AMINOSYN-PF- isoleucine, leucine, lysine acetate, methionine, phenylalanine, threonine, tryptophan, valine, alanine, arginine, aspartic acid, glutamic acid, glycine, histidine, proline, serine, taurine and tyrosine injection, solution
Hospira, Inc.

Aminosyn® -PF 7%
Sulfite-Free

AN AMINO ACID INJECTION - PEDIATRIC FORMULA

Flexible Plastic Container

Rx only

DESCRIPTION

Aminosyn®-PF 7%, Sulfite-Free, (an amino acid injection — pediatric formula) is a sterile, nonpyrogenic solution for intravenous infusion. Aminosyn®-PF 7% is oxygen sensitive. The formulation is described below:

Aminosyn-PF 7% An Amino Acid Injection — Pediatric Formula	
Essential Amino Acids (mg/100 mL)	
Isoleucine	534
Leucine	831
Lysine (acetate)*	475
Methionine	125
Phenylalanine	300
Threonine	360
Tryptophan	125
Valine	452

* Amount cited is for lysine alone and does not include the acetate salt.

Nonessential Amino Acids (mg/100 mL)	
Alanine	490
Arginine	861
L-Aspartic Acid	370
L-Glutamic Acid	576
Glycine	270
Histidine	220
Proline	570
Serine	347
Taurine	50
Tyrosine	44

Electrolytes (mEq/L)	
Sodium (Na^+) (mEq/L)	None
Potassium (K^+) (mEq/L)	None

Chloride (Cl^-) (mEq/L)	None
Acetate ($C_2H_3O_2^-$)[a] (mEq/L)	32.5

[a] From lysine acetate.

Product Characteristics	
Protein Equivalent (Approx. grams/L)	70
Total Nitrogen (grams/L)	10.69
Osmolarity (mOsmol/L)	561
pH (range)	5.5 (5.0 to 6.5)

The formulas for the individual amino acids present in Aminosyn-PF 7% are as follows:

Essential Amino Acids	
Isoleucine, USP	$C_6H_{13}NO_2$
Leucine, USP	$C_6H_{13}NO_2$
Lysine Acetate, USP	$C_6H_{14}N_2O_2 \bullet CH_3COOH$
Methionine, USP	$C_5H_{11}NO_2S$
Phenylalanine, USP	$C_9H_{11}NO_2$
Threonine, USP	$C_4H_9NO_3$
Tryptophan, USP	$C_{11}H_{12}N_2O_2$
Valine, USP	$C_5H_{11}NO_2$

Nonessential Amino Acids	
Alanine, USP	$C_3H_7NO_2$
Glycine, USP	$C_2H_5NO_2$
Arginine, USP	$C_6H_{14}N_4O_2$
L-Aspartic Acid	$C_4H_7NO_4$
	$HO_2CCH_2CH(NH_2)CO_2H$
L-Glutamic Acid	$C_5H_9NO_4$
	$HO_2CCH_2CHCH(NH_2)CO_2H$
Histidine, USP	$C_6H_9N_3O_2$
Proline, USP	$C_5H_9NO_2$
Serine, USP	$C_3H_7NO_3$
Taurine	$C_2H_7NO_3S$
Tyrosine, USP	$C_9H_{11}NO_3$

The flexible plastic container is fabricated from a specially formulated polyvinylchloride. Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly.

Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials.

Exposure to temperatures above 25°C/77°F during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period.

CLINICAL PHARMACOLOGY

Aminosyn-PF 7% Sulfite-Free, (an amino acid injection — pediatric formula) contains a mixture of essential and nonessential amino acids as well as taurine. The amino acid composition has been specifically formulated to provide a well-tolerated nitrogen source for nutritional support and therapy for infants and young children. When administered in conjunction with a cysteine hydrochloride additive, Aminosyn-PF 7% results in plasma amino acid concentrations approximating a profile consistent with that of a breast-fed infant.

The rationale for Aminosyn-PF 7% is based on the observation of inadequate levels of essential amino acids in the plasma of infants receiving total parenteral nutrition (TPN) using conventional amino acid solutions.

Clinical studies in infants who required TPN therapy showed that infusion of Aminosyn-PF 7% resulted in plasma amino acid concentrations approximating those of normal breast or formula fed infants. In addition, weight gains, nitrogen balance, and serum protein concentrations were consistent with an improving nutritional status.

When infused with hypertonic dextrose as a calorie source, supplemented with cysteine hydrochloride, electrolytes, vitamins, and minerals, Aminosyn-PF 7% provides TPN for infants and young children, with the exception of essential fatty acids.

It is thought that the acetate from lysine acetate under the conditions of parenteral nutrition, does not impact net acid-base balance when renal and respiratory functions are normal. Clinical evidence seems to support this thinking; however, confirmatory experimental evidence is not available. The amounts of sodium and acetate in Aminosyn-PF 7% are not of clinical significance.

The addition of a cysteine hydrochloride additive will contribute to the chloride load.

The electrolyte content of any additives that are introduced should be carefully considered and included in input computations.

The human newborn conjugates bile with taurine which becomes the primary method of biliary excretion. Taurine deficiency because of its effect on bile salt conjugation and, therefore, on bile salt flow may be of major importance in the genesis of cholestasis. Taurine has also been shown to play a role in central nervous system development.

INDICATIONS AND USAGE

Aminosyn-PF 7%, Sulfite-Free, (an amino acid injection — pediatric formula) is indicated for the nutritional support of infants (including those of low birth weight) and young children requiring TPN via either central or peripheral infusion routes. Parenteral nutrition with Aminosyn-PF 7% is indicated to prevent nitrogen and weight loss or treat negative nitrogen balance in infants and young children where (1) the alimentary tract by the oral gastrostomy, or jejunostomy route, cannot or should not be used or adequate protein intake is not feasible by these routes, (2) gastrointestinal absorption of protein is impaired; or (3) protein requirements are substantially increased as with extensive burns. Dosage, route of administration, and concomitant infusion of non-protein calories are dependent on various factors, such as nutritional and metabolic status of the patient, anticipated duration of parenteral nutrition support, and vein tolerance. See ***DOSAGE AND ADMINISTRATION*** for additional information.

Central Venous Infusion

Central venous infusion should be considered when amino acid solutions are to be admixed with hypertonic dextrose to promote protein synthesis in hypercatabolic or severely depleted infants or those requiring long-term parenteral nutrition.

Peripheral Parenteral Nutrition

For moderately catabolic or depleted patients in whom the central venous route is not indicated, diluted

amino acid solutions mixed with 5 to 10% dextrose solutions may be infused by peripheral vein, supplemented, if desired, with fat emulsion.

CONTRAINDICATIONS

Aminosyn-PF 7%, Sulfite-Free, (an amino acid injection — pediatric formula) is contraindicated in patients with untreated anuria, hepatic coma, inborn errors of amino acid metabolism (including those involving branched chain amino acid metabolism such as maple syrup urine disease and isovaleric acidemia), or hypersensitivity to one or more amino acids present in the solution.

WARNINGS

Safe, effective use of parenteral nutrition requires a knowledge of nutrition as well as clinical expertise in recognition and treatment of the complications which can occur. FREQUENT EVALUATION AND LABORATORY DETERMINATIONS ARE NECESSARY FOR PROPER MONITORING OF PARENTERAL NUTRITION. Studies should include blood sugar, serum proteins, kidney and liver function tests, electrolytes, hemogram, carbon dioxide content, serum osmolalities, blood cultures, and blood ammonia levels.

Administration of amino acids in the presence of impaired renal function or gastrointestinal bleeding may augment an already elevated blood urea nitrogen. Patients with azotemia from any cause should not be infused with amino acids without regard to total nitrogen intake.

Administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the solutions.

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

Hyperammonemia is of *special significance in infants*, as its occurrence in the syndrome caused by genetic metabolic defects is sometimes associated, although not necessarily in a causal relationship, with mental retardation. This reaction appears to be dose-related and is more likely to develop during prolonged therapy. It is essential that blood ammonia be measured frequently in infants.

Conservative doses of amino acids should be given, dictated by the nutritional status of the patient. Should symptoms of hyperammonemia develop, amino acid dosage levels should be reduced and titrated against serum ammonia levels.

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

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation. Significant deviations from normal concentrations may require the use of additional electrolyte supplements.

Strongly hypertonic nutrient solutions should be administered via an intravenous catheter placed in a

central vein, preferably the superior vena cava.

Care should be taken to avoid circulatory overload, particularly in patients with cardiac insufficiency.

Special care must be taken when giving hypertonic dextrose to a diabetic or pre-diabetic patient. To prevent severe hyperglycemia in such patients, insulin may be required.

Administration of glucose at a rate exceeding the patient's utilization rate may lead to hyperglycemia, coma, and death.

The effect of infusion of amino acids, without dextrose, upon carbohydrate metabolism of children is not known at this time. It is essential to provide adequate exogenous dextrose calories concurrently with amino acids. Administration of amino acids without carbohydrates may result in the accumulation of ketone bodies in the blood. Correction of this ketonemia may be achieved by the administration of carbohydrate.

Essential fatty acid deficiency (EFAD) is becoming increasingly recognized in patients on long term TPN (more than 5 days). The use of fat emulsion to provide 4 — 10% of total caloric intake as linoleic acid may prevent EFAD.

Peripheral administration of Aminosyn-PF 7%, Sulfite-Free, (an amino acid injection — pediatric formula) requires appropriate dilution and provision of adequate calories. Care should be taken to assure proper placement of the needle within the lumen of the vein. The venipuncture site should be inspected frequently for signs of infiltration. If venous thrombosis or phlebitis occurs, discontinue infusions or change infusion site and initiate appropriate treatment.

Extraordinary electrolyte losses such as may occur during protracted nasogastric suction, vomiting, diarrhea, or gastrointestinal fistula drainage may necessitate additional electrolyte supplementation.

Metabolic acidosis can be prevented or readily controlled by adding a portion of the cations in the electrolyte mixture as acetate salts and in the case of hyperchloremic acidosis, by keeping the total chloride content of the infusate to a minimum.

Aminosyn-PF 7% contains no chloride.

Aminosyn-PF 7% 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. To assure adequate intake, serum levels should be monitored frequently.

Aminosyn-PF 7% contains no more than 25 mcg/L of aluminum.

To minimize the risk of possible incompatabilities arising from mixing this solution with other additives that may be prescribed, the final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration, and periodically during administration.

SPECIAL PRECAUTIONS FOR

CENTRAL INFUSIONS

ADMINISTRATION BY CENTRAL VENOUS CATHETER SHOULD BE USED ONLY BY THOSE FAMILIAR WITH THIS TECHNIQUE AND ITS COMPLICATIONS.

Central vein infusion (with added concentrated carbohydrate solutions) of amino acid solutions requires a knowledge of nutrition as well as clinical expertise in recognition and treatment of complications. Attention must be given to solution preparation, administration and patient monitoring. IT IS ESSENTIAL THAT A CAREFULLY PREPARED PROTOCOL, BASED ON CURRENT MEDICAL PRACTICES, BE FOLLOWED, PREFERABLY BY AN EXPERIENCED TEAM.

SUMMARY HIGHLIGHTS OF COMPLICATIONS (See also Current Medical Literature).

1. **Technical**

   The placement of a central venous catheter should be regarded as a surgical procedure. One should be fully acquainted with various techniques of catheter insertion. For details of technique and placement sites, consult the medical literature. X-ray is the best means of verifying catheter placement. Complications known to occur from the placement of central venous catheters 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 and catheter emboli.

2. **Septic**

   The constant risk of sepsis is present during administration of total parenteral nutrition. It is imperative that the preparation of the solution and the placement and care of catheters be accomplished under strict aseptic conditions.

   Solutions should ideally be prepared in the hospital pharmacy under a laminar flow hood using careful aseptic technique to avoid inadvertent touch contamination. Solutions should be used promptly after mixing. Storage should be under refrigeration and limited to a brief period of time, preferably less than 24 hours.

   Administration time for a single container and set should never exceed 24 hours.

3. **Metabolic**

   The following metabolic complications have been reported with TPN administration: Metabolic acidosis and alkalosis, hypophosphatemia, hypocalcemia, osteoporosis, hyperglycemia and glycosuria, rebound hypoglycemia, osmotic diuresis and dehydration, elevated liver enzymes, hypo- and hypervitaminosis, electrolyte imbalances and hyperammonemia in children. Frequent evaluations are necessary especially during the first few days of therapy to prevent or minimize these complications.

   Administration of glucose at a rate exceeding the patient’s utilization rate may lead to hyperglycemia, coma and death. CLINICAL EVALUATION AND LABORATORY DETERMINATIONS, AT THE DISCRETION OF THE ATTENDING PHYSICIAN ARE NECESSARY FOR PROPER MONITORING DURING ADMINISTRATION. Do not withdraw venous blood for blood chemistries through the peripheral infusion site, as interference with estimations of nitrogen-containing substances may occur. Blood studies should include glucose, urea nitrogen, serum electrolytes, ammonia, cholesterol, acid-base balance, serum proteins, kidney and liver function tests, osmolarity and hemogram. White blood count and blood cultures are to be determined if indicated. Urinary osmolality and glucose should be determined as necessary.

Pregnancy Category C

Animal reproduction studies have not been conducted with Aminosyn-PF 7%. It is also not known whether Aminosyn-PF 7% can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Aminosyn-PF 7% should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS

Local reactions consisting of erythema, phlebitis and thrombosis at the infusion site have occurred with peripheral intravenous infusion of amino acids particularly if other substances, such as antibiotics, are also administered through the same site. In such cases the infusion site should be changed promptly to another vein. Use of large peripheral veins, inline filters, and slowing the rate of infusion may reduce

the incidence of local venous irritation. Electrolyte additives should be spread throughout the day. Irritating additive medications may need to be injected at another venous site.

Generalized flushing, fever and nausea also have been reported during peripheral infusions of amino acid solutions.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

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 total daily dose of the solution depends on the daily protein requirements and on the patient's metabolic and clinical response.

Pediatric requirements for parenteral nutrition are constrained by the greater relative fluid requirements of the infant and greater caloric requirements per kilogram than in the adult.

The recommended intravenous dose of Aminosyn-PF 7%, Sulfite-Free, (an amino acid injection — pediatric formula) is up to 2.5 g amino acid/kg/day for infants up to 10 kg. For infants and children larger than 10 kg, the total daily dose of amino acids should be up to 25 g amino acids/day for the first 10 kg of body weight plus 1 to 1.25 g amino acid for each kg of body weight over 10 kg. Initial amino acid dosage levels of 1 g/kg/day may be increased gradually in increments of 0.5 g/kg/day to approximate desired intake levels.

Aminosyn-PF 7% should be diluted with dextrose prior to use. Nonprotein calories should constitute approximately 100 to 130 kcal/kg/day. Part of the nonprotein caloric requirement may be provided as lipid emulsion administered concurrently to provide up to 60% of daily calories at a dose not to exceed 4 g fat/kg/day. Fluid intake for the infant receiving central venous TPN should be approximately 125 mL/kg/day (range: 100 to 175 mL/kg/day), depending on the clinical condition of the patient. Premature infants with respiratory distress syndrome suspected of having a patent ductus arteriosus should be given fluids more cautiously.

Cysteine is considered to be an essential amino acid for infants, especially preterm infants with potentially immature enzyme pathways. Therefore, addition of a cysteine supplement to the TPN admixture is recommended. The intake of cysteine by the preterm infant ingesting maternal milk is approximately 78 mg/kg/day. The suggested intravenous dosage level for Cysteine Hydrochloride Injection, USP is 500 mg (10 mL) for every 12.5 g (179 mL) of Aminosyn-PF 7% administered (see package insert for Cysteine Hydrochloride Injection, USP). In order to avoid potential insolubility of cysteine hydrochloride in admixtures, the foregoing concentration should not be exceeded.

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. To prevent rebound hypoglycemia, a solution containing 5% dextrose should be administered when hypertonic dextrose solutions are abruptly discontinued.

SERUM ELECTROLYTES SHOULD BE MONITORED FREQUENTLY. Electrolytes may be added to the nutrient solution as indicated by the patient's clinical condition and laboratory determinations of plasma values. Major electrolytes are sodium, chloride, potassium, phosphate, magnesium and calcium. Daily administration of intravenous vitamin supplements including a complete complement of fat and water-soluble vitamins is required. Trace metal additives including zinc, copper, manganese, and chromium should also be provided, especially when long-term parenteral therapy is anticipated.

Calcium and phosphorus are added to the solution as indicated.

Potentially incompatible ions such as calcium and phosphate may be added to alternate infusate bottles to avoid precipitation. In patients with hyperchloremic or other metabolic acidosis, sodium and potassium may be added as the acetate or lactate salts to provide bicarbonate alternates. Bicarbonate should not be administered during infusion of the nutritional solution unless deemed absolutely necessary.

Additives may be incompatible. Consult with pharmacist, if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.

To ensure the precise delivery of the small volumes of fluid necessary for total parenteral nutrition in infants, accurately calibrated and reliable infusion systems should be used.

Central Venous Nutrition

Hypertonic mixtures of amino acids and dextrose may be safely administered by continuous infusion through a central venous catheter with the tip located in the superior vena cava. Initial infusion rates should be slow, and gradually increased to the recommended 60-125 mL per kilogram body weight per day. If administration rate should fall behind schedule, no attempt to “catch up” to planned intake should be made. In addition to meeting protein needs, the rate of administration, particularly during the first few days of therapy, is governed by the patient’s glucose tolerance. Daily intake of amino acids and dextrose should be increased gradually to the maximum required dose as indicated by frequent determinations of glucose levels in blood and urine.

Peripheral Parenteral Nutrition

For patients in whom the central venous route is not indicated and who can consume adequate calories enterally, Aminosyn-PF 7% may be administered by peripheral vein with parenteral nonprotein calories. The concentration of dextrose in the final admixture is 5 to 10%, and simultaneous administration of lipid emulsion is recommended both as a calorie source and to attenuate the potentially irritating effects of the hypertonic nutritional admixture. Fat emulsion may comprise up to 60% of the daily caloric intake at a dosage level not to exceed 4 g fat/kg/day. It is essential that peripheral infusion be accompanied by adequate caloric intake.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. COLOR VARIATION FROM PALE YELLOW TO YELLOW IS NORMAL AND DOES NOT ALTER EFFICACY.

WARNING: Do not use flexible container in series connections.

HOW SUPPLIED

NDC No.	Concentration	Container (mL)
0409-4178-03	Aminosyn-PF 7%, Sulfite-Free, (an amino acid injection - pediaric formula)	500

Store at 20 to 25ºC (68 to 77ºF). [See USP Controlled Room Temperature.] Protect from freezing. **Avoid exposure to light.**

Revised: June, 2008

Printed in USA	EN-1816
Hospira, Inc., Lake Forest, IL 60045 USA	

IM-0735

500 mL NDC 0409-4178-03

Aminosyn®-PF 7%

Sulfite-Free

AN AMINO ACID INJECTION – PEDIATRIC FORMULA

EACH 100 mL CONTAINS: TOTAL AMINO ACIDS APPROX. 7 g. **ESSENTIAL AMINO ACIDS/100 mL:** ISOLEUCINE 534 mg; LEUCINE 831 mg; LYSINE (AS ACETATE SALT) 475 mg; METHIONINE 125 mg; PHENYLALANINE 300 mg; THREONINE 360 mg; TRYPTOPHAN 125 mg; VALINE 452 mg. **NONESSENTIAL AMINO ACIDS/100 mL:** TYROSINE 44 mg; ALANINE 490 mg; ARGININE 861 mg; GLYCINE 270 mg; PROLINE 570 mg; HISTIDINE 220 mg; SERINE 347 mg; L-GLUTAMIC ACID 576 mg; L-ASPARTIC ACID 370 mg; TAURINE 50 mg. **ELECTROLYTES (mEq/LITER):** ACETATE 32.5.

pH 5.5 (5.0 to 6.5)

561 mOsmol/LITER

SPECIFIC GRAVITY = 1.02

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

SINGLE DOSE CONTAINER. CONTAINS NO BACTERIOSTAT. DISCARD UNUSED PORTION. FOR I.V. USE. USUAL DOSAGE: SEE INSERT. STERILE, NONPYROGENIC. STORE AT 20 TO 25°C (68 TO 77°F). [SEE USP CONTROLLED ROOM TEMPERATURE.] AVOID EXCESSIVE HEAT. PROTECT FROM FREEZING. AVOID EXPOSURE TO LIGHT. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. MUST NOT BE USED IN SERIES CONNECTIONS.

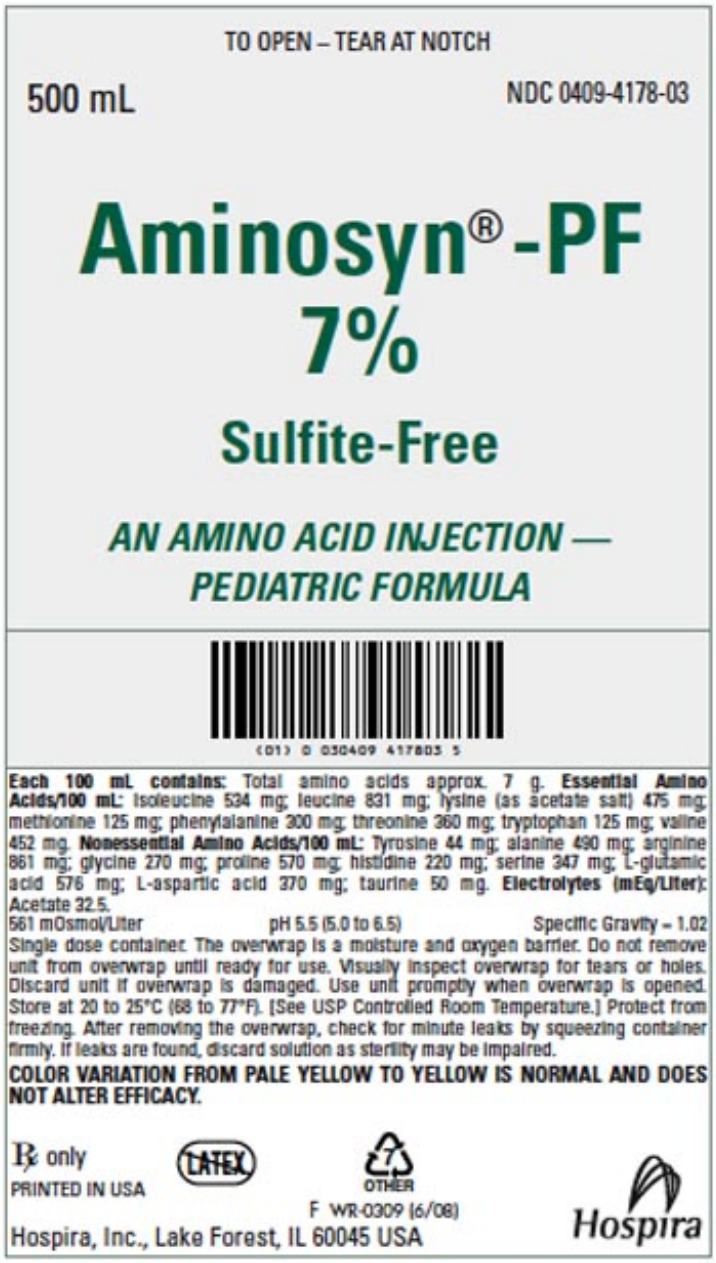
(01) 0 30409 41783 5

Rx ONLY LATEX 3 V CONTAINS DEHP Hospira

PRINTED IN USA
©HOSPIRA 2004 IM-0735 (10/04)
HOSPIRA, INC., LAKE FOREST, IL 60045 USA

iv bag ndc 0409-4178-03

WR-0309



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AMINOSYN-PF

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

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-4178
Route of Administration	INTRAVENOUS	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ISOLEUCINE (UNII: 04Y7590D77) (ISOLEUCINE - UNII:04Y7590D77)	ISOLEUCINE	534 mg in 100 mL
LEUCINE (UNII: GMW67QNF9C) (LEUCINE - UNII:GMW67QNF9C)	LEUCINE	831 mg in 100 mL
LYSINE ACETATE (UNII: TTL6G7LIWZ) (LYSINE - UNII:K3Z4F929H6)	LYSINE	475 mg in 100 mL

METHIONINE (UNII: AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL)	METHIONINE	125 mg in 100 mL
PHENYLALANINE (UNII: 47E5O17Y3R) (PHENYLALANINE - UNII:47E5O17Y3R)	PHENYLALANINE	300 mg in 100 mL
THREONINE (UNII: 2ZD004190S) (THREONINE - UNII:2ZD004190S)	THREONINE	360 mg in 100 mL
TRYPTOPHAN (UNII: 8DUH1N11BX) (TRYPTOPHAN - UNII:8DUH1N11BX)	TRYPTOPHAN	125 mg in 100 mL
VALINE (UNII: HG18B9YRS7) (VALINE - UNII:HG18B9YRS7)	VALINE	452 mg in 100 mL
ALANINE (UNII: OF5P57N2ZX) (ALANINE - UNII:OF5P57N2ZX)	ALANINE	490 mg in 100 mL
ARGININE (UNII: 94ZLA3W45F) (ARGININE - UNII:94ZLA3W45F)	ARGININE	861 mg in 100 mL
ASPARTIC ACID (UNII: 30KYC7MIAI) (ASPARTIC ACID - UNII:30KYC7MIAI)	ASPARTIC ACID	370 mg in 100 mL
GLUTAMIC ACID (UNII: 3KX376GY7L) (GLUTAMIC ACID - UNII:3KX376GY7L)	GLUTAMIC ACID	576 mg in 100 mL
GLYCINE (UNII: TE7660XO1C) (GLYCINE - UNII:TE7660XO1C)	GLYCINE	270 mg in 100 mL
HISTIDINE (UNII: 4QD397987E) (HISTIDINE - UNII:4QD397987E)	HISTIDINE	220 mg in 100 mL
PROLINE (UNII: 9DLQ4CIU6V) (PROLINE - UNII:9DLQ4CIU6V)	PROLINE	570 mg in 100 mL
SERINE (UNII: 452VLY9402) (SERINE - UNII:452VLY9402)	SERINE	347 mg in 100 mL
TAURINE (UNII: 1EQV5MLY3D) (TAURINE - UNII:1EQV5MLY3D)	TAURINE	50 mg in 100 mL
TYROSINE (UNII: 42HK56048U) (TYROSINE - UNII:42HK56048U)	TYROSINE	44 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0409-4178-03	12 in 1 CASE		
1		500 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019398	09/06/1985	

Labeler - Hospira, Inc. (141588017)

Revised: 7/2012 Hospira, Inc.