PRESCRIBING INFORMATION

AMINOSYN® II IN DEXTROSE INJECTION

AMINOSYN® II WITH ELECTROLYTES IN DEXTROSE INJECTION

AMINOSYN® II WITH ELECTROLYTES IN DEXTROSE INJECTION WITH CALCIUM

NUTRIMIX® DUAL CHAMBER CONTAINERS

Nutritive with and without Electrolyte Supplements for Intravenous Infusion

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PRESCRIBING INFORMATION

NAME OF DRUGS

AMINOSYN® II IN DEXTROSE INJECTION

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THERAPEUTIC OR PHARMACOLOGICAL CLASSIFICATION

Nutritive with and without Electrolyte Supplements for Intravenous Infusion

CLINICAL PHARMACOLOGY

Total parenteral nutrition consists of appropriate amino acids, electrolytes, trace metals, vitamins and an energy source. This may be accomplished by administering AMINOSYN® II (amino acids) with or without electrolytes, fat emulsion plus concentrated dextrose, vitamins and trace metals.

AMINOSYN® II (an amino acid injection) with or without Electrolytes in Dextrose Injection with or without Calcium obtained after thoroughly mixing the contents of the two chambers provides carbohydrate calories and amino acids to promote protein synthesis and wound healing, to reduce the rate of endogenous protein catabolism and to minimize liver glycogen depletion.

INDICATIONS AND CLINICAL USES

1. **Peripheral Vein Administration**

AMINOSYN® II 3.5% in 5% Dextrose Injection and AMINOSYN® II 3.5% M (amino acid injection 3.5% with maintenance electrolytes) in 5% Dextrose Injection are indicated for peripheral vein infusion as a source of nitrogen in the intravenous treatment of acute surgical patients with adequate store of body fat, in whom, for short periods of time, oral nutrition cannot be tolerated or is not desirable. In such instances, the patients' energy needs are met from their own fat stores.

2. **Central Vein Administration**

Because AMINOSYN® II 3.5% in 25% Dextrose Injection, AMINOSYN® II 4.25% in 10%, 20% or 25% Dextrose Injection and AMINOSYN® II 5% in 25% Dextrose Injection, AMINOSYN® II 4.25% M (amino acid injection 4.25% with maintenance electrolytes) in 10% Dextrose Injection, and AMINOSYN® II with electrolytes in Dextrose Injection with Calcium are strongly hypertonic, they are designed for central vein infusion only.

When given by central venous infusion in combination with electrolytes, vitamins, trace metals, and ancillary fat supplements these solutions 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 emulsions, are indicated for central vein infusion in the prevention of nitrogen loss or in the reversal of negative nitrogen balance in patients 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 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® II SOLUTIONS WITHOUT ELECTROLYTES.

CONTRAINDICATIONS

Aminosyn® II is contraindicated in patients with previous hypersensitivity to this product or any of its components.

These preparations should not be used in patients with anuria unless hemodialysis or continuous arteriovenous hemofiltration is being employed in the management of these patients or hepatic coma or metabolic disorders involving impaired nitrogen utilization and/or inborn errors in amino acid metabolism. Patients with azotemia from any cause should not be infused with amino acids without regard to total nitrogen intake.

Concentration of amino acids greater than 2.5% are contraindicated in infants.

AMINOSYN® II 3.5% M in 5% Dextrose Injection contains inadequate calories for use in nutritionally depleted or hypermetabolic patients who require additional energy intake.

AMINOSYN® II 3.5% M in 5% Dextrose Injection should not be used in patients who will require intravenous alimentation for a longer time period (more than 5 days).

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 (see **PRECAUTIONS - Laboratory Tests**).

Administration of amino acids in the presence of impaired renal function or gastrointestinal bleeding may augment an already elevated blood urea nitrogen (BUN). 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: CONCENTRATED DEXTROSE SOLUTIONS, IF ADMINISTERED TOO RAPIDLY MAY RESULT IN SIGNIFICANT HYPERGLYCAEMIA AND POSSIBLE HYPEROSMOLAR SYNDROME WITH ALL ITS METABOLIC AND CIRCULATORY CONSEQUENCES.

Use in Pregnancy: Use in pregnancy has not yet been studied. Animal reproduction studies have not been conducted with AMINOSYN® II with or without Electrolytes in Dextrose Injection with or without Calcium. It is not known whether these admixtures can cause fetal harm when administered to a pregnant woman. AMINOSYN® II with or without Electrolytes in Dextrose Injection with or without Calcium should be given to a pregnant woman only if clearly needed.

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 acid 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 which contain potassium ion should be used with great care, if at all, in patients with hyperkalemia, severe renal failure and in conditions in which potassium retention is present.

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.

AMINOSYN® II contains sodium hydrosulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people. Reports exist of allergic symptoms including anaphylaxis where a sulfite-sensitive history cannot be confirmed.

Because AMINOSYN® II 3.5% in 25% Dextrose Injection, AMINOSYN® II 4.25% in 10%, 20% or 25% Dextrose Injection, AMINOSYN® II 5% in 25% Dextrose Injection, AMINOSYN® II 4.25% M in 10% Dextrose Injection, and AMINOSYN® II with electrolytes in Dextrose Injection with Calcium are strongly hypertonic, they should be given by central vein infusion only.

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

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: AMINOSYN® II WITH ELECTROLYTES IN DEXTROSE INJECTION WITH AND WITHOUT CALCIUM MAY NOT BE SUITABLE FOR USE IN YOUNG CHILDREN WHO REQUIRE INDIVIDUALIZED ELECTROLYTE THERAPY.

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 an effective source of such energy. Strong hypertonic nutrient solutions should be administered through an indwelling intravenous catheter with the tip located in the superior vena cava.

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 a 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, preferably less than 24 hours.

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

3. Metabolic:

The following complications have been reported: 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.

Do not use unless the solutions are clear and container is undamaged. Discard unused portion. Do not use if solution in either chamber is discolored or if clamp is open or missing.

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 at 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 large 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

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

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 amino acid solution depends on daily protein requirements and the patient's metabolic and clinical response.

As with all intravenous therapy, the primary aim is to provide sufficient water to compensate for insensible, urinary and other (nasogastric suction, fistula drainage, diarrhea) fluid losses. Those requirements, as well as electrolyte and acid-base needs, should be estimated and appropriately prescribed.

Given an amino acid solution of specified total concentration, the volume needed to meet amino acid requirements per 24 hours can be calculated. After making an estimate of the total daily fluid (water) requirement, the balance of fluid needed beyond the volume of amino acid solution required can be provided either as a noncarbohydrate- or a carbohydrate-containing electrolyte solution.

1. Peripheral Vein Administration

The AMINOSYN® II 3.5% in 5% Dextrose Injection and AMINOSYN® II 3.5% M (amino acid injection 3.5% with maintenance electrolytes) in 5% Dextrose Injection admixtures are suitable for peripheral vein administration.

For peripheral vein infusion 1.0 to 1.5 g/kg/day of total amino acids will reduce protein catabolism. Infusion or ingestion of carbohydrate or lipid will not reduce the nitrogen-sparing effect of intravenous amino acid infusions at this dose.

A patient given the recommended maintenance fluid requirement of 45 mL/kg/day in the form of AMINOSYN® II 3.5% M (an amino acid injection 3.5% with maintenance electrolytes) will receive the average daily requirements for sodium, potassium, magnesium, phosphate and chloride, along with an optimal amount of amino acids for preservation of nitrogen balance.

If desired, one-half of an estimated daily amino acid requirement of 1.5 g/kg can be given on the first day. The degree of fat mobilization can be gauged by the presence and amount of acetonuria. Amino acid dosage may be increased on the second day. AMINOSYN® II 3.5% in 5% Dextrose Injection and AMINOSYN® II 3.5% M in 5% Dextrose Injection infused into a peripheral vein can be continued as long as oral nutrition is impaired. However, if a patient is unable to take oral nourishment at the end of 5 days, institution of total parenteral nutrition (TPN) with exogenous energy should be considered.

2. Central Vein Administration

For central vein infusion with concentrated dextrose solution, with or without fat emulsion, the total daily dose of the amino acid solution depends on daily protein requirements and the patient's metabolic and clinical response. The determination of nitrogen balance and accurate daily body weights, corrected for fluid balance, are probably the best means of assessing individual protein requirements.

Adult: AMINOSYN® II 3.5% in 25% Dextrose Injection, AMINOSYN® II 4.25% in 10%, 20% or 25% Dextrose Injection, AMINOSYN® II 5% in 25% Dextrose Injection, AMINOSYN® II 4.25% M in 10% Dextrose Injection, as well as AMINOSYN® II with Electrolytes in Dextrose Injection with Calcium are strongly hypertonic and should only be infused via a central vein in patients who require prolonged TPN. Fat emulsion may be administered to provide part of the energy, if desired. Serum lipids should be monitored for evidence of essential fatty acid deficiency (EFAD) in patients maintained on fat-free TPN.

TPN may be started with AMINOSYN® II 4.25% in 10% Dextrose Injection and AMINOSYN® II 4.25% M in 10% Dextrose Injection. The calculated daily requirement of amino acids for a metabolically stable patient is 1.5 g/kg. Dextrose content is increased to the estimated daily energy requirements. Each gram of dextrose provides approximately 14 kJ (3.4 kcal). Each gram of fat provides 37 kJ (9 kcal).

The average depleted major surgical patient with complications requires between 10.5 and 16.7 MJ (2500 and 4000 kcal) and between 12 and 24 grams of nitrogen per day. An adult patient in an acceptable weight range with restricted activity who is not hypermetabolic, requires about 125 kJ (30 kcal)/kg of body weight/day. Average daily adult fluid requirements are between 2500 and 3000 mL and may be much higher with losses from fistula drainage or severe burns. Typically, a hospitalized patient may lose 12 to 18 grams of nitrogen a day, and in severe trauma the daily loss may be 20 to 25 grams or more.

AMINOSYN® II 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, and magnesium. All these electrolytes are included in AMINOSYN® II with Electrolytes in Dextrose Injection with and without Calcium. Vitamins, including folic acid and vitamin K are required additives. The trace element supplements should be given when long-term TPN is undertaken.

In the AMINOSYN® II with and without Electrolytes in Dextrose Injection admixtures, calcium and phosphorus are added to the solution as indicated. The usual dose of phosphorus added to a liter of TPN solution (containing 25% dextrose) is 12 mmol. This requirement is related to the energy delivered by carbohydrates. 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.

In adults, 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.

The initial rate of intravenous infusion of AMINOSYN® II with and without Electrolytes in Dextrose Injection with and without Calcium should be 2 mL/min and may be increased gradually. If administration 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 is governed by the patient's glucose tolerance estimated by glucose levels in blood and urine.

Amongst the three categories of product (AMINOSYN® II in Dextrose Injection, AMINOSYN® II with Electrolytes in Dextrose Injection and AMINOSYN® II with Electrolytes in Dextrose Injection with Calcium), AMINOSYN® II 5% in 25% Dextrose Injection offers a higher concentration of energy and nitrogen per unit volume respectively. These solutions are 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.

The maximum rate at which dextrose can be infused without producing glycosuria is 0.5 g/kg/hour; at a rate of 0.8 g/kg/hour, about 95% of the infused dextrose is retained.

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.

Pediatric: 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.

PHARMACEUTICAL INFORMATION

Drug Substances

All the amino acids are present in the metabolizable L-form; lysine is present as the acetate salt and tyrosine is made available by the addition of N-acetyl-L-tyrosine. The acetate salt of lysine is used instead of the hydrochloride salt in order to reduce the potential for precipitation or exacerbating metabolic acidosis during infusion of the solution. Tyrosine is present as N-acetyl-L-tyrosine to circumvent the limited solubility of L-tyrosine and to limit the amount of phenylalanine being administered.

Dextrose USP is chemically designated as D-glucose monohydrate, a hexose sugar freely soluble in water.

Composition

Upper Chamber: Contains 500 mL or 1000 mL of AMINOSYN® II (an amino acid injection) with or without Electrolytes - a sterile, nonpyrogenic solution for intravenous infusion. Formulations are described in Table 1.

Lower Chamber: Contains 500 mL or 1000 mL of Dextrose Injection USP with or without Calcium - a sterile, nonpyrogenic, hypertonic solution of Dextrose USP with or without calcium chloride in water for injection. Table 2 indicates the characteristics of these concentrated solutions.

Storage conditions of the NUTRIMIX® Dual Chamber Containers

Store between 15° and 25°C. Do not freeze. Protect from light

Reconstituted Solutions:

The container must be used only after removing the clamp or bar clamp and thoroughly mixing the contents of the two chambers. Mixing the contents of the upper and lower chambers yields a concentrated source of amino acids and carbohydrate calories for intravenous injection. The composition of these combined admixtures is described in Table 3.

Instructions for Use: After removing the overwrap, check for minute leaks by squeezing the container firmly. If leaks are found, discard the solution as sterility may be impaired. Do not use if AMINOSYN® II with or without Electrolytes is discolored or if clamp or bar clamp is open or missing. Color variation in the Dextrose Injection with or without Calcium from pale yellow to yellow is normal and does not alter efficacy.

If supplemental medication is desired, follow directions below before preparing for administration.

To Add Medication:

1. Prepare the appropriate additive port.
2. Using aseptic technique and an additive delivery needle of appropriate length, puncture resealable additive port at target area through inner diaphragm and inject. Withdraw needle after injecting medication.
3. The additive ports should be protected by covering with additive caps.
4. Mix container contents thoroughly.

WARNING: Additives may be incompatible. Consult with your pharmacist when introducing additives. Do not add fat emulsions.

Preparation for Administration
(Use aseptic technique)

1. Open clamp between the two chambers or remove bar clamp by grasping the flexible rod and peeling it away from the primary container. Completely drain all the solution and air into the lower chamber. To achieve this, stretch the side wall of the emptied top chamber.

2. Close flow-control clamp of administration set.
3. Remove cover from outlet port at bottom of container.
4. Insert piercing pin of administration set into port with a twisting motion until the set is firmly seated. **NOTE**: when using a vented administration set, replace bacterial retentive air filter with piercing pin cover. Insert piercing pin with twisting motion until shoulder of air filter housing rests against the outlet port flange.
5. Suspend from hanger at top of container.
6. Squeeze and release drip chamber to establish proper fluid level in chamber.
7. Open flow-control clamp to expel air from set. Close flow-control clamp.
8. Connect to central or peripheral vein infusion catheter as appropriate.
9. Regulate rate of administration with flow-control clamp or an electronic flow-control device. Ensure that all solution and air are in the lower chamber when reading fluid levels.

WARNING: Do not use flexible container in series connections.

Availability

The NUTRIMIX® Dual Chamber Flexible Containers provide 500 mL or 1000 mL of AMINOSYN® II with or without Electrolytes in the upper chamber and 500 mL or 1000 mL of Dextrose Injection USP with or without Calcium in the lower chamber. The available concentrations provided in the separate chambers and in the combined 1000 mL or 2000 mL volume after release of the clamp or bar clamp and mixing are shown in Tables 4, 5, and 6.

Storage recommendations of the admixtures

The AMINOSYN® II with and without Electrolytes in Dextrose Injection with and without Calcium admixtures should be stored under refrigeration and used within 24 hours.

Table 1
UPPER CHAMBER COMPOSITION

	AMINOSYN® II in Dextrose Injection						**AMINOSYN® II with Electrolytes in Dextrose Injection**		**AMINOSYN® with Electrolytes in Dextrose Injection with Calcium**		
List No.	7701	7700	7751	7752	7702	7744	7740	7742	7756	7753	7757
AMINOSYN II solutions	7%	7%	8.5%	8.5%	8.5%	10%	7%M[1]	8.5%M[1]	7% w/elec.	8.5% w/elec.	8.5% w/elec.
Essential Amino Acids (mg/100 mL)											
L-Isoleucine	462	462	561	561	561	660	462	561	462	561	561
L-Leucine	700	700	850	850	850	1000	700	850	700	850	850
L-Lysine (as acetate)	735	735	893	893	893	1050	735	893	735	893	893
L-Methionine	120	120	146	146	146	172	120	146	120	146	146
L-Phenylalanine	209	209	253	253	253	298	209	253	209	253	253
L-Threonine	280	280	340	340	340	400	280	340	280	340	340
L-Tryptophan	140	140	170	170	170	200	140	170	140	170	170
L-Valine	350	350	425	425	425	500	350	425	350	425	425
Non-Essential Amino Acids (mg/100 mL)											
L-Alanine	695	695	844	844	844	993	695	844	695	844	844
L-Arginine	713	713	865	865	865	1018	713	865	713	865	865
L-Aspartic Acid	490	490	595	595	595	700	490	595	490	595	595
L-Glutamic Acid	517	517	627	627	627	738	517	627	517	627	627
Glycine	350	350	425	425	425	500	350	425	350	425	425
L-Histidine	210	210	255	255	255	300	210	255	210	255	255
L-Proline	505	505	614	614	614	722	505	614	505	614	614
L-Serine	371	371	450	450	450	530	371	450	371	450	450
N-Acetyl-L-Tyrosine	189	189	230	230	230	270	189	230	189	230	230
Sodium Hydrosulfite (mg/100 mL)	≤60	≤60	≤60	≤60	≤60	≤60	≤60	≤60	≤60	≤60	≤60

Table 1
UPPER CHAMBER COMPOSITION

	AMINOSYN® II in Dextrose Injection						**AMINOSYN® II with Electrolytes in Dextrose Injection**		**AMINOSYN® with Electrolytes in Dextrose Injection with Calcium**		
List No.	7701	7700	7751	7752	7702	7744	7740	7742	7756	7753	7757
AMINOSYN II solutions	7%	7%	8.5%	8.5%	8.5%	10%	7%M[1]	8.5%M[1]	7% w/elec.	8.5% w/elec.	8.5% w/elec.
Electrolytes (mg/100 mL)											
Sodium Chloride	-	-	-	-	-	-	240	240	410	410	410
Potassium Chloride	-	-	-	-	-	-	194	194	45	45	45
Magnesium Chloride Hexahydrate	-	-	-	-	-	-	60	60	102	102	102
Dibasic Sodium Phosphate	-	-	-	-	-	-	99	99	-	-	-
Dibasic Potassium Phosphate	-	-	-	-	-	-	-	-	522	522	522
Potassium Acetate	-	-	-	-	-	-	-	-	-	-	-
Electrolytes approx. mmol/L (mEq/L)											
Sodium (Na^+)	36	36	38	38	38	44	82	87	80	84	84
Potassium (K^+)	-	-	-	-	-	-	26	26	66	66	66
Chloride (Cl^-)	-	-	-	-	-	-	73	73	86	86	86
Magnesium (Mg^{++})	-	-	-	-	-	-	3 (6)	3 (6)	5 (10)	5 (10)	5 (10)
Phosphorus (P)[2]	-	-	-	-	-	-	7	7	30	30	30
Acetate ($C_2H_3O_2^-$)	50	50	61	61	61	72	50	61	50	61	61
Osmolarity Approx. mOsm/L	647	647	780	780	780	868	719	811	806	896	896
pH (approx.)[3]	5.8	5.8	5.8	5.8	5.8	5.8	5.8	5.8	5.8	5.8	5.8

[1] Contains maintenance electrolytes; [2] One mmol of phosphorus = 31 mg; [3] pH adjusted with sodium hydroxide.

Table 2

LOWER CHAMBER COMPOSITION

	AMINOSYN® II in Dextrose Injection						AMINOSYN® II with Electrolytes in Dextrose Injection		AMINOSYN® II with Electrolytes in Dextrose Injection with Calcium		
List No.	7701	7700	7751	7752	7702	7744	7740	7742	7756	7753	7757
Dextrose Injection USP solutions	10%	50%	20%	40%	50%	50%	10%	20%	50%	40%	50%
Dextrose monohydrate (g/100 mL)	10	50	20	40	50	50	10	20	50	40	50
Calcium Chloride (Dihydrate) (mg/100 mL)	-	-	-	-	-	-	-	-	73.5	73.5	73.5
Energy kJ (Cal)/100 mL	142 (34)	710 (170)	284 (68)	568 (136)	710 (170)	710 (170)	142 (34)	284 (68)	710 (170)	568 (136)	710 (170)
Osmolarity (approx., mOsm/L)	546	1997	934	1740	1997	1977	546	934	1916	1720	1916
pH (approx.)	4.0	4.3	4.1	4.2	4.3	4.3	4.3	4.3	4.3	4.3	4.3

Table 3
COMBINED ADMIXUTRE COMPOSITION

	AMINOSYN® II in Dextrose Injection						**AMINOSYN® II with Electrolytes in Dextrose Injection**		**AMINOSYN® II with Electrolytes in Dextrose Injection with Calcium**		
List No.	7701	7700	7751	7752	7702	7744	7740	7742	7756	7753	7757
AMINOSYN II solutions /Dextrose solutions	3.5 /5%	3.5% /25%	4.25% /10%	4.25% /20%	4.25% /25%	5% /25%	3.5% M[1] /5%	4.25% M[1] /10%	3.5% w/elec. /25%	4.25% w/elec. /20%	4.25% w/elec. /25%
Essential Amino Acids (mg/100 mL)											
L-Isoleucine	231	231	280	280	280	330	231	280	231	280	280
L-Leucine	350	350	425	425	425	500	350	425	350	425	425
L-Lysine (as acetate)	368	368	446	446	446	525	368	446	368	446	446
L-Methionine	60	60	73	73	73	86	60	73	60	73	73
L-Phenylalanine	104	104	126	126	126	149	104	126	104	126	126
L-Threonine	140	140	170	170	170	200	140	170	140	170	170
L-Tryptophan	70	70	85	85	85	100	70	85	70	85	85
L-Valine	175	175	212	212	212	250	175	212	175	212	212
Non-Essential amino Acids (mg/100 mL)											
L-Alanine	348	348	422	422	422	496	348	422	348	422	422
L-Arginine	356	356	432	432	432	509	356	432	356	432	432
L-Aspartic Acid	245	245	298	298	298	350	245	298	245	298	298
L-Glutamic Acid	258	258	314	314	314	369	258	314	258	314	314
Glycine	175	175	212	212	212	250	175	212	175	212	212
L-Histidine	105	105	128	128	128	150	105	128	105	128	128
L-Proline	252	252	307	307	307	361	252	307	252	307	307
L-Serine	186	186	225	225	225	265	186	225	186	225	225
N-Acetyl-L-Tyrosine	94	94	115	115	115	135	94	115	94	115	115
Dextrose (g/100 mL)	5	25	10	20	25	25	5	10	25	20	25
Sodium Hydrosulfite (mg/100 mL)	≤30	≤30	≤30	≤30	≤30	≤30	≤30	≤30	≤30	≤30	≤30

Table 3
COMBINED ADMIXUTRE COMPOSITION

	AMINOSYN® II in Dextrose Injection						**AMINOSYN® II with Electrolytes in Dextrose Injection**		**AMINOSYN® II with Electrolytes in Dextrose Injection with Calcium**		
List No.	7701	7700	7751	7752	7702	7744	7740	7742	7756	7753	7757
AMINOSYN II solutions /Dextrose solutions	3.5 /5%	3.5% /25%	4.25% /10%	4.25% /20%	4.25% /25%	5% /25%	3.5% M[1] /5%	4.25% M[1] /10%	3.5% w/elec. /25%	4.25% w/elec. /20%	4.25% w/elec. /25%
Electrolytes (mg/100 mL)											
Sodium Chloride	-	-	-	-	-	-	120	120	205	205	205
Potassium Chloride	-	-	-	-	-	-	97	97	22	22	22
Magnesium Chloride Hexahydrate	-	-	-	-	-	-	30	30	51	51	51
Dibasic Sodium Phosphate	-	-	-	-	-	-	49	49	-	-	-
Calcium Chloride Dihydrate	-	-	-	-	-	-	-	-	37	37	37
Potassium Acetate	-	-	-	-	-	-	-	-	-	-	-
Dibasic Potassium Phosphate	-	-	-	-	-	-	-	-	261	261	261
Electrolytes approx. mmol/L (mEq/L)											
Sodium (Na^+)	18	18	19	19	19	22	41	44	40	42	42
Potassium (K^+)	-	-	-	-	-	-	13	13	33	33	33
Chloride (Cl^-)	-	-	-	-	-	-	37	37	48	48	48
Magnesium (Mg^{++})	-	-	-	-	-	-	1.5 (3)	1.5 (3)	2.5 (5)	2.5 (5)	2.5 (5)
Calcium (Ca^{++})	-	-	-	-	-	-	-	-	2.5 (5)	2.5 (5)	2.5 (5)
Phosphorus (P)[2]	-	-	-	-	-	-	3.5	3.5	15	15	15
Acetate ($C_2H_3O_2^-$)	25	25	31	31	31	36	25	31	25	31	31
Osmolarity Approx. mOsm/L	585	1515	894	1295	1536	1539	616	919	1556	1353	1563
pH (approx.)[3]	5.8	5.8	5.8	5.8	5.8	5.8	5.8	5.8	5.8	5.8	5.8
Total Amino Acids (g/L)	35	35	42.5	42.5	42.5	50	35	42.5	35	42.5	42.5
Protein Equivalent (g/L)	35	35	42.5	42.5	42.5	50	35	42.5	35	42.5	42.5
Total Nitrogen (g/L)	5.35	5.35	6.5	6.5	6.5	7.7	5.35	6.5	5.35	6.5	6.5

1 Contains maintenance electrolytes; 2 One mmol of phosphorus = 31 mg; 3 pH adjusted with sodium hydroxide.

Table 4

AMINOSYN® II IN DEXTROSE INJECTION

	CONCENTRATION PRIOR TO ADMIXTURE		CONCENTRATION FOLLOWING ADMIXTURE TOTAL ADMIXTURE		
LIST NO.	**AMINOSYN® II**	**Dextrose**	**AMINOSYN® II**	**Dextrose**	**Volume**
7701	7%	10%	3.5%	5%	1000 mL
7700	7%	50%	3.5%	25%	1000 mL
7751	8.5%	20%	4.25%	10%	1000 mL
7752	8.5%	40%	4.25%	20%	1000 mL
7702	8.5%	50%	4.25%	25%	1000 mL
7744	10%	50%	5%	25%	1000 mL

Table 5

AMINOSYN® II WITH ELECTROLYTES IN DEXTROSE INJECTION

	CONCENTRATION PRIOR TO ADMIXTURE		CONCENTRATION FOLLOWING ADMIXTURE TOTAL ADMIXTURE		
LIST NO.	**AMINOSYN® II**	**Dextrose**	**AMINOSYN® II**	**Dextrose**	**Volume**
7740	7% M[1]	10%	3.5% M[1]	5%	1000 mL
7742	8.5% M[1]	20%	4.25% M[1]	10%	1000 mL

[1] Contains maintenance electrolytes

Table 6

AMINOSYN® II WITH ELECTROLYTES IN DEXTROSE WITH CALCIUM

	CONCENTRATION PRIOR TO ADMIXTURE		CONCENTRATION FOLLOWING ADMIXTURE TOTAL ADMIXTURE		
LIST NO.	**AMINOSYN® II with Electrolytes**	**Dextrose with Calcium**	**AMINOSYN® II with Electrolytes**	**Dextrose with Calcium**	**Volume**
7756	7%	50%	3.5%	25%	1000 mL
7753	8.5%	40%	4.25%	20%	1000 mL
7757	8.5%	50%	4.25%	25%	1000 mL