PLENAMINE- lysine acetate, leucine, phenylalanine, valine, isoleucine, methionine, threonine, tryptophan, alanine, arginine, glycine, histidine, proline, glutamic acid, serine, aspartic acid, and tyrosine solution
B. Braun Medical Inc.

Plenamine™
15% Amino Acids Injection

Package Insert

PHARMACY BULK PACKAGE
NOT FOR DIRECT INFUSION

Protect from light until use.

DESCRIPTION

Plenamine™ 15% Amino Acids Injection in a Pharmacy Bulk Package is a sterile, clear, nonpyrogenic solution of essential and nonessential amino acids for intravenous infusion in parenteral nutrition following appropriate dilution.

Plenamine™ 15% in a Pharmacy Bulk Package is not for direct infusion. It is a sterile dosage form which contains several single doses for use in a pharmacy admixture program in the preparation of intravenous parenteral fluids.

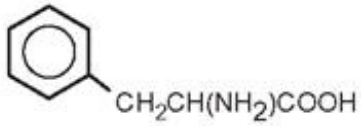
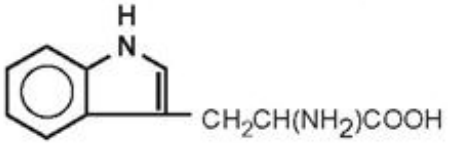
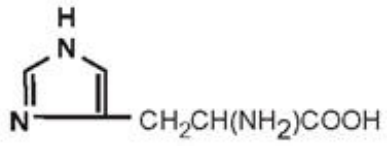
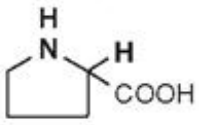
Each 100 mL contains:

Essential Amino Acids		
Lysine (from Lysine Acetate, USP)	1.18	g
Leucine, USP	1.04	g
Phenylalanine, USP	1.04	g
Valine, USP	960	mg
Isoleucine, USP	749	mg
Methionine, USP	749	mg
Threonine, USP	749	mg
Tryptophan, USP	250	mg
Nonessential Amino Acids		
Alanine, USP	2.17	g
Arginine, USP	1.47	g
Glycine, USP	1.04	g
Histidine, USP	894	mg
Proline, USP	894	mg
Glutamic Acid	749	mg
Serine, USP	592	mg
Aspartic Acid, USP	434	mg
Tyrosine, USP	39	mg

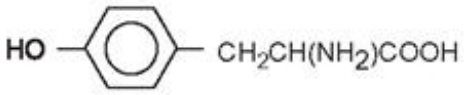
Water for Injection, USP		qs
Essential Amino Acids	6.7	g
Nonessential Amino Acids	8.3	g
Total Amino Acids	15.0	g
Total Nitrogen	2.37	g
Acetate*	147.4	mEq/L
Osmolarity (calculated)	1378	mOsmol/L
pH 5.6 (5.2–6.0)		

* Acetate from Lysine Acetate, USP and acetic acid used for pH adjustment.

The formulas for the individual amino acids are as follows:

Essential Amino Acids	
Lysine Acetate	$H_2N(CH_2)_4CH(NH_2)COOH \bullet CH_3COOH$
Leucine	$(CH_3)_2CHCH_2CH(NH_2)COOH$
Phenylalanine	
Valine	$(CH_3)_2CHCH(NH_2)COOH$
Isoleucine	$CH_3CH_2CH(CH_3)CH(NH_2)COOH$
Methionine	$CH_3S(CH_2)_2CH(NH_2)COOH$
Threonine	$CH_3CH(OH)CH(NH_2)COOH$
Tryptophan	
Nonessential Amino Acids	
Alanine	$CH_3CH(NH_2)COOH$
Arginine	$H_2NC(NH)NH(CH_2)_3CH(NH_2)COOH$
Glycine	H_2NCH_2COOH
Histidine	
Proline	
Glutamic Acid	$HOOC(CH_2)_2CH(NH_2)COOH$
Serine	$HOCH_2CH(NH_2)COOH$
Aspartic Acid	$HOOCCH_2CH(NH_2)COOH$

Tyrosine



CLINICAL PHARMACOLOGY

Plenamine™ 15% Amino Acids Injection provides seventeen crystalline amino acids. This completely utilizable substrate promotes protein synthesis and wound healing and reduces the rate of protein catabolism.

A. Total Parenteral Nutrition (Central Infusion)

When enteral feeding is inadvisable, Plenamine™ 15% given by central venous infusion in combination with energy sources, vitamins, trace elements and electrolytes, will completely satisfy the requirements for weight maintenance or weight gain, depending upon the dose selected. The energy component in parenteral nutrition by central infusion may be derived solely from dextrose or may be provided by a combination of dextrose and intravenous fat emulsion. The addition of intravenous fat emulsion provides essential fatty acids and permits a dietary balance of fat and carbohydrate, at the same time offering the option of reducing the dextrose load and/or increasing the total caloric input. An adequate energy supply is essential for optimal utilization of amino acids.

B. Total Parenteral Nutrition (Peripheral Infusion)

Plenamine™ 15% can also be administered as part of a total parenteral nutrition program by peripheral vein when the enteral route is inadvisable and use of the central venous catheter is contraindicated.

Reduction of protein loss can be achieved by use of diluted Plenamine™ 15% in combination with dextrose or with dextrose and intravenous fat emulsion by peripheral infusion. Complete peripheral intravenous nutrition can be achieved in patients with low caloric requirements by a Plenamine™ 15% dextrose-fat regimen.

INDICATIONS AND USAGE

Plenamine™ 15% is indicated as an amino acid (nitrogen) source in parenteral nutrition regimens. This use is appropriate when the enteral route is inadvisable, inadequate or not possible, as when:

— Gastrointestinal absorption is impaired by obstruction, inflammatory disease or its complications, or antineoplastic therapy;

— Bowel rest is needed because of gastrointestinal surgery or its complications such as ileus, fistulae or anastomotic leaks;

— Tube feeding methods alone cannot provide adequate nutrition.

CONTRAINDICATIONS

This solution should not be used in patients in hepatic coma, severe renal failure,

metabolic disorders involving impaired nitrogen utilization or hypersensitivity to one or more amino acids.

WARNINGS

Administration of amino acids solutions at excessive rates or to patients with hepatic insufficiency may result in plasma amino acid imbalances, hyperammonemia, prerenal azotemia, stupor and coma. Conservative doses of amino acids should be given to these patients, dictated by the nutritional status of the patient. Should symptoms of hyperammonemia develop, amino acid administration should be discontinued and the patient's clinical status re-evaluated.

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, 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.

PRECAUTIONS

A. General

It is essential to provide adequate calories concurrently if parenterally administered amino acids are to be retained by the body and utilized for protein synthesis.

The administration of Plenamine™ 15% Amino Acids Injection as part of total parenteral nutrition (TPN) with large volumes of hyperosmotic fluids requires periodic monitoring of the patient for signs of hyperosmolarity, hyperglycemia, glycosuria and hypertriglyceridemia.

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

For complete nutritional support, TPN regimens must also include multiple vitamins and trace elements. Potentially incompatible ions such as calcium and phosphate may be added to alternate infusate bottles to avoid precipitation. Although the metabolizable acetate ion in Plenamine™ 15% diminishes the risk of acidosis, the physician must be alert to the potential appearance of this disorder.

Initiation and termination of infusions of TPN fluids must be gradual to permit adjustment of endogenous insulin release.

Undiluted Plenamine™ 15% should not be administered peripherally. When administered centrally, it should be diluted with appropriate diluents, e.g., dextrose, electrolytes and other nutrient components, to at least half strength. (See **DOSAGE AND**

ADMINISTRATION.)

Caution against volume overload should be exercised.

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

B. Laboratory Tests

Infusion of Plenamine™ 15% without concomitant infusion of an adequate number of non-protein calories may result in elevated BUN. Monitoring of BUN is required and the balance between Plenamine™ 15% and the calorie source may require adjustment. Frequent clinical evaluations and laboratory determinations are required to prevent the complications which may occur during the administration of solutions used in TPN. Laboratory tests should include blood glucose, serum electrolytes, liver and kidney function, serum osmolarity, blood ammonia, serum protein, pH, hematocrit, WBC and urinary glucose. When Plenamine™ 15% is combined with electrolytes, care should be used in administering this solution to patients with congestive heart failure, renal failure, edema, adrenal hyperactivity, acid-base imbalance and those receiving diuretics or antihypertensive therapy. Total volume infused should be closely monitored. Serum electrolytes should be monitored daily in these patients.

C. Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies with Plenamine™ 15% have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

D. Pregnancy Category C

Animal reproduction studies have not been conducted with Plenamine™ 15%. It is also not known whether Plenamine™ 15% can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Plenamine™ 15% should be given to a pregnant woman only if clearly needed.

E. Nursing Mothers

Caution should be exercised when Plenamine™ 15% is administered to a nursing woman.

F. Pediatric Use

Safety and effectiveness of Plenamine™ 15% Amino Acids Injection in pediatric patients have not been established by adequate and well-controlled studies. However, the use of amino acids injections in pediatric patients as an adjunct in the offsetting of nitrogen loss or in the treatment of negative nitrogen balance is referenced in the medical literature.

G. Special Precautions for Central Infusion

TPN delivered by indwelling catheter through a central or large peripheral vein is a special technique requiring a team effort by physician, nurse and pharmacist. The responsibility for administering this therapy should be confined to those trained in the procedures and alert to signs of complications. Complications known to occur from the placement of central venous catheter are pneumothorax, hemothorax, hydrothorax, artery puncture and transection, injury to the brachial plexus, malposition of the catheter, formation of arteriovenous fistula, phlebitis, thrombosis, and air/catheter emboli. The risk of sepsis is

present during intravenous therapy, especially when using central venous catheters for prolonged periods. It is imperative that the preparation of admixtures and the placement and care of the catheters be accomplished under controlled aseptic conditions.

H. Admixtures

Admixtures should be prepared under a laminar flow hood using aseptic technique.

Admixtures should be stored under refrigeration and must be administered within 24 hours after removal from refrigerator.

Filters of less than 1.2 micron pore size must not be used with admixtures containing lipid emulsion.

I. Use only if bag and seal are undamaged and solution is clear.

IT IS ESSENTIAL THAT A CAREFULLY PREPARED PROTOCOL, BASED ON CURRENT MEDICAL PRACTICES, BE FOLLOWED, PREFERABLY BY AN EXPERIENCED TEAM.

ADVERSE REACTIONS

(See **WARNINGS, PRECAUTIONS** and **Special Precautions for Central Infusion**.)

OVERDOSAGE

In the event of overhydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. (See **WARNINGS** and **PRECAUTIONS**.)

DOSAGE AND ADMINISTRATION

The appropriate daily dose of amino acids to be used with dextrose or with dextrose and intravenous fat emulsion will depend upon the metabolic status and clinical response of the patient as therapy proceeds. Doses which achieve nitrogen equilibrium or positive balance are the most desirable. The dosage on the first day should be approximately half the anticipated optimal dosage and should be increased gradually to minimize glycosuria; similarly, withdrawal should be accomplished gradually to avoid rebound hypoglycemia.

Fat emulsion coadministration should be considered when prolonged (more than 5 days) parenteral nutrition is required in order to prevent essential fatty acid deficiency (EFAD). Serum lipids should be monitored for evidence of EFAD in patients maintained on fat free TPN.

The amount administered is dosed on the basis of amino acids/kg of body weight/day. In general, two to three g/kg of body weight for neonates and infants with adequate calories are sufficient to satisfy protein needs and promote positive nitrogen balance. In pediatric patients, the final solution should not exceed twice normal serum osmolarity (718 mOsmol/L).

DIRECTIONS FOR PROPER USE OF PHARMACY BULK PACKAGE

Plenamine™ 15% in a Pharmacy Bulk Package is not intended for direct infusion. The container closure may be penetrated only once using a suitable unvented sterile transfer

device or dispensing set which allows measured dispensing of the contents. The Pharmacy Bulk Package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area). Once the closure is penetrated, the contents should be dispensed as soon as possible; the transfer of contents must be completed within 4 hours of closure entry. The bag may be stored at room temperature (25°C) after the closure has been entered.

When using Plenamine™ 15% in patients with a need for fluid volume restriction, it can be diluted as follows:

	Volume	Amount	Final Concentration
Plenamine™ 15%	500 mL	75 g	7.5%
Dextrose 70%	250 mL	175 g	17.5%
Intralipid® 20%	250 mL	50 g	5.0%

This will provide 1395 kilocalories (kcal) per 1000 mL of admixture with a ratio of 118 non-protein calories per gram of nitrogen and an osmolarity of 1559 mOsmol/L.

In patients where the need for fluid restriction is not so marked, either of the following regimens may be used dependent upon the energy needs of the patient.

	Volume	Amount	Final Concentration
Plenamine™ 15%	500 mL	75 g	3.75%
Dextrose 50%	1000 mL	500 g	25%
Intralipid® 20%	500 mL	100 g	5%

This will provide 1500 kcal per 1000 mL of admixture with a ratio of 228 non-protein calories per gram of nitrogen and an osmolarity of 1631 mOsmol/L.

	Volume	Amount	Final Concentration
Plenamine™ 15%	500 mL	75 g	3.75%
Dextrose 30%	1000 mL	300 g	15%
Intralipid® 10%	500 mL	50 g	2.5%

This will provide 935 kcal per 1000 mL of admixture with a ratio of 158 non-protein calories per gram of nitrogen and an osmolarity of 1126 mOsmol/L.

A. Total Parenteral Nutrition (Central Infusion)

In unstressed adult patients with no unusual nitrogen losses, a minimum dosage of 0.1 gram nitrogen (4.2 mL of Plenamine™ 15%) plus 4.4 grams (15 calories) of dextrose per kilogram of body weight per day are required to achieve nitrogen balance and weight stability. Intravenous fat emulsion may be used as a partial substitute for dextrose. This regimen provides a ratio of 150 non-protein calories per gram of nitrogen.

For patients stressed by surgery, trauma or sepsis, and those with unusual nitrogen losses, the dosage required for maintenance may be as high as 0.3 to 0.4 grams of nitrogen (13 to 17 mL Plenamine™ 15%) per kilogram of body weight per day, with

proportionate increases in non-protein calories. Periodic assessment of nitrogen balance of the individual patient is the best indicator of proper dosage. Volume overload and glycosuria may be encountered at high dosage, and nitrogen balance may not be achieved in extremely hypermetabolic patients under these constraints. Concomitant insulin administration may be required to minimize glycosuria. Daily laboratory monitoring is essential.

Use of an infusion pump is advisable to maintain a steady infusion rate during central venous infusion.

B. Peripheral Nutrition

In patients for whom central venous catheterization is not advisable, protein catabolism can be reduced by peripheral use of diluted Plenamine™ 15% plus non-protein calorie sources. Dilution of 250 mL Plenamine™ 15% in 750 mL of 10% dextrose will reduce the osmolarity to a level (724 mOsmol/L) which is more favorable to the maintenance of the integrity of the walls of the veins. Intravenous fat emulsion can be infused separately or simultaneously; if infused simultaneously the fat emulsion will provide a dilution effect upon the osmolarity while increasing the energy supply.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

To reduce the risk of bacterial contamination, all intravenous administration sets should be replaced at least every 24 hours. Usage of admixtures must be initiated within 24 hours after mixing. If storage is necessary during this 24 hour period, admixtures must be refrigerated and completely used within 24 hours of beginning administration.

HOW SUPPLIED

Plenamine™ 15% Amino Acids Injection is supplied sterile and nonpyrogenic in flexible plastic bags, Pharmacy Bulk Packages, 1000 mL packaged 8 per case and 2000 mL packaged 4 per case.

NDC	REF	Size
0264-4500-05	S4505	2000 mL
0264-4500-00	S4500	1000 mL

Not made with natural rubber latex, DEHP or PVC.

Storage

Store in the closed corrugated case; do not expose solution to light until ready for use. Do not remove container from overwrap until ready to use. Do not use if overwrap has been opened or damaged. Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended that the product be stored at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Brief exposure to temperatures above 25°C during transport and storage will not adversely affect the product. Solution that has been frozen must not be used.

Rx only

Intralipid is a registered trademark of Fresenius Kabi AB.

Preparation Instructions for Plenamine™ 15% Bags for Direct Infusion

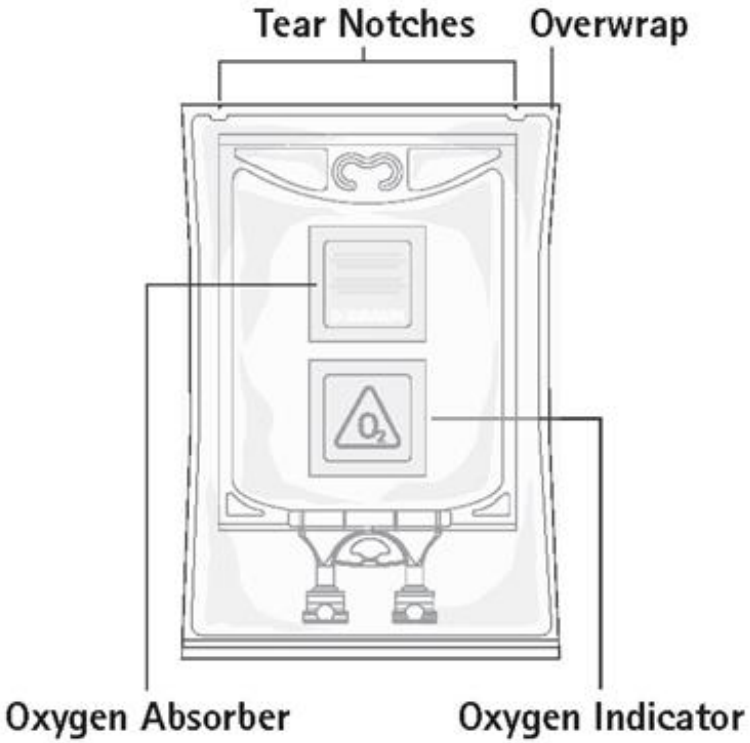
Caution: Plenamine™ 15% Pharmacy Bulk Package is not intended for direct intravenous administration.

The pharmacy bulk package is for use in a Pharmacy Admixture Service only. Use of this product is restricted to a suitable work area, such as a laminar flow hood (or an equivalent clean air compounding area).

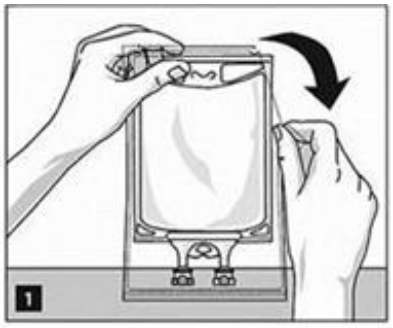
Additives should not be made to Pharmacy Bulk Packages.

Designed for use with an unvented sterile dispensing set.

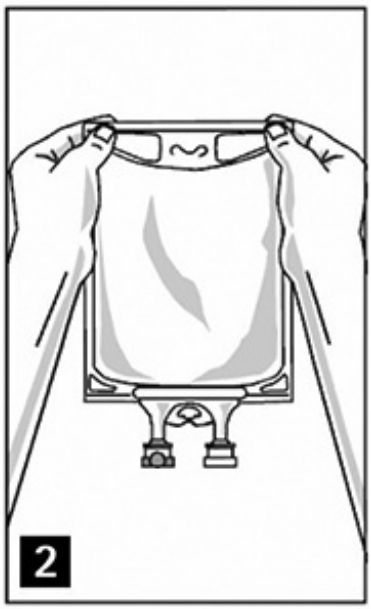
Step 1: Inspect Pharmacy Bulk Package overwrap and primary bag and do not use if damaged. Inspect oxygen indicator and do not use if oxygen indicator is pink or dark pink. Use only if container and seals are intact.



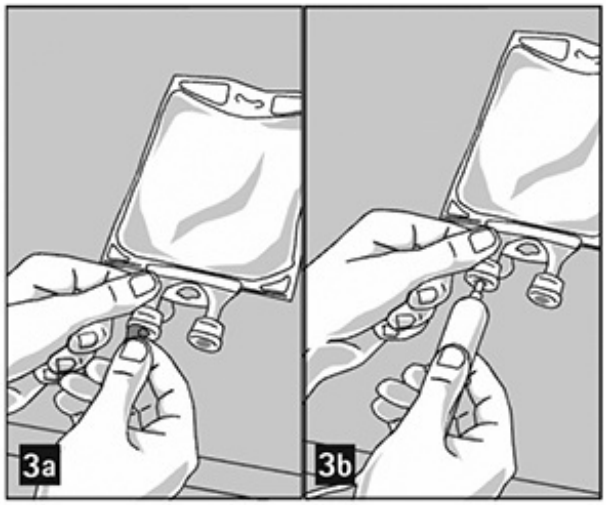
Step 2: To open, tear overwrap starting from the tear notches (Figure 1). Remove Plenamine™ 15% Pharmacy Bulk Package bag from overwrap and discard oxygen indicator, oxygen absorber and overwrap.



Step 3: Inspect Plenamine™ 15% Pharmacy Bulk Package bag visually (Figure 2). Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Inspect Plenamine™ 15% for cloudiness, haze or particulate matter in good lighting. Discard the bag if any particulates or discoloration are observed.



Step 4: Remove aluminum foil of outlet port at the bottom of the Pharmacy Bulk Package bag (Figure 3a) and attach an unvented sterile dispensing set (Figure 3b).



The container closure may be penetrated only one time, utilizing a suitable sterile dispensing set which allows measured dispensing of the contents.

The withdrawal of container contents should be accomplished without delay using aseptic technique. Discard container no later than 4 hours after initial closure puncture.

Use of a syringe with needle is not recommended. Multiple entries increase the potential of the microbial and particulate contamination.

B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862
Made in Germany

Revised: October 2019

LD-537-2

PRINCIPAL DISPLAY PANEL - 1000 mL Bag Label

857/12624147/0118

NDC 0264-4500-00
REF S4500

LOT
EXP:
SN:

Plenamine™
15% Amino Acids Injection

1000 mL

PHARMACY BULK PACKAGE -
NOT FOR DIRECT INFUSION

Protect from light until use.

For Intravenous Use

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Solution that has been frozen must not be used.
Do not expose to light before using. Once closure is penetrated, transfer contents promptly, total time not to exceed 4 hours.
See package insert for proper use of Pharmacy Bulk Package.

Affix accompanying label
for date and time of entry

Each 100 mL contains:

Essential Amino Acids	
Lysine (from Lysine Acetate, USP)	1.18 g
Leucine, USP	1.04 g
Phenylalanine, USP	1.04 g
Valine, USP	960 mg
Isoleucine, USP	749 mg
Methionine, USP	749 mg
Threonine, USP	749 mg
Tryptophan, USP	250 mg
Nonessential Amino Acids	
Alanine, USP	2.17 g
Arginine, USP	1.47 g
Glycine, USP	1.04 g
Histidine, USP	894 mg
Proline, USP	894 mg
Glutamic Acid	749 mg
Serine, USP	592 mg
Aspartic Acid, USP	434 mg
Tyrosine, USP	39 mg
Water for Injection USP	qs

pH 5.6 (5.2-6.0),
adjusted with acetic acid.

Acetate: 147.4 mEq/L, including quantity used for pH adjustment.

Calculated Osmolarity: 1378 mOsmol/L
Contains no more than 25 mcg/L of aluminum.
Sterile, nonpyrogenic.

Single dose container. Use only if bag and seal are undamaged and solution is clear.
Do not remove container from overwrap until ready for use. Do not use if overwrap has been opened or damaged.
Administer intravenously.

Not made with natural rubber latex, DEHP or PVC.

Rx only

B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862
Made in Germany

LD-558-1

SET

PRINCIPAL DISPLAY PANEL - Accompanying 1000 mL and 2000 mL Bag Label

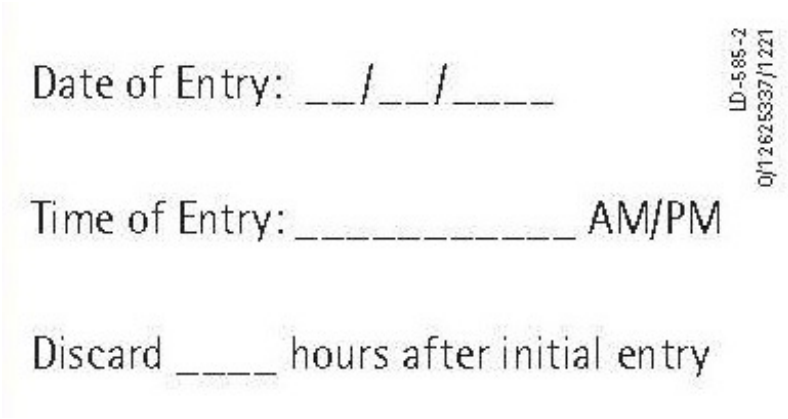
Date of Entry:___/____/_____

Time of Entry:_____AM/PM

Discard_____hours after initial entry

LD-585-2

0/12625337/1221



PRINCIPAL DISPLAY PANEL - 2000 mL Bag Label

857/12627286/0619

NDC 0264-4500-05
REF S4505

LOT
EXP:
SN:

Plenamine™
15% Amino Acids Injection

2000 mL

PHARMACY BULK PACKAGE -
NOT FOR DIRECT INFUSION

Protect from light until use.
For Intravenous Use

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]
Solution that has been frozen must not be used.
Do not expose to light before using. Once closure is penetrated, transfer contents promptly, total time not to exceed 4 hours.
See package insert for proper use of Pharmacy Bulk Package.

Affix accompanying label for date and time of entry

Each 100 mL contains:

Essential Amino Acids	
Lysine (from Lysine Acetate, USP)	1.18 g
Leucine, USP	1.04 g

Phenylalanine, USP	1.04 g
Valine, USP	960 mg
Isoleucine, USP	749 mg
Methionine, USP	749 mg
Threonine, USP	749 mg
Tryptophan, USP	250 mg
Nonessential AminoAcids	
Alanine, USP	2.17 g
Arginine, USP	1.47 g
Glycine, USP	1.04 g
Histidine, USP	894 mg
Proline, USP	894 mg
Glutamic Acid	749 mg
Serine, USP	592 mg
Aspartic Acid, USP	434 mg
Tyrosine, USP	39 mg
Water for Injection USP	qs

pH 5.6 (5.2-6.0),
adjusted with acetic acid.

Acetate: 147.4 mEq/L, including quantity used for pH adjustment.

Calculated Osmolarity: 1378 mOsmol/L
Contains no more than 25 mcg/L of aluminum.

Sterile, nonpyrogenic. Single dose container. Use only if bag and seal are undamaged and solution is clear.
Do not remove container from overwrap until ready to use. Do not use if overwrap has been opened or damaged.
Administer intravenously.

Not made with natural rubber latex, DEHP or PVC.

Rx only

B. Braun Medical Inc.

Bethlehem, PA 18018-3524 USA
1-800-227-2862
Made in Germany

LD-633-1

SET

857/12627286/0619

REF S4505
NDC 0264-4500-05

BARCODE

LOT
EXP:
SN:

Plenamine™
15% Amino Acids Injection

2000 mL

PHARMACY BULK PACKAGE - NOT FOR DIRECT INFUSION

1500 mL

Protect from light until use.
For Intravenous Use
Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]
Solution that has been frozen must not be used.
Do not expose to light before using. Once closure is penetrated, transfer contents promptly, total time not to exceed 4 hours.
See package insert for proper use of Pharmacy Bulk Package.

1000 mL

Affix accompanying label for date and time of entry

Each 100 mL contains:

Essential Amino Acids	
Lysine (from Lysine Acetate, USP)	1.18 g
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Valine, USP	960 mg
Isoleucine, USP	749 mg
Methionine, USP	749 mg
Threonine, USP	749 mg

Nonessential Amino Acids	
Alanine, USP	2.17 g
Arginine, USP	1.47 g
Glycine, USP	1.04 g
Histidine, USP	894 mg
Proline, USP	894 mg
Glutamic Acid	749 mg
Serine, USP	592 mg
Aspartic Acid, USP	434 mg
Tyrosine, USP	39 mg
Water for Injection USP	qs

pH 5.6 (5.2-6.0), adjusted with acetic acid.

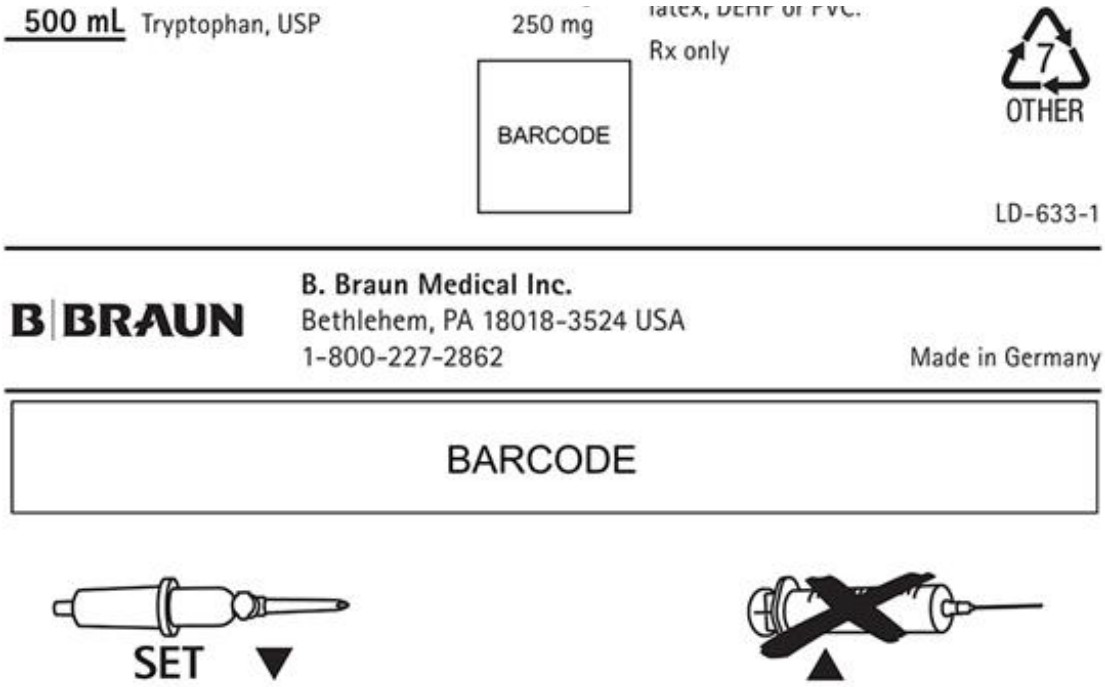
Acetate: 147.4 mEq/L, including quantity used for pH adjustment.

Calculated Osmolarity: 1378 mOsmol/L

Contains no more than 25 mcg/L of aluminum.

Sterile, nonpyrogenic. Single dose container. Use only if bag and seal are undamaged and solution is clear.
Do not remove container from overwrap until ready to use. Do not use if overwrap has been opened or damaged.
Administer intravenously.

Not made with natural rubber latex, DEHP or PVC



PLENAMINE

lysine acetate, leucine, phenylalanine, valine, isoleucine, methionine, threonine, tryptophan, alanine, arginine, glycine, histidine, proline, glutamic acid, serine, aspartic acid, and tyrosine solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0264-4500
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LYSINE ACETATE (UNII: TTL6G7LIWZ) (LYSINE - UNII:K3Z4F929H6)	LYSINE	1.18 g in 100 mL
LEUCINE (UNII: GMW67QNF9C) (LEUCINE - UNII:GMW67QNF9C)	LEUCINE	1.04 g in 100 mL
PHENYLALANINE (UNII: 47E5O17Y3R) (PHENYLALANINE - UNII:47E5O17Y3R)	PHENYLALANINE	1.04 g in 100 mL
VALINE (UNII: HG18B9YRS7) (VALINE - UNII:HG18B9YRS7)	VALINE	960 mg in 100 mL
ISOLEUCINE (UNII: 04Y7590D77) (ISOLEUCINE - UNII:04Y7590D77)	ISOLEUCINE	749 mg in 100 mL
METHIONINE (UNII: AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL)	METHIONINE	749 mg in 100 mL
THREONINE (UNII: 2ZD004190S) (THREONINE - UNII:2ZD004190S)	THREONINE	749 mg in 100 mL
TRYPTOPHAN (UNII: 8DUH1N11BX) (TRYPTOPHAN - UNII:8DUH1N11BX)	TRYPTOPHAN	250 mg in 100 mL
ALANINE (UNII: OF5P57N2ZX) (ALANINE - UNII:OF5P57N2ZX)	ALANINE	2.17 g in 100 mL
ARGININE (UNII: 94ZLA3W45F) (ARGININE - UNII:94ZLA3W45F)	ARGININE	1.47 g in 100 mL
GLYCINE (UNII: TE7660XO1C) (GLYCINE - UNII:TE7660XO1C)	GLYCINE	1.04 g in 100 mL
HISTIDINE (UNII: 4QD397987E) (HISTIDINE - UNII:4QD397987E)	HISTIDINE	894 mg in 100 mL
PROLINE (UNII: 9DLQ4CIU6V) (PROLINE - UNII:9DLQ4CIU6V)	PROLINE	894 mg in 100 mL
GLUTAMIC ACID (UNII: 3KX376GY7L) (GLUTAMIC ACID - UNII:3KX376GY7L)	GLUTAMIC ACID	749 mg in 100 mL
SERINE (UNII: 452VLY9402) (SERINE - UNII:452VLY9402)	SERINE	592 mg in 100 mL
ASPARTIC ACID (UNII: 30KYC7MIAI) (ASPARTIC ACID - UNII:30KYC7MIAI)	ASPARTIC ACID	434 mg in 100 mL

TYROSINE (UNII: 42HK56048U) (TYROSINE - UNII:42HK56048U)	TYROSINE	39 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ACETIC ACID (UNII: Q40Q9N063P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0264-4500-00	8 in 1 CASE	09/28/2018	
1		1000 mL in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:0264-4500-05	4 in 1 CASE	10/29/2019	
2		2000 mL in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091112	09/28/2018	

Labeler - B. Braun Medical Inc. (002397347)

Revised: 4/2023 B. Braun Medical Inc.