AMINOSIN PLUS

AMINO ACID WITH GLUCOSE & ELECTROLYTES

Compositions:
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

Pharmacology:
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.

Dosage And Administration:
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

Contraindications:
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.

Warning And 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.

Side Effects:
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.

Use in Pregnancy and Lactation:
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.

Drug Interaction:
At the recommended dosage the amino acid have no pharmacological effects and is not expected to interact with other medicaments.

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.

Storage:
Protect from light and store between 15° C to 25° C temperature. Avoid freezing.

Packing:
Aminosin Plus is available in 500 ml glass bottle

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.