PRESCRIBING INFORMATION

AMINOSYN® II with Electrolytes

(Amino Acid Injection with Electrolytes)

Nutritive and Electrolyte Supplements for Intravenous Infusion

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NAME OF DRUGS

AMINOSYN® II with Electrolytes

(Amino Acid Injection with Electrolytes)

THERAPEUTIC OR PHARMACOLOGICAL CLASSIFICATION

Nutritive and Electrolyte Supplements
for Intravenous Infusion

DESCRIPTION

AMINOSYN II with Electrolytes Solutions can be described as follows:

AMINOSYN® II with Electrolytes Formulation

Essential Amino Acids (mg/100mL)

AMINOSYN® II	**10%[1]**
L-Isoleucine	660
L-Leucine	1000
L-Lysine (acetate)[2]	1050
L-Methionine	172
L-Phenylalanine	298
L-Threonine	400
L-Tryptophane	200
L-Valine	500

[1] With Electrolytes
[2] Amount cited is for Lysine alone and does not include the acetate

Non essential Amino Acids (mg/100mL)

AMINOSYN® II	10%[1]
L-Alanine	993
L-Arginine	1018
L-Aspartic Acid	700
L-Glutamic Acid	738
L-Histidine	300
L-Proline	722
L-Serine	530
N-Acetyl-L-Tyrosine	270
Glycine	500

AMINOSYN® II	10%[1]
Protein Equivalent (approx. g/L)	100
Total Nitrogen (g/L)	15.3
Osmolarity (mOsm/L, calc.)	1130
pH (approx.)[2]	5.8

[1] With electrolytes
[2] May contain sodium hydroxide for pH adjustment

The electrolyte content of the formulation in mmol (mEq)/L is listed as follows:

AMINOSYN® II	10%[1]
mg/ 100 mL	
Sodium chloride	410
Potassium chloride	45
Sodium phosphate, dibasic	-
Magnesium chloride, hexahydrate	102
Potassium phosphate, dibasic	522
Sodium hydrosulfite	20
Electrolytes [mmol (mEq)/L]	
Sodium (Na^+)[2]	87
Potassium (K^+)	66
Magnesium (Mg^{++})	5(10)
Phosphorus ($HPO_4^=$)	30
Chloride (Cl^-)	86
Acetate ($C_2H_3O_2^-$)	72[3]

[1] With Electrolytes
[2] Includes sodium from antioxidant, sodium hydrosulfite (20mg/ 100 mL) and pH adjustor.
[3] Includes acetate from lysine acetate

ACTIONS, CLINICAL PHARMACOLOGY

AMINOSYN® II with Electrolytes (an amino acid injection with electrolytes) provides crystalline amino acids to promote protein synthesis and wound healing, and to reduce the rate of endogenous protein catabolism. AMINOSYN® II with Electrolytes, given by central venous infusion in combination with concentrated dextrose, electrolytes, vitamins, trace metals and ancillary fat supplements, constitutes total parenteral nutrition (TPN). AMINOSYN® II with Electrolytes 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 TPN or peripheral vein administration of AMINOSYN® II with Electrolytes.

INDICATIONS AND CLINICAL USES

1. **Peripheral Vein Administration**

   AMINOSYN® II 10% with Electrolytes (amino acid injection with electrolytes) 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 patients' energy needs are met from their own fat stores.

   Because AMINOSYN® II 10% with Electrolytes is strongly hypertonic it must be diluted before administration by peripheral vein (see DOSAGE AND ADMINISTRATION).

2. **Central Vein Administration**

   AMINOSYN® II 10% Injection with Electrolytes, when administered with Dextrose 50% Injection, with or without fat emulsions, is designed for central vein infusion only. When given by central venous infusion in combination with concentrated dextrose, 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 emulsions, are indicated for central vein infusion in the prevention of nitrogen loss or in the reversal of negative nitrogen balance in patients where: (1) the alimentary tract, by the oral, gastrostomy or jejunostomy route cannot or should not be used; (2) gastrointestinal absorption of protein is impaired; (3) metabolic requirements for protein are substantially increased as with extensive burns and (4) morbidity and mortality may be reduced by replacing amino acids lost from tissue breakdown, thereby preserving tissue reserves, as in acute renal failure.

CONTRAINDICATIONS

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

This preparation should not be used in patients with hepatic coma or anuria or metabolic disorders involving impaired nitrogen utilization. Patients with azotemia from any cause should not be infused with amino acids without regard to total nitrogen intake.

AMINOSYN® II with Electrolytes Injection has a concentration of amino acids greater than 2.5% and is thus contraindicated in infants.

WARNINGS

Intravenous infusion of amino acids 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 normal postprandial limits and continue to rise. It should be noted that a modest rise in BUN normally occurs as a result of increased protein 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.

Should symptoms of hyperammonemia develop, amino acid administration should be discontinued and the patient's clinical status re-evaluated.

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.

This product 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 individuals. The overall prevalence of sulfite sensitivity in the general population in unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic individuals. Reports exist of allergic symptoms including anaphylaxis where a sulfite-sensitive history cannot be confirmed.

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).

Use in Pregnancy

Use in pregnancy has not yet been studied.

Animal reproduction studies have not been conducted with AMINOSYN® II with Electrolytes. It is not known whether AMINOSYN® II with Electrolytes can cause fetal harm when administered to a pregnant woman. AMINOSYN® II with Electrolytes should be given to a pregnant woman only if clearly needed.

PRECAUTIONS

General

Because AMINOSYN® II 10% Injection with Electrolytes (Amino Acid Injections 10% with Electrolytes) is strongly hypertonic, it must not be given by peripheral vein unless diluted. All additives, such as trace elements, etc., should be taken into account for the dilution.

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 glucose 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 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.

Use in Children

The effect of infusion of amino acids, without dextrose, upon carbohydrate metabolism of children is not known at this time. AMINOSYN® II WITH ELECTROLYTES 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 anabolic effects of infused amino acids.

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

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.

Long-Term Total Parenteral Nutrition (TPN)

For long-term TPN, or if a patient has inadequate fat stores, 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 cave.

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.

   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 metabolic 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.

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.

See also WARNINGS and Special Precautions for Central Venous Infusions.

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.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

In the event of overhydration or solute overload, re-evaluate the patient and institute appropriate corrective measures (see **WARNINGS** ant **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**

AMINOSYN® II 10% with Electrolytes Injection (amino acid injections 10% with electrolytes) is strongly hypertonic and must be diluted with Sterile Water for Injection or 5% to 10% Dextrose Injection to achieve a final amino acid solution of 5% 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 acids at this dose.

A patient given the recommended maintenance fluid requirement of 45 mL/kg/day in the form of 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. Amino acids, together with dextrose in concentrations of 5% to 10% 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 emulsions, 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 10% with Electrolytes should only be infused via a central vein when admixed with sufficient dextrose to provide full energy requirements 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 10% dextrose added to the calculated daily requirement of amino acids (1.5 g/kg for a metabolically stable patient). Dextrose content is gradually increased over the next few days to the estimated daily energy requirements 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).

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 a grams or more.

AMINOSYN® II 10% with Electrolytes is designed to supply necessary electrolytes to patients in a stable metabolic state (about three-fourths of all patients on TPN). Other patients may require more or less of the electrolytes present, e.g., cardiac patients who should not receive sodium. AMINOSYN® II 10% with Electrolytes does not contain calcium, and this should be added as indicated.

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 liter 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.

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 vena cave. Typically, the 10% solution is used in equal volume with 50% dextrose to provide an admixture containing 5% amino acids and 25% dextrose.

The rate of intravenous infusion initially 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.

AMINOSYN® II 10% with Electrolytes, when mixed with an appropriate volume of concentrated dextrose, offers a higher energy content 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.

Provision of adequate energy in the form of hypertonic dextrose may require exogenous insulin to prevent hyperglycemia and glycosuria. To prevent rebound hypoglycemia, do not abruptly discontinue administration of nutritional solutions.

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 pediatric practice.

PHARMACEUTICAL INFORMATION

Drug Substance

AMINOSYN® II Solution with Electrolytes (amino acid injection with electrolytes) is sterile, non-pyrogenic solution for intravenous infusion.

The following formula represents component amino acids and the optimal proportions of each in AMINOSYN® II 10% with Electrolytes (amino acid injection 10% with electrolytes) expressed in grams (g) per 100 grams of amino acid content.

ESSENTIAL AMINO ACIDS		NON-ESSENTIAL AMINO ACIDS	
L-Isoleucine	6.6	L-Alanine	9.9
L-Leucine	10	L-Arginine	10.2
L-Lysine (as acetate)	10.5	L-Aspartic Acid	7
L-Methionine	1.7	L-Glutamic Acid	7.4
L-Phenylalanine	3	L-Histidine	3
L-Threonine	4	L-Proline	7.2
L-Tryptophan	2	L-Serine	5.3
L-Valine	5	N-Acetyl-L-Tyrosine	2.7
		Glycine	5

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 precipitating 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.

Stability and Storage Recommendations

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

Constitution

It is absolutely essential that the admixture be prepared using strict aseptic techniques as this nutrient mixture is a good growth medium for microorganisms.

i) Peripheral Vein Administration

AMINOSYN® II 10% with Electrolytes is strongly hypertonic and must be diluted before peripheral vein administration. Sterile Water for Injection or 5% to 10% Dextrose Injection are usually added in an equal volume with the amino acid solution to achieve a final amino acid concentration 5% for peripheral administration.

ii) Central Vein Administration

Typically, the 10% solution with Electrolytes is used in equal volume with 50% Dextrose Injection to provide an admixture containing 5% amino acids and 25% dextrose.

Stability and Storage Recommendations Following Constitution

AMINOSYN® II solutions with Electrolytes mixed with dextrose should be stores under refrigeration and used within 24 hours.

DOSAGE FORMS

Availability

AMINOSYN® II with Electrolytes (an amino acid injection with electrolytes) is available in the following presentation:

AMINOSYN® II Concentration	**Volume of Glass Container (mL)**
10% with Electrolytes	1000

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