

Aminosin Plus

Amino Acid, Glucose and Electrolytes

Composition

Each 100 ml IV Infusion contains

Essential Amino Acids	Specification	Quantity
L-Isoleucine	USP	0.390 g
L-Leucine	USP	0.530 g
L-Lysine Hydrochloride	USP	0.390 g
L-Methionine	USP	0.190 g
L-Phenylalanine	USP	0.550 g
L-Threonine	USP	0.300 g
L-Tryptophan	USP	0.100 g
L-Valine	USP	0.430 g
L-Histidine	USP	0.240 g
L-Tyrosine	USP	0.050 g
Non-Essential Amino Acids		
L-Arginine	USP	0.330 g
L-Aspartic Acid	USP	0.410 g
L-Glutamic Acid	BP	0.900 g
L-Alanine	USP	0.300 g
L-Cysteine	BP	0.140 g
Glycine	USP	0.210 g
L-Proline	USP	0.810 g
L-Serine	USP	0.750 g
Carbohydrate		
Anhydrous Glucose	BP	10.000 g
Electrolytes (mmol/L)		
Sodium (Na ⁺)		50.0
Potassium (K ⁺)		20.0
Calcium (Ca ⁺⁺)		2.5
Magnesium (Mg ⁺⁺)		1.5
Chloride (Cl ⁻)		32.0

Description

Aminosin Plus is a sterile aqueous solution of Amino Acids IV Infusion and 10% Glucose with electrolytes, which is necessary as the nitrogen sources for parenteral nutrition. Nitrogen is provided in the form of essential and non-essential amino acids.

Pharmacology

Pharmacodynamics: Amino Acid IV Infusion with 10% Glucose and Electrolytes contains amino acids and electrolytes, which are all present in ordinary food. Apart from the nutritive properties Amino Acid IV Infusion with 10% Glucose and Electrolytes should have no specific pharmacodynamic effects. To optimize the utilization of supplied amino acids, adequate energy should be supplied in the form of carbohydrates (preferably Glucose) and fat.

Pharmacokinetics: The principle pharmacokinetic properties for Amino Acid IV Infusion with 10% Glucose and Electrolytes are essentially the same as for amino acids supplied by ordinary food. However, the amino acids of

dietary protein first enter the portal vein and then the systemic circulation, while intravenously infused amino acids reach the systemic circulation directly. Toxicology: Preclinical Safety Data: Preclinical safety studies with Amino Acid IV Infusion with 10% Glucose and Electrolytes demonstrated good tolerance.

Indication

As a source of amino acids, Glucose and electrolytes in adult and pediatric patients needing IV nutrition. Amino Acid IV Infusion with 10% Glucose and Electrolytes is particularly suitable for patients with basal amino acids requirements.

Dosage

Adult: The nitrogen requirement for maintenance of body protein mass depends on the condition of the patient (nutritional state and degree of metabolic stress). The requirements are 0.1-0.15 g nitrogen/kg body weight/day (no or minor metabolic stress and normal nutritional state), 0.15-0.2 g nitrogen/kg body weight/day (moderate metabolic stress with or without malnutrition) and up to 0.2-0.25 g nitrogen/kg body weight/day (severe catabolism as in burns, sepsis and trauma). The dosage range 0.1-0.25 g nitrogen/kg body weight/day corresponds to 11-27 mL Amino Acid IV Infusion with 10% Glucose and Electrolytes /kg body weight/day, respectively. In obese patients, the dose should be based on the estimated ideal weight. Depending upon patient requirements, up to 1000-2000 mL of Amino Acid IV Infusion with 10% Glucose and Electrolytes may be infused IV per 24 hrs. Amino Acid IV Infusion with 10% Glucose and Electrolytes should be infused slowly, at a rate not exceeding 1000 mL in 6 hrs corresponding to approximately 2.8 mL/min. In patients with basal amino acids requirements, the less concentrated Amino Acid IV Infusion with 10% Glucose and Electrolytes may be used.

Infant and Children: In children and infants, a maximal rate of infusion of 30 mL Amino Acid IV Infusion with 10% Glucose and Electrolytes/kg body weight/day is recommended, with a stepwise increase in the rate of administration during the 1st week of treatment

Contraindication

Patients with inborn errors of amino acid metabolism, severe liver dysfunction and in severe uremia when dialysis facilities are not available. Due to the content of Glucose, Amino Acids IV Infusion and 10% Glucose with electrolytes is contraindicated in patients with hyperosmolar nonketotic diabetic coma.

Precaution

IV infusion of amino acids is accompanied by increased urinary excretion of the trace elements copper and, in particular zinc, which should be taken into account in the dosing of trace elements, particularly during long-term IV nutrition. Hyperphenylalaninemia has been noted in severely ill premature infants. In these patients, monitoring of the phenylalanine level is recommended and the infusion rate adjusted as needed. Amino Acids IV Infusion and 10% Glucose with electrolytes should be used with caution in patients with diabetes mellitus, severe heart failure or with renal function in combination with fluid restrictions or oliguria/anuria of other origin. In patients with hyperglycemia, administration of exogenous insulin might be necessary. In severely malnourished patients refeeding carbohydrates can trigger a thiamine (vitamin B1) deficiency syndrome. Those at high risk are patients with a history of alcohol abuse, anorexia nervosa, prolonged fasting or starvation and pregnant women with hyperemesis gravidarum. In this kind of patients parenteral nutrition containing Glucose should be given with caution and parenteral administration of thiamine should be considered before and during the administration of Glucose. Monitoring of serum potassium and blood Glucose is recommended if Amino Acids IV Infusion and 10% Glucose with electrolytes is infused rapidly or in a large quantity. For patients with hypophosphatemia, an additional supply of phosphate is recommended.

Use in Pregnancy

Animal reproduction studies or clinical investigations during pregnancy have not been carried out with Amino Acids IV Infusion and 10% Glucose with electrolytes. There are, however, published reports of successful and safe administration of amino acid solutions during pregnancy.

Adverse Drug Reaction

Nausea occurs rarely. Transient increases in liver tests during IV nutrition have been reported. The reasons are at present unclear. The underlying disease and the components and their amounts in the IV feeding regimens

have been suggested. Hypersensitivity reactions have been reported with amino acid solutions. As with all hypertonic infusion solutions, thrombophlebitis may occur when peripheral veins are used. The incidence may be reduced by the simultaneous infusion of Intralipid. Extravascular disposition may cause tissue necrosis. Hyperphenylalaninemia may occur in severely ill, premature infants.

Drug Interaction

Not to be expected.

Overdosage

If Amino Acid IV Infusion with 10% Glucose and Electrolytes is administered at a higher rate than recommended, there is an augmented risk for nausea, vomiting and sweating. When peripheral veins are used thrombophlebitis may occur. Osmotic diuresis with dehydration may occur if the dosage recommendations are exceeded. There is also a risk of symptoms related to hyperglycemia with Amino Acid IV Infusion with 10% Glucose and Electrolytes. In case of symptoms due to overdose, the infusion should be slowed down or discontinued.

Pharmaceutical Precaution

Protect from light and store between 15°C to 25°C temperature. Avoid freezing. Keep medications out of reach of children.

Presentation

Aminosin Plus is available in 500 ml glass bottle

Manufactured by:

The IBN SINA Pharmaceutical Industry Ltd.
Shafipur, Gazipur, Bangladesh.