	5 g in 100 mL
Inactive Ingredients		

		Strength					
AC	CETIC ACID (UNII:						
w	ATER (UNII: 059Q	F0KO0R)					
NI	TROGEN (UNII: N	762921K75)					
H١	YDROCHLORIC A	CID (UNII: QTT17582CB)					
P	ackaging						
#	ltem Code	Marketing Start Date	Marketing End Date				
1	NDC:0338-7003- 04	4 in 1 CARTON	07/15/2024				
1	NDC:0338-7003- 01	2000 mL in 1 BAG; Type 0: Not a Combination Product					
Marketing Information							
Marketing Application Number or Monograph Marketing Start Mark Category Citation Date							
NE	NDA NDA020734 07/15/2024						

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:0338-7005	
Route of Administration	INTRAVENOUS			

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEUCINE (UNII: GMW67QNF9C) (LEUCINE - UNII:GMW67QNF9C)	LEUCINE	311 mg in 100 mL
PHENYLALANINE (UNII: 47E5O17Y3R) (PHENYLALANINE - UNII:47E5O17Y3R)	PHENYLALANINE	238 mg in 100 mL
LYSINE (UNII: K3Z4F929H6) (LYSINE - UNII:K3Z4F929H6)	LYSINE	247 mg in 100 mL
METHIONINE (UNII: AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL)	METHIONINE	170 mg in 100 mL
ISOLEUCINE (UNII: 04Y7590D77) (ISOLEUCINE - UNII:04Y7590D77)	ISOLEUCINE	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: TE7660X01C) (GLYCINE - UNII:TE7660X01C)	GLYCINE	438 mg in 100 mL
ARGININE (UNII: 94Z LA3W45F) (ARGININE - UNII:94Z LA3W45F)	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: IY9XDZ 35W2) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE	10 g in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
ACETIC ACID (UNII: Q40Q9N063P)				
WATER (UNII: 059QF0KO0R)				
NITROGEN (UNII: N762921K75)				
HYDROCHLORIC ACID (UNII: QTT17582CB)				

Ρ	Packaging					
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:0338-7005- 06	6 in 1 CARTON	07/15/2024			
1	NDC:0338-7005- 01	1000 mL in 1 BAG; Type 0: Not a Combination Product				
M	Marketing Information					

Marketing Application Number or Monograph Marketing Start Marketing End

Category NDA	NDA020734	Citation	07/1	Date 5/2024	Date
	-	methionine, isoleucine, valin ine, serine, tyrosine, dextros			e, tryptophan,
Product Infor	mation				
Product Type		HUMAN PRESCRIPTION DRUG	ltem	Code (Source)	NDC:0338-7007
Route of Admini	stration	INTRAVENOUS			
Active Ingredi	ent/Active	Moiety			
	Ingred	ient Name		Basis of Strength	Strength
LEUCINE (UNII: GM)	N67QNF9C) (LEI	JCINE - UNII:GMW67QNF9C)		LEUCINE	311 mg in 100 mL
PHENYLALANINE (U	JNII: 47E5017Y	3R) (PHENYLALANINE - UNII:47E5O1	7Y3R)	PHENYLALANINE	238 mg in 100 mL
L YSINE (UNII: K3Z4	F929H6) (LYSIN	E - UNII:K3Z4F929H6)		LYSINE	247 mg
		METHIONINE - UNII:AE28F7PNPL)		METHIONINE	in 100 mL 170 mg
					in 100 mL 255 mg
		SOLEUCINE - UNII:04Y7590D77)		ISOLEUCINE	in 100 mL 247 mg
ALINE (UNII: HG18	B9YRS7) (VALIN	E - UNII:HG18B9YRS7)		VALINE	in 100 mL
HISTIDINE (UNII: 40	D397987E) (HI	STIDINE - UNII:4QD397987E)		HISTIDINE	204 mg in 100 mL
THREONINE (UNII: 2	2ZD004190S)(THREONINE - UNII:2ZD004190S)		THREONINE	179 mg in 100 mL
TRYPTOPHAN (UNI	: 8DUH1N11BX) (TRYPTOPHAN - UNII:8DUH1N11BX)	TRYPTOPHAN	77 mg in 100 m
ALANINE (UNII: OF5	P57N2ZX) (ALA	NINE - UNII:OF5P57N2ZX)		ALANINE	880 mg in 100 mL
GLYCINE (UNII: TE7	660XO1C) (GLY	CINE - UNII:TE7660XO1C)		GLYCINE	438 mg in 100 mL
ARGININE (UNII: 942	ZLA3W45F) (ARG	GININE - UNII:94ZLA3W45F)		ARGININE	489 mg in 100 mL
PROLINE (UNII: 9DL	Q4CIU6V) (PRO	LINE - UNII:9DLQ4CIU6V)		PROLINE	289 mg in 100 mL
5ERINE (UNII: 452VI	LY9402) (SERIN	E - UNII:452VLY9402)		SERINE	213 mg
	SERINE (UNII: 452VLY9402) (SERINE - UNII:452VLY9402)		TYROSINE	in 100 mL 17 mg in 100 ml	
TYROSINE (UNII: 42HK56048U) (TYROSINE - UNII:42HK56048U) DEXTROSE (UNII: IY9XDZ 35W2) (ANHYDROUS DEXTROSE -			TYROSINE	17 mg in 100 m	
DEXTROSE (UNII: IY UNII:5SLOG7ROOK)	'9XDZ 35W2) (AM			TYROSINE DEXTROSE	17 mg in 100 m 10 g in 100 mL
DEXTROSE (UNII: IY UNII:55L0G7ROOK) Inactive Ingre ACETIC ACID (UNII: WATER (UNII: 059Q NITROGEN (UNII: N'	9XDZ 35W2) (AM dients Q40Q9N063P) F0KO0R) 762921K75)	NHYDROUS DEXTROSE -			
DEXTROSE (UNII: IY UNII:55L0G7ROOK) Inactive Ingre ACETIC ACID (UNII: WATER (UNII: 059Q NITROGEN (UNII: N'	9XDZ 35W2) (AM dients Q40Q9N063P) F0KO0R) 762921K75)	NHYDROUS DEXTROSE -			10 g in 100 mL
DEXTROSE (UNII: IY UNII:55L0G7ROOK) Inactive Ingre ACETIC ACID (UNII: WATER (UNII: 059Q NITROGEN (UNII: N HYDROCHLORIC A	9XDZ 35W2) (AM dients Q40Q9N063P) F0KO0R) 762921K75)	NHYDROUS DEXTROSE -		DEXTROSE	10 g in 100 mL
DEXTROSE (UNII: IY UNII:55L0G7ROOK) Inactive Ingre ACETIC ACID (UNII: WATER (UNII: 059Q NITROGEN (UNII: N' HYDROCHLORIC A Packaging	9XDZ 35W2) (A dients Q40Q9N063P) F0K00R) F0K00R) 762921K75) CID (UNII: QTT1	NHYDROUS DEXTROSE -	Mai		10 g in 100 mL
DEXTROSE (UNII: IY UNII:55L0G7ROOK) Inactive Ingre ACETIC ACID (UNII: WATER (UNII: 059Q NITROGEN (UNII: 079Q NITROGEN (UNII: N' HYDROCHLORIC A Packaging # Item Code	9XDZ 35W2) (A dients Q40Q9N063P) F0K00R) F0K00R) 762921K75) CID (UNII: QTT1	Ingredient Name	Ma 1 07/15/	CEXTROSE	10 g in 100 mL Strength Marketing End
DEXTROSE (UNII: IY UNII:55L0G7ROOK) Inactive Ingre ACETIC ACID (UNII: WATER (UNII: 059Q NITROGEN (UNII: N' HYDROCHLORIC A Packaging # Item Code 1 NDC:0338-7007- 04	9XDZ 35W2) (A dients Q40Q9N063P) F0K00R) 762921K75) CID (UNII: QTT3 CID (UNII: QTT3 Par 4 in 1 CARTON	Ingredient Name		CEXTROSE	10 g in 100 mL Strength Marketing End
Destrose UNII: FY UNII: 55L0G7ROOK) Inactive Ingre ACETIC ACID (UNII: WATER (UNII: 059Q Initrogen (UNII: 079Q WATER (UNII: 059Q Initrogen (UNII: 079Q NITROGEN (UNII: N'HYDROCHLORIC A Initrogen (UNII: 079Q Packaging Item Code 1 NDC:0338-7007- 01	9XDZ 35W2) (A dients Q40Q9N063P) F0K00R) 762921K75) CID (UNII: QTT1 CID (UNII: QTT1 Par 4 in 1 CARTON 2000 mL in 1 E Product	HYDROUS DEXTROSE - Ingredient Name 17582CB) ckage Description BAG; Type 0: Not a Combination		CEXTROSE	10 g in 100 mL Strength Marketing End
ACETIC ACID (UNII: IY WILLISSLOG7ROOK) ACETIC ACID (UNII: WATER (UNII: 059Q NITROGEN (UNII: 059Q NITROGEN (UNII: 079Q NITROGEN (UNII: 0	9XDZ 35W2) (A dients Q40Q9N063P) FOKOOR) FOKOOR) 762921K75) CID (UNII: QTT1 CID (UNII: QTT1 CID (UNII: QTT1 Product n 1 E Product n 1 E	Ingredient Name Ingredient Nam	07/15/	DEXTROSE	10 g in 100 mL Strength Marketing End Date
DEXTROSE (UNII: IY UNII:55L0G7ROOK) Inactive Ingre ACETIC ACID (UNII: WATER (UNII: 059Q NITROGEN (UNII: 079Q NITROGEN (UNII: 079Q HYDROCHLORIC A Packaging # Item Code 1 NDC:0338-7007- 01	9XDZ 35W2) (A dients Q40Q9N063P) F0KO0R) 762921K75) CID (UNII: QTT3 CID (UNII: QTT3 Pau 4 in 1 CARTON 2000 mL in 1 E Product Informat Applicat	HYDROUS DEXTROSE - Ingredient Name 17582CB) ckage Description BAG; Type 0: Not a Combination	07/15/ Ma	DEXTROSE	10 g in 100 mL Strength Marketing End
DEXTROSE (UNII: Y UNII:55LOG7ROOK)	9XDZ 35W2) (A dients Q40Q9N063P) FOKOOR) FOKOOR) 762921K75) CID (UNII: QTT1 CID (UNII: QTT1 CID (UNII: QTT1 Product n 1 E Product n 1 E	NHYDROUS DEXTROSE - Ingredient Name 17582CB) ckage Description 3AG; Type 0: Not a Combination ion	07/15/ Ma	DEXTROSE	10 g in 100 mL Strength Marketing End Date Marketing End
DEXTROSE (UNII: IY UNII:55LOG7ROOK) Inactive Ingre ACETIC ACID (UNII: WATER (UNII: 059Q NITROGEN (UNII: 079Q NITROGEN (UNII: 0	9XDZ 35W2) (A dients Q40Q9N063P) F0KO0R) 762921K75) CID (UNII: QTT3 CID (UNII: QTT3 Pau 4 in 1 CARTON 2000 mL in 1 E Product Informat Applicat	NHYDROUS DEXTROSE - Ingredient Name 17582CB) ckage Description 3AG; Type 0: Not a Combination ion	07/15/ Ma	DEXTROSE	10 g in 100 mL Strength Marketing End Date Marketing End
DEXTROSE (UNII: IY UNII:55LOG7ROOK) Inactive Ingre ACETIC ACID (UNII: WATER (UNII: 059Q NITROGEN (UNII: 079Q NITROGEN (UNII: 0	9xDZ 35W2) (Ai dients Q40Q9N063P) FOKOOR) 762921K75) CID (UNII: QTT3 Pa 4 in 1 CARTON 2000 mL in 1 E Product Informat Applicat NDA020734 anine, lysine,	NHYDROUS DEXTROSE - Ingredient Name 17582CB) ckage Description 3AG; Type 0: Not a Combination ion	07/15/ Ma 07/1	DEXTROSE	10 g in 100 mL Strength Marketing End Date Marketing End
DEXTROSE (UNII: IY UNII:55LOG7ROOK) Inactive Ingre ACETIC ACID (UNII: WATER (UNII: 059Q NITROGEN (UNII: 079Q NITROGEN (UNII: 0	anine, lysine, arginine, prol	Ingredient Name Ingredient Nam	07/15/ Ma 07/1	DEXTROSE	10 g in 100 mL Strength Marketing End Date Marketing End
DEXTROSE (UNII: IY UNII:55LOG7ROOK) Inactive Ingre ACETIC ACID (UNII: WATER (UNII: 059Q NITROGEN (UNII: 079Q NITROGEN (UNII: 0	anine, lysine, arginine, prol	Ingredient Name Ingredient Nam	07/15/ Mi 07/1 07/1	DEXTROSE	10 g in 100 mL Strength Marketing End Date Marketing End
DEXTROSE (UNII: Y UNII: 55 LOG 7 ROOK) Inactive Ingre ACETIC ACID (UNII: WATER (UNII: 059Q NITROGEN (UNII: 079Q NITROGEN (UNII: 079Q NITROGEN (UNII: 079Q NITROGEN (UNII: 079Q NITROGEN (UNII: 079Q NITROGEN (UNII: 079Q MATERING NDC:0338-7007- 1 NDC:0338-7007- 1 NDC:038-7007- 1 NDC:038-7007- 1 NDC:040- 1 NDC:040-	9XDZ 35W2) (Ai dients Q40Q9N063P) FOKOOR) 762921K75) CID (UNII: QTT3 Pai 4 in 1 CARTON 2000 mL in 1 E Product Informat Applicat NDA020734 anine, lysine, arginine, prol	Ingredient Name Ingredient Name I7582CB) Ingredient Name I7582CB Ingredient Name Ingredient Na	07/15/ Mi 07/1 07/1	DEXTROSE	10 g in 100 mL Strength Marketing End Date Marketing End Date tryptophan,
DEXTROSE (UNII: IY UNII: 55LOG7ROOK) Inactive Ingre ACETIC ACID (UNII: WATER (UNII: 059Q NITROGEN (UNII: 079Q NITROGEN (UNII: 079Q NITROGEN (UNII: 079Q NITROGEN (UNII: 079Q INTROGEN (UNII:	anine, lysine, arginine, prol	Ingredient Name Ingredient Nam	07/15/ Mi 07/1 07/1	DEXTROSE	10 g in 100 mL Strength Marketing End Date Marketing End Date tryptophan,
DEXTROSE (UNII: M UNII:55LOG7ROOK)	9XDZ 35W2) (A) dients Q40Q9N063P) FOKOOR) FOKOOR) FOKOOR FOKOOR CID (UNII: QTT3 Pai 4 in 1 CARTON 2000 mL in 1 E Product Applicat NDA020734 anine, lysine, arginine, prol mation stration ent/Active	Ingredient Name Ingredient Nam	07/15/ Mi 07/1 07/1	DEXTROSE	10 g in 100 mL Strength Marketing End Date Marketing End Date tryptophan,

PHENYLALANINE (UNII: 47E5O17Y3R) (PHENYLALANINE - UNII:47E5O17Y3R)	PHENYLALANINE	280 mg in 100 mL
LYSINE (UNII: K3Z4F929H6) (LYSINE - UNII:K3Z4F929H6)	LYSINE	290 mg in 100 mL
METHIONINE (UNII: AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL)	METHIONINE	200 mg in 100 mL
ISOLEUCINE (UNII: 04Y7590D77) (ISOLEUCINE - UNII:04Y7590D77)	ISOLEUCINE	300 mg in 100 mL
VALINE (UNII: HG18B9YRS7) (VALINE - UNII:HG18B9YRS7)	VALINE	290 mg in 100 mL
HISTIDINE (UNII: 4QD397987E) (HISTIDINE - UNII:4QD397987E)	HISTIDINE	240 mg in 100 mL
THREONINE (UNII: 2ZD004190S) (THREONINE - UNII:2ZD004190S)	THREONINE	210 mg in 100 mL
TRYPTOPHAN (UNII: 8DUH1N11BX) (TRYPTOPHAN - UNII:8DUH1N11BX)	TRYPTOPHAN	90 mg in 100 mL
ALANINE (UNII: OF5P57N2ZX) (ALANINE - UNII:OF5P57N2ZX)	ALANINE	1035 mg in 100 mL
GLYCINE (UNII: TE7660XO1C) (GLYCINE - UNII:TE7660XO1C)	GLYCINE	515 mg in 100 mL
ARGININE (UNII: 94ZLA3W45F) (ARGININE - UNII:94ZLA3W45F)	ARGININE	575 mg in 100 mL
PROLINE (UNII: 9DLQ4CIU6V) (PROLINE - UNII:9DLQ4CIU6V)	PROLINE	340 mg in 100 mL
SERINE (UNII: 452VLY9402) (SERINE - UNII:452VLY9402)	SERINE	250 mg in 100 mL
TYROSINE (UNII: 42HK56048U) (TYROSINE - UNII:42HK56048U)	TYROSINE	20 mg in 100 mL
DEXTROSE (UNII: IY9XDZ 35W2) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE	15 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
ACETIC ACID (UNII: Q40Q9N063P)	
WATER (UNII: 059QF0KO0R)	
NITROGEN (UNII: N762921K75)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:0338-7009- 06	6 in 1 CARTON	07/15/2024				
1	NDC:0338-7009- 01	1000 mL in 1 BAG; Type 0: Not a Combination Product					
Μ	Marketing Information						
	Marketing	Application Number or Monograph	Marketing Start	Marketing End			

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020734	07/15/2024	

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:0338-7011	
Route of Administration	INTRAVENOUS			

Active	Ingredient/Active	Moiety

NITROGEN (UNII: N762921K75) HYDROCHLORIC ACID (UNII: QTT17582CB)

Ingredient Name	Basis of Strength	Strength
LEUCINE (UNII: GMW67QNF9C) (LEUCINE - UNII:GMW67QNF9C)	LEUCINE	365 mg in 100 mL
PHENYLALANINE (UNII: 47E5O17Y3R) (PHENYLALANINE - UNII:47E5O17Y3R)	PHENYLALANINE	280 mg in 100 mL
LYSINE (UNII: K3Z4F929H6) (LYSINE - UNII:K3Z4F929H6)	LYSINE	290 mg in 100 mL
METHIONINE (UNII: AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL)	METHIONINE	200 mg in 100 mL
ISOLEUCINE (UNII: 04Y7590D77) (ISOLEUCINE - UNII:04Y7590D77)	ISOLEUCINE	300 mg in 100 mL
VALINE (UNII: HG18B9YRS7) (VALINE - UNII:HG18B9YRS7)	VALINE	290 mg in 100 mL
HISTIDINE (UNII: 4QD397987E) (HISTIDINE - UNII:4QD397987E)	HISTIDINE	240 mg in 100 mL
THREONINE (UNII: 2Z D004190S) (THREONINE - UNII:2Z D004190S)	THREONINE	210 mg in 100 mL
TRYPTOPHAN (UNII: 8DUH1N11BX) (TRYPTOPHAN - UNII:8DUH1N11BX)	TRYPTOPHAN	90 mg in 100 mL
ALANINE (UNII: OF5P57N2ZX) (ALANINE - UNII:OF5P57N2ZX)	ALANINE	1035 mg in 100 mL
GLYCINE (UNII: TE7660XO1C) (GLYCINE - UNII:TE7660XO1C)	GLYCINE	515 mg in 100 mL
ARGININE (UNII: 94ZLA3W45F) (ARGININE - UNII:94ZLA3W45F)	ARGININE	575 mg in 100 mL
PROLINE (UNII: 9DLQ4CIU6V) (PROLINE - UNII:9DLQ4CIU6V)	PROLINE	340 mg in 100 mL
SERINE (UNII: 452VLY9402) (SERINE - UNII:452VLY9402)	SERINE	250 mg in 100 mL
TYROSINE (UNII: 42HK56048U) (TYROSINE - UNII:42HK56048U)	TYROSINE	20 mg in 100 mL
DEXTROSE (UNII: IY9XDZ 35W2) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE	15 g in 100 mL
Inactive Ingredients		
Ingredient Name		Strength
ACETIC ACID (UNII: Q40Q9N063P)		
WATER (UNII: 059QF0KO0R)		

NDC:0338-7011	Pa	4 in 1 CARTON 07/15/2024			
04					
NDC:0338-7011 01	- 2000 mL in 1 Product	BAG; Type 0: Not a Combination	ו		
.	1	•			
Marketing Marketing		:I ON tion Number or Monogra	h M	larketing Start	Marketing End
Category		Citation		Date	Date
NDA	NDA020734	,	07/:	15/2024	
	•	, methionine, isoleucine, v line, serine, tyrosine, dextr			e, tryptophan,
Product Info	rmation				
Product Type		HUMAN PRESCRIPTION DRUG	lten	n Code (Source)	NDC:0338-7013
Route of Admir		INTRAVENOUS			
Active Ingred		Moiety lient Name		Basis of	Strength
	-	UCINE - UNII:GMW67QNF9C)		Strength LEUCINE	365 mg in 100 mL
		(3R) (PHENYLALANINE - UNII:47E	5017Y3R)		280 mg in 100 mL
		IE - UNII:K3Z4F929H6)		LYSINE	290 mg in 100 mL
		(METHIONINE - UNII:AE28F7PNPL (ISOLEUCINE - UNII:04Y7590D77		METHIONINE ISOLEUCINE	200 mg in 100 mL 300 mg in 100 mL
		NE - UNII:HG18B9YRS7)	,	VALINE	290 mg in 100 mL
HISTIDINE (UNII: 4	QD397987E) (H	ISTIDINE - UNII:4QD397987E)		HISTIDINE	240 mg in 100 mL
		THREONINE - UNII:2Z D004190S		THREONINE	210 mg in 100 mL
		() (TRYPTOPHAN - UNII:8DUH1N1	1BX)	TRYPTOPHAN	90 mg in 100 mL 1035 mg
ALANINE (UNII: OF	in 100 mL				
		CINE - UNII:TE7660XO1C)		GLYCINE	515 mg in 100 mL
		GININE - UNII:94ZLA3W45F) DLINE - UNII:9DLQ4CIU6V)		ARGININE PROLINE	575 mg in 100 mL 340 mg in 100 mL
		IE - UNII:452VLY9402)		SERINE	250 mg in 100 mL
		(ROSINE - UNII:42HK56048U)		TYROSINE	20 mg in 100 mL
UNII:5SL0G7R0OK)	IY9XDZ 35W2) (A	NHYDROUS DEXTROSE -		DEXTROSE	20 g in 100 mL
Inactive Ingr	edients				
		Ingredient Name			Strength
ACETIC ACID (UN WATER (UNII: 059					
NITROGEN (UNII: I					
HYDROCHLORIC	ACID (UNII: QTT	17582CB)			
Packaging					
# Item Code	Pa	ckage Description	Ма	rketing Start Date	Marketing End Date
1 NDC:0338-7013	6 in 1 CARTON	N	07/15	/2024	240
00		BAG; Type 0: Not a Combination	1		
Marketing					
Marketing Category	Applica	tion Number or Monogra Citation	oh M	larketing Start Date	Marketing End Date
	NDA020734		07/	15/2024	
NDA					
NDA					

Product Information					
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0338-7015		
Route of Administration	INTRAVENOUS				

Active Ingredient/Active Moiety

		Ingredient Name	Basis Streng	Strength
LEI	JCINE (UNII: GM)	V67QNF9C) (LEUCINE - UNII:GMW67QNF9C)	LEUCINE	365 mg in 100 m
н	ENYLALANINE (U	INII: 47E5O17Y3R) (PHENYLALANINE - UNII:47E5O1	7Y3R) PHENYLALAN	INE 280 mg in 100 m
YS.	SINE (UNII: K3Z4	F929H6) (LYSINE - UNII:K3Z4F929H6)	LYSINE	290 mg in 100 m
٩E	THIONINE (UNII:	AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL)	METHIONINE	200 mg in 100 m
sc	DLEUCINE (UNII:	ISOLEUCINE	300 mg in 100 m	
/A	LINE (UNII: HG18	B9YRS7) (VALINE - UNII:HG18B9YRS7)	VALINE	290 mg in 100 m
lis	STIDINE (UNII: 40	D397987E) (HISTIDINE - UNII:4QD397987E)	HISTIDINE	240 mg in 100 m
н	REONINE (UNII: 2	ZD004190S) (THREONINE - UNII:2ZD004190S)	THREONINE	210 mg in 100 m
R	YPTOPHAN (UNII	: 8DUH1N11BX) (TRYPTOPHAN - UNII:8DUH1N11B)	() TRYPTOPHAN	90 mg in 100 mL
۱L/	ANINE (UNII: OF5	P57N2ZX) (ALANINE - UNII:OF5P57N2ZX)	ALANINE	1035 mg in 100 mL
SL'	YCINE (UNII: TE7	660XO1C) (GLYCINE - UNII:TE7660XO1C)	GLYCINE	515 mg in 100 m
R	GININE (UNII: 942	ZLA3W45F) (ARGININE - UNII:94ZLA3W45F)	ARGININE	575 mg in 100 m
R	OLINE (UNII: 9DL	Q4CIU6V) (PROLINE - UNII:9DLQ4CIU6V)	PROLINE	340 mg in 100 m
E	RINE (UNII: 452VI	Y9402) (SERINE - UNII:452VLY9402)	SERINE	250 mg in 100 m
Y	ROSINE (UNII: 42	HK56048U) (TYROSINE - UNII:42HK56048U)	TYROSINE	20 mg in 100 mL
	XTROSE (UNII: IY II:5SL0G7R0OK)	9XDZ 35W2) (ANHYDROUS DEXTROSE -	DEXTROSE	20 g in 100 mL
		Q40Q9N063P)		
N # 111 1Y		F0KO0R)		
а и п п Ра	ROGEN (UNII: N DROCHLORIC A	FOKCOR) 762921K75) CID (UNII: QTT17582CB)	Markating St	at Marketing End
∨ <i>А</i> 11 1 1 Ра	ROGEN (UNII: N DROCHLORIC A Inckaging	Pokoor) P62921K75) CID (UNII: QTT17582CB) Package Description	Marketing St Date	art Marketing End Date
₩ ИП НҮ Эа	ROGEN (UNII: N DROCHLORIC A	Pokoor) P62921K75) CID (UNII: QTT17582CB) Package Description		
v # 111 1Y ₽ a	ROGEN (UNII: N DROCHLORIC A Ckaging Item Code NDC:0338-7015- 04	Pokoor) P62921K75) CID (UNII: QTT17582CB) Package Description	Date	
	ROGEN (UNII: N DROCHLORIC A Item Code NDC:0338-7015- 04 NDC:0338-7015- 01	POKOOR) 762921K75) CID (UNII: QTT17582CB) Package Description 4 in 1 CARTON 2000 mL in 1 BAG; Type 0: Not a Combination	Date	
N A NIT HY Pa #	ROGEN (UNII: N DROCHLORIC A Item Code NDC:0338-7015- 04 NDC:0338-7015- 01	Package Description 4 in 1 CARTON 2000 mL in 1 BAG; Type 0: Not a Combination Product	Date	Date

Labeler - Baxter Healthcare Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		189326168	ANALYSIS(0338-1133, 0338-1089, 0338-1134, 0338-1091, 0338-1137, 0338-1099, 0338-1138, 0338-1101), MANUFACTURE(0338-1133, 0338-1089, 0338-1137, 0338-1099, 0338-1138, 0338-1101, LBEL(0338-1133, 0338-1089, 0338-1134, 0338-1099, 0338-1137, 0338-1099, 0338-1138, 0338-1101), PACK(0338-1131, 0338-1099, 0338-1134, 0338-1099, 0338-1134, 0338-1101), STRULY (0338-1131, 0338-1099, 0338-1134, 0338-1101), STRULY (0338-1131, 0338-1091, 0338-1134, 0338-1101), I348, 0338-1101), STRULY (0338-1133, 0338-1134, 0338-1101), 0338-1134, 0338-1131, 0338-1133, 0338-1134, 0338-1101), I347, 0338-1134, 0338-1134, 0338-1101), STRULY (0338-1134, 0338-1101), I347, 0338-1099, 0338-1134, 0338-1101), I347, 0338-1099, 0338-1134, 0338-1101), I347, 0338-1099, 0338-1134, 0338-1101), I348, 0338-1101, I348, 0338-1101), I348, 0338-1101, I348, 0338-1101), I348, 0338-1101, I348, 0338-1101, I348, 0338-1101, I348, 0338-1101), I348, 0338-1101, I348, 0338-1101, I348, 0338-1101, I348, 0338-1101), I348, 0338-1101, I348, 0338-1101, I348, 0338-1101), I348, 0338-1134, 0338-1101, I348, 0338, I348, 0338, I348, 0338-1101, I348, 0338, I348, 0388, I348, 0338, I348, 0338, I348, 0338, I348, 0338, I348, 0388, I348

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		194684502	ANALYSIS(0338-1133, 0338-1089, 0338-1134, 0338-1091, 0338-1137, 0338-1099, 0338-1138, 0338-1101)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation			ANALYSIS(0338-1133, 0338-1089, 0338-1134, 0338-1091, 0338-1137, 0338-1099, 0338-1138, 0338-1101), MANUFACTURE(0338-1133, 0338-1089, 0338-1137, 0338-1099, 0338-1138, 0338-1139, 0338-1131, 0338-1131, 0338-1131, 0338-1131, 0338-1131, 0338-1131, 0338-1131, 0338-1131, 0338-1139, 0338-1131, 0338-1091, 0338-1131, 0338-1091, 0338-1131, 0338-1091, 0338-1131, 0338-1091, 0338-1131, 0338-1091, 0338-1131, 0338-1091, 0338-1131, 0338-1091, 0338-1131, 0338-1091, 0338-1131, 0338-1091, 0338-1131, 0338-1031,

Establishment

Name	Address	ID/FEI	Business Operations
Baxter SA		370353835	ANALYSIS(0338-0198, 0338-0188, 0338-0194, 0338-0180, 0338-0184, 0338-7001, 0338- 7003, 0338-7005, 0338-7007, 0338-7009, 0338-7011, 0338-7013, 0338-7015), MANUFACTURE(0338-0198, 0338-0188, 0338-0194, 0338-0180, 0338-0184, 0338-7001, 0338-7003, 0338-7005, 0338-7007, 0338-7009, 0338-7011, 0338-7013, 0338-7015), LABEL(0338-0198, 0338-0188, 0338-0194, 0338-0180, 0338-1014, 0338-7001, 0338- 7003, 0338-7005, 0338-7007, 0338-709, 0338-7011, 0338-7013, 0338-7001, 0338- 7003, 0338-7005, 0338-7007, 0338-7099, 0338-7011, 0338-7013, 0338-7015), STERILIZE(0338-0198, 0338-7007, 0338-7094, 0338-7011, 0338-7013, 0338-7015), STERILIZE(0338-705, 0338-7007, 0338-7094, 0338-7011, 0338-7013, 0338-7015), STERILIZE(0338-705, 0338-7007, 0338-7099, 0338-7011, 0338-7013, 0338-7015),

Baxter Healthcare Corporation