PRESCRIBING INFORMATION

# AMINOSYN™ II 7%

# AMINOSYN™ II 8.5%

# AMINOSYN™ II 10%

# AMINOSYN™ II 15%

(amino acids for injection 7%, 8.5%, 10% and 15% w/v)

**Sulfite-Free**

**Nutritive Supplement for Intravenous Infusion**

Hospira Healthcare Corporation
1111 Dr. Frederik-Philips
St-Laurent, Quebec
H4M 2X6

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Control # 151223

## PRESCRIBING INFORMATION

NAME OF DRUGS

AMINOSYN™ II 7%
AMINOSYN™ II 8.5%
AMINOSYN™ II 10%
AMINOSYN™ II 15%

(amino acids for injection 7%, 8.5%, 10% and 15% w/v)

Sulfite-Free

## THERAPEUTIC OR PHARMACOLOGICAL CLASSIFICATION

Nutritive Supplement for Intravenous Infusion

## ACTIONS AND CLINICAL PHARMACOLOGY

AMINOSYN® II 7%, 8.5%, 10% and 15% (amino acids for injection 7%, 8.5%, 10% and 15%) provides crystalline amino acids which, when administered with appropriate source of energy, promote protein synthesis and wound healing and prevent endogenous protein catabolism. AMINOSYN® II, when given by peripheral or central venous infusion in combination with dextrose, electrolytes, vitamins, trace metals and/or ancillary fat supplements, constitutes Total Parenteral Nutrition (TPN).

## INDICATIONS AND CLINICAL USE

Parenteral nutrition with AMINOSYN® II 7%, 8.5%, 10% and 15% is indicated to prevent nitrogen loss or treat negative nitrogen balance in adults and children where:

1. the alimentary tract, by the oral, gastrotomy, or jejunostomy route cannot or should not be used, or adequate protein intake is not feasible by these routes;
2. gastrointestinal absorption of protein is impaired; or
3. protein requirements are substantially increased as with extensive burns.

Dosage, route of administration, and concomitant infusion of non-protein calories are dependent on various factors, such as nutritional and metabolic status of the patient, anticipated duration of parenteral nutritional support, and vein tolerance. (See **DOSAGE AND ADMINISTRATION** for additional information).

## 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 hepatic coma, patients with anuria, unless dialysed, patients with metabolic disorders involving impaired nitrogen utilization or patients with hypersensitivity to one or more amino acids present in the solution. Patients with azotemia from any cause should not be infused with amino acids without regard to total nitrogen intake.

## WARNINGS

AMINOSYN® II SOLUTIONS WITHOUT ELECTROLYTES ARE INTENDED FOR PATIENTS REQUIRING INDIVIDUALIZED ELECTROLYTE THERAPY. SERUM ELECTROLYTES SHOULD BE FREQUENTLY MONITORED.

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.

Proper administration of these injections requires knowledge of fluid and electrolyte balance and nutrition as well as clinical expertise in recognition and treatment of the complications which may occur.

Frequent clinical evaluation and laboratory tests are necessary for proper monitoring during administration (see **PRECAUTIONS - Laboratory Tests**).

The intravenous administration of these solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of delusional states is inversely proportional to the solute concentration of the solution infused. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the concentration of the solution.

Administration of amino acid solutions 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. Conservative doses of amino acids should be given, dictated by the nutritional status of

the patient.

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 patients with hepatic insufficiency may result in serum amino acid imbalances, metabolic alkalosis, prerenal azotemia, hyperammonemia, stupor and coma.

Hyperammonemia is of special significance in infants, as it can result in mental retardation. It may be related to a deficiency of the urea cycle amino acids enzymes (see **CONTRAINDICATIONS**). It is essential that blood ammonia 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.

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

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.

The infusion of hypertonic dextrose may lead to hyperglycemia, glycosuria, and hyperosmolar syndrome, and administration into peripheral vein may result in vein irritation, damage and thrombosis.

**Use in Pregnancy**

Use in pregnancy has not yet been studied.

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

## 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:

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.

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

In patients with myocardial infarct, infusion of amino acids should always be accompanied by dextrose, since in anoxia, free fatty acids cannot be utilized by the myocardium, and energy must be produced anaerobically from glycogen or glucose.

It is essential to provide adequate calories concurrently if parenterally administered amino acids are to be retained by the body and utilized for protein synthesis. Concentrated dextrose solutions are an effective source of such calories. Blood and urine glucose should be monitored on a routine basis in patients receiving this therapy.

Special care must be taken when giving hypertonic dextrose to diabetic and prediabetic patients. To prevent severe hyperglycemia in such patients, insulin may be required. Administration of glucose at the rate exceeding the patient's maximum utilization level (5 mg/kg/min) may lead to hyperglycemia, glycosuria, coma and death. Caution should be exercised when giving these injections to patients receiving corticosteroids or corticotrophin.

**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.

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral

therapy or whenever the condition of the patient warrants such evaluation.

Strongly hypertonic nutrient solutions should be administered through an indwelling intravenous catheter with the tip located in the superior vena cava.

It is essential to provide adequate calories concurrently if parenterally administered amino acids are to be retained by the body and utilized for protein synthesis. Concentrated dextrose solutions are an effective source of such calories. Blood and urine glucose should be monitored on a routine basis in patients receiving this therapy.

Administration of amino acids without carbohydrates may result in the accumulation of ketone bodies in the blood. Correction of this ketonemia may be achieved by the administration of carbohydrate.

Extraordinary electrolyte losses that may occur during protracted nasogastric suction, vomiting, diarrhea or gastrointestinal fistula drainage may necessitate additional electrolyte supplementation.
Metabolic acidosis can be prevented or readily controlled by adding a portion of the cations in the electrolyte mixture as acetate salts, and in the case of hyperchloremic acidosis, by keeping the total chloride content of the infusate to a minimum.

**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 infused with dextrose as part of a parenteral feeding regimen.

Additives may be incompatible. When introducing additives, always consult with hospital pharmacist, use aseptic technique, mix thoroughly, and do not store. Final infusate should be inspected for cloudiness or precipitation immediately after mixing and prior to administration, and periodically during administration. Use only if solution is clear.

**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 effective sources of such energy. Strongly hypertonic nutrient solutions (those containing dextrose at a final concentration greater than 10%) 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 PERFORMED 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.

   The typical management of sepsis includes replacing the solution being administered with a fresh container and set, and culturing the remaining solution for bacterial or fungal contamination. If sepsis persists and another source of infection is not identified, the catheter is removed, proximal tip cultured and a new catheter inserted when the fever has subsided. Non-specific prophylactic treatment is not recommended. Clinical experience indicates that the catheter is likely to be the prime source of infection, as opposed to aseptically prepared and properly stored solutions.

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. See **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.

Reactions which may occur because of the solution or the technique of administration include infection at injection site, extravasation and hypervolemia.

Electrolyte additives should be spread throughout the day, and 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** and **PRECAUTIONS**).

For management of a suspected drug overdose, contact your regional Poison Control Centre.

## DOSAGE AND ADMINISTRATION

DO NOT USE FLEXIBLE CONTAINER IN SERIES CONNECTIONS.

Parenteral products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Care must be taken to avoid incompatible mixtures. Consult with pharmacist. Colour variation from pale yellow to yellow is normal and does not alter efficacy.

Dosage and rate of administration of AMINOSYN® II depend on daily protein requirements and are guided by the patient's fluid intake limits and glucose and nitrogen tolerance.

The determination of nitrogen balance and accurate daily body weight, corrected for fluid balance, are probably the best means of assessing individual protein requirement.

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.

### Peripheral Vein Administration

AMINOSYN® II solutions are 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 3.5%, 4.25%, 5% or 7.5% for peripheral vein administration. For peripheral vein infusion 1.0 to 1.5 g/kg/day of total amino acids will reduce protein catabolism.

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.

**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.

Adults

AMINOSYN® II solutions 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 and 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 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).

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, 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.

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. Calcium and phosphate are added to the solution as indicated. The usual dose of phosphorous added to a litre of TPN solution (containing 25% dextrose) is 12 to 15 mmol. This requirement is related to the energy delivered by carbohydrate.

Calcium and phosphate 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 B12, 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 cava. Typically, the 7%, 8.5%, 10% and 15% solution is used in equal volume with 50% dextrose to provide an admixture containing 3.5%, 4.25%, 5% or 7.5% amino acids and 25% dextrose respectively.

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 solutions, when mixed with an appropriate volume of concentrated dextrose, offer 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 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 state 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

AMINOSYN® II solutions are sterile, non pyrogenic solutions for intravenous infusion.

### Drug Substance

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

| ESSENTIAL AMINO ACIDS | g/100 g | NON-ESSENTIAL AMINO ACIDS | g/100 g |
|---|---|---|---|
| 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 provided as 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.

### Composition

AMINOSYN® II solutions can be described as follows:

| **AMINOSYN® II FORMULATIONS**<br>**Essential Amino Acids (mg/100 mL)** | | | | |
|---|---|---|---|---|
| **AMINOSYN® II** | **7% w/v** | **8.5% w/v** | **10% w/v** | **15% w/v** |
| L-Isoleucine | 462 | 561 | 660 | 990 |
| L-Leucine | 700 | 850 | 1000 | 1500 |
| L-Lysine (acetate)* | 735 | 893 | 1050 | 1575 |
| L-Methionine | 120 | 146 | 172 | 258 |
| L-Phenylalanine | 209 | 253 | 298 | 447 |
| L-Threonine | 280 | 340 | 400 | 600 |
| L-Tryptophan | 140 | 170 | 200 | 300 |
| L-Valine | 350 | 425 | 500 | 750 |
| * Amount cited is for Lysine alone and does not include the acetate. | | | | |

| Nonessential Amino Acids (mg/100 mL) | | | | |
|---|---|---|---|---|
| **AMINOSYN® II** | **7% w/v** | **8.5% v/w** | **10% w/v** | **15% w/v** |
| L-Alanine | 695 | 844 | 993 | 1490 |
| L-Arginine | 713 | 865 | 1018 | 1527 |
| L-Aspartic Acid | 490 | 595 | 700 | 1050 |
| L-Glutamic Acid | 517 | 627 | 738 | 1107 |
| L-Histidine | 210 | 255 | 300 | 450 |
| L-Proline | 505 | 614 | 722 | 1083 |
| L-Serine | 371 | 450 | 530 | 795 |
| N-Acetyl-L-Tyrosine | 189 | 230 | 270 | 405 |
| Glycine | 350 | 425 | 500 | 750 |

| **AMINOSYN® II** | **7% w/v** | **8.5% w/v** | **10% w/v** | **15% w/v** |
|---|---|---|---|---|
| Protein Equivalent (approx. g/L) | 70 | 85 | 100 | 150 |
| Total Nitrogen (g/L) | 10.7 | 13.0 | 15.3 | 23.0 |
| Osmolarity (mOsm/L) | 589 | 706 | 840 | 1270 |
| pH (approx.)[a] | 5.8 | 5.8 | 5.8 | 5.8 |
| a Contains sodium hydroxide for pH adjustment | | | | |

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

| **AMINOSYN™ II** | **7% w/v** | **8.5% w/v** | **10% w/v** | **15% w/v** |
|---|---|---|---|---|
| Electrolytes [mmol (mEq)/L] | | | | |
| Sodium (Na+)[b] | 25 | 32 | 38 | 50.0 |
| Acetate (C2H302-)[c] | 50 | 61 | 72 | 107.6 |
| b Includes Na+ from pH adjustor<br>c Includes acetate from lysine acetate | | | | |

## 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.

## 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.

## Stability and Storage Recommendations following Constitution

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™ II is available in the following presentations:

| AMINOSYN™ II CONCENTRATION | VOLUME OF CONTAINERS (mL) |
|---|---|
| 7% | 500 and 1000 |
| 8.5% | 500 and 1000 |
| 10% | 500, 1000 and 2000 |
| 15% | 2000 |

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