AMINOSYN SULFITE FREE

Generic Name: crystalline amino acid solution

Brand Name: Aminosyn Sulfite Free

Last reviewed on RxList: 10/15/2019

Drug Description

Aminosyn®
Sulfite-Free

A CRYSTALLINE AMINO ACID SOLUTION
Flexible Plastic Container

DESCRIPTION

Aminosyn®, Sulfite-Free, (a crystalline amino acid solution) is a sterile, nonpyrogenic solution for intravenous infusion. Aminosyn is oxygen sensitive. Five different formulations are available:

Aminosyn Formulations Essential Amino Acids (mg/100 mL)

Aminosyn	3.5%	5%	7%	8.5%	10%
Isoleucine	252	360	510	620	720
Leucine	329	470	660	810	940
Lysine (acetate)*	252	360	510	624	720
Methionine	140	200	280	340	400
Phenylalanine	154	220	310	380	440
Threonine	182	260	370	460	520
Tryptophan	56	80	120	150	160
Valine	280	400	560	680	800

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

Nonessential Amino Acids (mg/100 mL)

Aminosyn	3.5%	5%	7%	8.5%	10%
Alanine	448	640	900	1100	1280
Arginine	343	490	690	850	980
Histidine	105	150	210	260	300
Proline	300	430	610	750	860
Serine	147	210	300	370	420
Tyrosine	31	44	44	44	44
Glycine	448	640	900	1100	1280

Electrolytes (mEq/Liter)

Aminosyn	3.5%	5%	7%	8.5%	10%
Sodium (Na^+)	None	None	None	None	None
Potassium (K^+)	None	None	None	None	None
Chloride (Cl^-)	None	None	None	35[a]	None
Acetate ($C_2H_3O_2^-$)[b]	51	86	105	90	147

[a] Includes chloride from HCl added for processing and pH adjustment.
[b] Includes acetate from acetic acid used in processing and from Lysine acetate.

Product Characteristics

Aminosyn	3.5%	5%	7%	8.5%	10%
Protein Equivalent (approx. grams/liter)	35	50	70	85	100
Total Nitrogen (grams/liter)	5.5	7.86	11.00	13.4	15.72
Osmolarity (mOsmol/liter)	322	462	655	802	932
pH	5.2	5.2	5.2	5.2	5.2
Range	(4.5 –6.0[c])	(4.5 – 6.0[c])	(4.5 – 6.0[c])	(4.5 – 6.0[d])	(4.5 – 6.0[c])

[c] Adjusted with acetic acid.
[d] Adjusted with acetic acid and hydrochloric acid.

The formulas for the individual amino acids present in Aminosyn are as follows:

Essential Amino Acids

Isoleucine	$(C_6H_{13}NO_2)$
Leucine	$(C_6H_{13}NO_2)$
Lysine Acetate	$(C_6H_{14}N_2O_2 \cdot CH_3COOH)$
Methionine	$(C_5H_{11}NO_2S)$
Phenylalanine	$(C_9H_{11}NO_2)$
Threonine	$(C_4H_9NO_3)$
Tryptophan	$(C_{11}H_{12}N2O_2)$
Valine	$(C_5H_{11}NO_2)$

Nonessential Amino Acids

Alanine	$(C_3H_7NO_2)$
Arginine	$(C_6H_{14}N_4O_2)$
Histidine	$(C_6H_9N_3O_2)$
Proline	$(C_5H_9NO_2)$
Serine	$(C_3H_7NO_3)$
Tyrosine	$(C_9H_{11}NO_3)$
Glycine	$(C_2H_5NO_2)$

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

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

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

Indications

INDICATIONS

Aminosyn, Sulfite-Free, (a crystalline amino acid solution) infused with dextrose by peripheral vein infusion is indicated as a source of nitrogen in the nutritional support of patients with adequate stores of body fat, in whom, for short periods of time, oral nutrition cannot be tolerated, is undesirable, or inadequate.

SUPPLEMENTAL ELECTROLYTES, IN ACCORDANCE WITH THE PRESCRIPTION OF THE ATTENDING PHYSICIAN, MUST BE ADDED TO AMINOSYN SOLUTIONS WITHOUT ELECTROLYTES.

Aminosyn can be administered peripherally with dilute (5 to 10%) dextrose solution and I.V. fat emulsion as a source of nutritional support. This form of nutritional support can help to preserve protein and reduce catabolism in stress conditions where oral intake is inadequate.

When administered with concentrated dextrose solutions with or without fat emulsions, Aminosyn is also indicated for central vein infusion to prevent or reverse 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; (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.

Dosage

DOSAGE AND ADMINISTRATION

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

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

1. Peripheral Vein Nutritional Maintenance

Aminosyn® 3.5%, Sulfite-Free, (a crystalline amino acid solution) together with dextrose in concentrations of 5% to 10% is suitable for administration by peripheral vein. This solution is not intended for central vein infusion since it does not contain adequate amounts of amino acids or electrolytes for administration with high concentrations of dextrose. Aminosyn 7%, 8.5% or 10% may be diluted with sterile water for injection or 5 to 10% Dextrose Injection to achieve a final amino acid concentration of 3.5, 4.25 or 5% for peripheral administration.

For peripheral intravenous 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.

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

For an amino acid solution of specified total concentration, the volume required 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. I.V. lipid emulsion may be substituted for part of the carbohydrate containing solution. Vitamins and additional electrolytes as needed for maintenance or to correct imbalances may be added to the amino acid solution.

If desired, only one-half of an estimated daily amino acid requirement of 1.5 g/kg can be given on the first day. Amino acids together with dextrose in concentrations of 5% to 10% infused into a peripheral vein can be continued while oral nutrition is impaired. However, if a patient is unable to take oral nourishment for a prolonged period of time, institution of total parenteral nutrition with exogenous calories should be considered.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.