Aminomax Gold

Amino Acid IV Infusion with 10% Glucose and Electrolytes

Description:

Aminomax Gold is a sterile aqueous solution of Amino Acids IV infusion & 10% Glucose with Electrolytes, which are necessary as the nitrogen sources for parenteral nutrition. Nitrogen is provided in the form of essential and non-essential amino acids.

Composition:

Each 100 ml contains

Active ingredients	Specification	Quantity
Essential Amino Acids		
L-Isoleucine	USP	$0.390\ gm$
L-Leucine	USP	$0.530~\mathrm{gm}$
L-Lysine Hydrochloride	USP	0.390 gm
L-Methionine	USP	0.190 gm
L-Phenylalanine	USP	0.550 gm
L-Threonine	USP	$0.300~\mathrm{gm}$
L-Tryptophan	USP	$0.100~\mathrm{gm}$
L-Valine	USP	$0.430~\mathrm{gm}$
L-Histidine	USP	$0.240~\mathrm{gm}$
L-Tyrosine	USP	$0.050~\mathrm{gm}$
Non-Essential Amino Acids		
L-Arginine	USP	0.330 gm
L-Aspartic Acid	USP	0.410 gm
L-Glutamic Acid	BP	0.900 gm
L-Alanine	USP	0.300 gm
L-Cystine	BP	0.140 gm
Glycine (Aminoacetic Acid) USP	0.210 gm
L-Proline	USP	0.810 gm
L-Serine	USP	0.750 gm
Carbohydrate:		
Anhydrous Glucose	BP	10.00 gm
Electrolytes (mmol/L)		
Sodium (Na+)		50.0
Potassium (K+)		20.0
Calcium (Ca++)		2.50
Magnesium (Mg++)		1.50
Chloride (Cl ⁻)		32.0

Clinical Pharmacology:

Pharmacodynamics: Aminomax Acid IV Infusion with 10% Glucose and Electrolytes contains amino 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 should be supplied in the form of carbohydrates (preferably glucose) and fat. *Pharmacokinetics*: The principle pharmacokinetic properties for Amino Infusion with 10% Glucose IV 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.

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.

Adults: The nitrogen requirement for maintenance of body protein mass depends on the patient's condition (nutritional state and degree of metabolic stress). The requirements are 0.1-0.15 gm nitrogen/kg body weight/day (no or minor metabolic stress and normal nutritional state), 0.15-0.20 gm nitrogen/kg body weight /day (moderate metabolic stress with or without malnutrition) and up to 0.2-0.25 gm nitrogen/kg body weight /day (severe catabolism as in burns, sepsis and trauma). The dosage range 0.1-0.25 gm nitrogen/kg body weight /day corresponds to 11-27 ml Amino Acids 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 patients requirements, up to 1000-2000 ml Amino Acid IV infusion with 10% Glucose and Electrolytes may be infused intravenously per 24 hours. 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. **Infants and children:** In infants and children, a maximal

rate of infusion 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:

Aminomax Gold is contraindicated in patients with inborn errors of amino acids metabolism, severe liver dysfunction and in severe uremia when dialysis facilities are not available. Due to content of glucose, Amino Acids IV infusion and 10% Glucose with Electrolytes is contraindicated in patients with hyperosmolar nonketotic diabetic coma.

Adverse Effects:

Aminomax Gold is usually well tolerated . Nausea Occurs rarely. Hypersensitivity reactions have been reported with amino acid solution. As with all hypertonic infusion solution, thrombophlebitis may occur when peripheral veins are used. The incidence may be reduced by the simultaneous infusion of intralipid. Hyperphenylalaninemia may occur in severely ill, premature infants.

Drug Interaction:

At the recommended dosage the amino acid in Aminomax Gold solution have no adverse effects and is not expected to interact with other medicaments.

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 may occur 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.

If Amino Acids IV infusion and 10% Glucose with Electrolytes is administered at a higher rate than recommended, there is an augmented risk for nausea, vomiting and sweating. When peripheral 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 Acids IV infusion and 10% Glucose with Electrolytes. In case of symptoms due to overdose, the infusion should be slowed down or discontinued.

Pharmaceutical Precaution:

Protect from light and store in between 15° C to 25° C temperature. Avoid freezing & keep out of the reach of children.

Commercial Pack: Aminomax Gold is available in 500 ml glass

