PRESCRIBING INFORMATION

AMINOSYN®-PF 7%

AMINOSYN®-PF 10%

(amino acids for injection 7% and 10% - pediatric formula)

Sulfite-Free

Nutritive Supplement for Intravenous Infusion

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DATE OF PREPARATION:
October 26, 2009

Control #131561

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THERAPEUTIC OR PHARMACOLOGIC CLASSIFICATION

Nutritive Supplement for Intravenous Infusion

ACTIONS AND CLINICAL PHARMACOLOGY

Total parenteral nutrition consists of appropriate amino acids, electrolytes, trace metals, vitamins and an energy source; this may be accomplished in children by administering AMINOSYN®-PF 7% and 10% (amino acids for injection 7% and 10% - pediatric formula), Sulfite-Free plus electrolytes, concentrated dextrose or fat emulsion, vitamins and trace metals.

Clinical studies in infants who required TPN therapy showed that infusion of AMINOSYN®-PF 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.

AMINOSYN®-PF 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 results in plasma amino acid concentrations approximating a profile consistent with that of a breastfed infant.

AMINOSYN®-PF 7% and 10% provide amino acids to promote protein synthesis and wound healing, and to reduce the rate of endogenous protein catabolism.

AMINOSYN®-PF can be given by central venous infusion in combination with concentrated dextrose, cysteine hydrochloride, electrolytes, vitamins, trace metals and ancillary fat supplements to infants and young children. AMINOSYN®-PF can also be administered by peripheral vein with dextrose and maintenance electrolytes. Intravenous fat emulsion may be substituted for part of the carbohydrate energy during either central or peripheral vein administration of AMINOSYN®-PF.

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 CLINICAL USE

AMINOSYN®-PF 7% and 10% are indicated for the nutritional support of infants (including those of low birth weight) and young children requiring parenteral infusion either by peripheral or central infusion routes.

Peripheral Vein Administration

For peripheral vein administration, the concentration of dextrose in the final solution should be equal to or lower than 5%.

AMINOSYN®-PF in 5% to 10% Dextrose Injection is indicated for peripheral vein infusion as a source of nitrogen in the intravenous treatment of acute surgical patients with adequate stores of body fat, in whom, for short periods of time, oral nutrition cannot be tolerated or is not desirable. In such instances, the patient's energy needs are met from his own fat stores.

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.

Central Vein Administration

AMINOSYN®-PF, when administered with hypertonic dextrose solutions, is designed for central vein infusion only. When given by central venous infusion in combination with concentrated dextrose, cysteine hydrochloride, electrolytes, vitamins, trace metals, and ancillary fat supplements these mixtures constitute total parenteral nutrition (TPN). They are intended to meet the needs of hypermetabolic patients, such as those with burns or trauma. They permit administration of great amounts of nitrogen and energy without excessive fluid. This latter consideration is of importance in patients with cardiac or renal disease (See **PRECAUTIONS** and **WARNINGS**).

Amino acids, when administered with concentrated dextrose solutions with or without fat emulsion, are indicated for central vein infusion in the prevention of nitrogen loss or in the reversal of negative nitrogen balance in infants and children where: (a) the alimentary tract, by the oral, gastrostomy or jejunostomy route cannot or should not be used; (b) gastrointestinal absorption of protein is impaired due to protein losing enteropathies, Crohn's disease, and short bowel syndrome secondary to repeated surgeries or congenital defects of the bowel, due either to a malfunctioning bowel or due to a diminished availability of bowel surface; (c) metabolic requirements for protein are substantially increased, as with extensive burns, and (d) morbidity and mortality may be reduced by replacing amino acids lost from tissue breakdown, thereby preserving tissue reserves, as in acute renal failure.

SUPPLEMENTAL ELECTROLYTES, IN ACCORDANCE WITH THE PRESCRIPTION OF THE ATTENDING PHYSICIAN MUST BE ADDED TO ALL AMINOSYN®-PF SOLUTIONS.

CONTRAINDICATIONS

AMINOSYN®-PF 7% and 10% are contraindicated in patients with previous hypersensitivity to this product or any of its components.

These preparations are contraindicated in patients with anuria unless hemodialysis or continuous arterio-venous hemofiltration is being employed with management of these patients or hepatic coma or metabolic

disorders involving impaired nitrogen utilization and/or inborn errors of amino acid metabolism. Patients with azotemia from any cause should not be infused with amino acids without regard to total nitrogen intake.

WARNINGS

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 μG/KG/DAY ACCUMULATE ALUMINUM AT LEVELS ASSOCIATED WITH CENTRAL NERVOUS SYSTEM AND BONE TOXICITY. TISSUE LOADING MAY OCCUR AT EVEN LOWER RATES OF ADMINISTRATION.

Safe, effective use of parenteral nutrition requires 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 (see **PRECAUTIONS - Laboratory Tests**).

Administration of amino acids in the presence of impaired renal function or gastrointestinal bleeding may augment 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 amino acid solutions that have not been specifically formulated to treat 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, 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.

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

Central Vein Infusions: **HYPEROSMOLAR SYNDROME, RESULTING FROM EXCESSIVELY RAPID ADMINISTRATION OF CONCENTRATED DEXTROSE MAY CAUSE MENTAL CONFUSION AND/OR LOSS OF CONSCIOUSNESS (SEE ALSO SPECIAL PRECAUTIONS FOR CENTRAL VENOUS INFUSIONS).**

Use in Pregnancy: Use in pregnancy has not yet been studied. Animal reproduction studies have not been conducted with AMINOSYN®-PF with Dextrose Injection. It is not known whether this admixture can cause fetal harm when administered to a pregnant woman. AMINOSYN®-PF with Dextrose Injection should be given to a pregnant woman only if clearly needed.

Concentrated dextrose solutions, if administered too rapidly, may result in significant hyperglycemia and possible hyperosmolar syndrome characterized by mental confusion and loss of consciousness.

Intravenous infusion of amino acid solutions may induce a rise in blood urea nitrogen (BUN), especially in patients with impaired hepatic or renal function. Appropriate laboratory tests should be performed periodically and infusion discontinued if BUN levels exceed, for example, 7.0 mmol/L and continue to rise. It should be noted that a modest rise in BUN normally occurs as a result of increased amino acids intake.

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

Administration of amino acid solutions in the presence of impaired renal function may augment an increasing BUN, as does any protein dietary component.

Solutions containing sodium ion should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency and in clinical states in which there exists edema with sodium retention.

Solutions containing acetate ion should be used with great care in patients with metabolic or respiratory alkalosis. Acetate should be administered with great care in those conditions in which there is an increased level or an impaired utilization of this ion, such as severe hepatic insufficiency.

Hyperammonemia is of special significance in infants as it can result in mental retardation. Therefore, it is essential that blood ammonia levels be measured frequently in infants.

Instances of asymptomatic hyperammonemia have been reported in patients without overt liver dysfunction. The mechanisms of this reaction are not clearly defined, but may involve genetic defects and immature or subclinically impaired liver function.

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 (see **PRECAUTIONS**).

ADMINISTRATION BY CENTRAL VENOUS CATHETER SHOULD BE USED ONLY BY THOSE FAMILIAR WITH THIS TECHNIQUE AND ITS COMPLICATIONS (see Special Precautions for Central Venous Infusions).

PRECAUTIONS

General

Because Aminosyn®-PF 7% and 10% are strongly hypertonic, they should not be given by peripheral vein unless they are diluted prior to administration. All additives such as trace elements, etc., should be taken into account for the dilution (see **DOSAGE** and **ADMINISTRATION**).

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 infusions are abruptly discontinued.

Patients with Special Diseases and Conditions: Special care must be taken when administering dextrose to provide energy in diabetic or prediabetic patients. Frequent blood sugar determinations should govern insulin dosage.

Feeding regimens which include amino acids should be used with caution in patients with a history of renal disease, pulmonary disease, or with cardiac insufficiency so as to avoid excessive fluid accumulation.

Nitrogen intake should be carefully monitored in patients with impaired renal function.

Laboratory Tests: 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.

Use in Children: The effect of infusion of amino acids, without dextrose, upon carbohydrate metabolism of children is not known at this time.

Drug Interactions: Because of its antianabolic activity, concurrent administration of tetracycline may reduce the potential effects of amino acids.

Additives may be incompatible. When introducing additives, always consult with hospital pharmacist, use aseptic technique, mix thoroughly, and do not store.

Long-Term Total Parenteral Nutrition (TPN): For long-term TPN it is essential to provide adequate exogenous energy concurrently, if parenterally administered amino acids are to be retained by the body and utilized for protein synthesis. Concentrated dextrose solutions, with or without fat emulsions, are effective sources of such energy. Strong hypertonic nutrient solutions should be administered through an indwelling intravenous catheter with the tip located in the superior vena cave.

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 linoic acid may prevent EFAD.
Aminosyn-PF contains no more than 25 µg/L of aluminum (see **WARNINGS**).

Special Precautions for Central Venous Infusions: ADMINISTRATION BY CENTRAL VENOUS CATHETER SHOULD BE USED ONLY BY THOSE FAMILIAR WITH THIS TECHNIQUE AND ITS COMPLICATIONS.

Central vein infusion of amino acid solutions (with added concentrated carbohydrate solutions) requires knowledge of nutrition as well as clinical expertise in recognition and treatment of complications which can occur. Complications can be prevented or minimized by paying careful attention 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.

Although a detailed discussion of the complications is beyond the scope of this monograph, the following summary lists those based on current 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 as well as recognition and treatment of complications. For details of techniques 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, especially fungal septicemia, is present during administration of all parenteral nutritional solutions. Since contaminated solutions and infusion catheters are potential sources of infection, it is imperative that the preparation of the solution and the placement and care of catheters be accomplished under controlled aseptic conditions.

Ideally, solutions should be prepared in the hospital pharmacy under a laminar-flow hood using careful aseptic technique to avoid inadvertent touch contamination during mixing of solutions and addition of other nutrients. Solutions should be used promptly after mixing. Any storage should be under refrigeration and limited to a brief period of time less than 24 hours.

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

Do not administer any parenteral nutrition as a 3 in 1 mixture if the emulsion is cracked and/or oil is visible at the surface of the parenteral nutrition.

3. Metabolic: The following complications have been reported with TPN administration: metabolic acidosis and alkalosis, hypophosphatemia, hypocalcemia, osteoporosis, hyperglycemia and glycosuria, hyperosmotic nonketotic states and dehydration, osmotic diuresis and dehydration, rebound hypoglycemia, elevated liver enzymes, hypo- and hyper-vitaminosis, electrolyte imbalances and hyperammonemia in children. Frequent clinical evaluation and laboratory determinations 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.

ADVERSE REACTIONS

Hypersensitivity reactions ranging from rash and fever to hives, respiratory difficulties and anaphylaxis have been noted. Local injection site reactions have also been noted.

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

Peripheral Infusions: Local reactions consisting of a warm sensation, erythema, phlebitis and thrombosis of the infusion site have been reported 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 larger peripheral veins, inline filters, and slowing the rate of infusion may be helpful in decreasing the incidence of local venous irritation. Irritating additive medications may need to be injected at another venous site.

See **WARNINGS** and **Special Precautions for Central Venous Infusions**.

SYMPTOMS AND TREATMENT OF 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

DO NOT USE FLEXIBLE CONTAINER IN SERIES CONNECTIONS.

Because AMINOSYN®-PF 7% and l0% are strongly hypertonic they must be diluted before administration by peripheral vein.

Additives may be incompatible. When introducing additives, always consult with hospital pharmacist, use aseptic technique, mix thoroughly, and do not store.

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 requirements of the infant and greater energy requirements per kilogram than in the adult.

The recommended intravenous dose of AMINOSYN®-PF 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 1.0 to 1.25 g amino acid for each kg of body weight over 10 kg. Initial amino acid dosage levels of 1.0 g/kg/day may be increased gradually in increments of 0.5 g/kg/day to approximate desired intake levels. Dextrose content is gradually increased over the next few days to the estimated daily energy requirement as the patient adapts to the increasing amounts of dextrose. Each gram of dextrose monohydrate provides approximately 14 kJ (3.4 kcal). Each gram of fat provides 37 kJ (9 kcal). AMINOSYN®-PF should be diluted with dextrose prior to use. Nonprotein calories should constitute approximately 418 to 544 kJ/kg/day (100 to 130 kcal/kg/day). Part of the nonprotein caloric requirements may be provided as lipid emulsion administered concurrently to provide up to 60% of daily energy requirements 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 0.5 g (50 mg/mL) for every 12.5 g of AMINOSYN®-PF (179 mL of AMINOSYN®-PF 7%; or 125 mL of AMINOSYN®-PF 10%) administered (see package insert for Cysteine Hydrochloride Injection, USP). In order to avoid potential insolubility for cysteine hydrochloride in admixtures, the foregoing concentration should not be exceeded.

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

AMINOSYN®-PF SOLUTIONS WITHOUT ELECTROLYTES ARE INTENDED FOR PATIENTS REQUIRING INDIVIDUALIZED ELECTROLYTE THERAPY. SERUM ELECTROLYTES SHOULD BE MONITORED AS INDICATED. 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. Vitamins, including folic acid and vitamin K are required additives. The trace element supplements should be given when long-term TPN is undertaken.

Calcium and phosphorus are added to the solution as indicated. The usual dose of phosphorus added to a litre of TPN solution (containing 25% dextrose) is 12 mmol. This requirement is related to the energy delivered by carbohydrate.

Calcium and phosphorus additives are potentially incompatible when added to the TPN admixture. However, if one additive is added to the amino acid container and the other to the container of concentrated dextrose, and if the contents of both containers are swirled before they are combined, then the likelihood of physical incompatibility is reduced.

Iron is added to the solution or given intramuscularly in depot form as indicated. Vitamin B_{12} , vitamin K and folic acid are given intramuscularly or added to the solution as desired.

In patients with hyperchloremic or other metabolic acidosis, sodium and potassium may be added as the acetate or lactate salts to provide bicarbonate alternates.

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

In view of the changing physiological states of the pediatric patient, total daily fluid and nutritional requirements should be calculated according to age, weight and medical condition of all pediatric patients in accordance with accepted practice.

Provisions of adequate energy in the form of hypertonic dextrose may require exogenous insulin to prevent hyperglycemia and glycosuria. Ensure that exogenous insulin activity has ceased before abruptly discontinuing nutrient solution.

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.

1. **Peripheral Vein Administration**

For patients in whom the central venous route is not indicated and who can consume adequate

calories enterally, Aminosyn®-PF 7% and 10% may be administered by peripheral vein with parenteral nonprotein calories. The concentration of dextrose in the final admixture is ≤5%, 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. It is essential that peripheral infusion be accompanied by adequate caloric intake.

2. **Central Vein Administration**

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 cave. Initial infusion rates should be slow and gradually increased to the recommended 60-125 mL per kilogram body weight per day. If administration rate would 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.

AMINOSYN®-PF 10% solution, when mixed with an appropriate volume of concentrated dextrose, offers a higher concentration of energy and nitrogen per unit volume. This solution is indicated for patients requiring larger amounts of nitrogen than could otherwise be provided or where total fluid load must be kept to a minimum, for example, patients with renal failure.

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

PHARMACEUTICAL INFORMATION

AMINOSYN®-PF 7% and 10% are sterile, non-pyrogenic solutions for intravenous infusion. Aminosyn-PF 10% is oxygen sensitive.

Drug Substances

All the amino acids are present in the metabolizable L-form and lysine is present as the acetate salt. The acetate salt of lysine is used instead of the hydrochloride salt in order to reduce the potential for precipitating or exacerbating metabolic acidosis during infusion of the solution.

Composition

AMINOSYN®-PF 7% and 10% is composed of the following ingredients:

AMINOSYN®-PF Formulations		
AMINOSYN®-PF	**7%**	**10%**
Essential Amino Acids (mg/100 mL)		
L-Isoleucine	534	760
L-Leucine	831	1200
L-Lysine (as acetate)	475	677
L-Methionine	125	180
L-Phenylalanine	300	427
L-Threonine	360	512
L-Tryptophan	125	180
L-Valine	452	673
Nonessential Amino Acids (mg/100 mL)		
L-Alanine	490	698
L-Arginine	861	1227
L-Aspartic Acid	370	527
L-Glutamic Acid	576	820
L-Glycine	270	385
L-Histidine	220	312
L-Proline	570	812
L-Serine	347	495
L-Taurine	50	70
L-Tyrosine	44	44
Electrolytes (mmol/L)		
Acetate ($C_2H_3O_2^-$)[1]	32.5	46.3
Protein Equivalent (approx. g/L)	70	100
Total Nitrogen (g/L)	10.69	15.2
Osmolarity (mOsm/L	561	788
pH (approx.) [2]	5.5	5.5

[1] From Lysine acetate
[2] May contain HCl for pH adjustment

Storage Recommendations:

Store between 20° and 25°C. Do not freeze. Protect from light. Avoid excessive heat.

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 temperature 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.

Reconstituted Solutions:

AMINOSYN®-PF 7% or 10% is strongly hypertonic and must be diluted with Dextrose Injection prior to use. It is absolutely essential that the admixture be prepared using strict aseptic techniques under a laminar flow hood.

Storage Recommendations of the admixture:

Solutions should be used promptly after mixing. Any storage should be under refrigeration and limited to a brief period of time less than 24 hours.

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

AVAILABILITY OF DOSAGE FORMS

AMINOSYN®-PF 7% and 10% are available in the following presentations:

AMINOSYN®-PF Concentration	Volume of Flexible Plastic Containers (mL)
7%	500
10%	1000

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 temperature 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.