

Clinosol® Gold IV

Amino Acid IV Infusion with 10%
Glucose and Electrolytes

Description

Clinosol® Gold IV is a sterile aqueous solution of crystalline amino acids and 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. The solution is clear and light golden color.

Pharmacokinetics

The principle pharmacokinetic properties for **Clinosol® Gold IV** are essentially the same as for amino acid 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.

Composition

Each 100 ml contains

Active Ingredient	Specification	Quantity
L-Isoleucine	USP	0.390 gm
L-Leucine	USP	0.530 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 gm
L-Tryptophan	USP	0.100 gm
L-Valine	USP	0.430 gm
L-Arginine Hydrochloride	USP	0.330 gm
L-Histidine Hydrochloride Monohydrate	USP	0.240 gm
L-Aspartic Acid	USP	0.410 gm
L-Glutamic Acid	USP	0.900 gm
L-Alanine	USP	0.300 gm
L-Cystine	USP	0.140 gm
Amino Acetic Acid (Glycine)	USP	0.210 gm
L-Proline	USP	0.810 gm
L-Serine	USP	0.750 gm
L-Tyrosine	USP	0.050 gm

Carbohydrate

Anhydrous Glucose	BP	10.000 gm
-------------------	----	-----------

Water for Injection (in Bulk) BP q.s to 100 ml

Electrolytes (per litre)

Sodium (Na⁺) : 50 mmol
Potassium (K⁺) : 20 mmol
Calcium (Ca⁺⁺) : 2.5 mmol
Magnesium (Mg⁺⁺) : 1.5 mmol
Chloride (Cl⁻) : 32 mmol

Nitrogen content : 9.4 g / L

Energy content : 650 Kcal / L

Indications

Clinosol® Gold IV is indicated as a source of amino acids for protein synthesis in patients needing intravenous nutrition. It is particularly suitable for a patient with basal amino acid requirements. It is also indicated in faster recovery in surgery, burns, renal insufficiency, hepatic insufficiency and effective management of cancer.

Dosage & administration

Adults: The requirement for maintenance body protein

mass depends on the patient's condition (nutritional state and degree of metabolic stress). The requirements are 0.10-0.15 g nitrogen/kg/day (no or minor metabolic stress and normal nutritional state), 0.15-0.20g nitrogen/day/moderate metabolic stress with or without malnutrition) and up to 0.20-0.25 g nitrogen/kg/day, (severe catabolism as in burn, sepsis and trauma). The dosage range 0.10-0.25 g nitrogen/kg/day corresponds to 15-35 ml Clinosol Gold IV/kg/day. In obese patients, the dose should be based on the estimated ideal weight. Depending upon patient's requirements, 1000-2000ml **Clinosol® Gold IV** may be infused intravenously per 24 hours. **Clinosol® Gold IV** should be infused slowly at rates 1.4-2.8 mg (30-60 drops) per minute.

Infants and children: In children and infants, the rate of infusion is 28-35 ml/kg body weight per day is recommended, with a stepwise increase in the rate of administration during the first week of treatment.

Contraindications

Clinosol® Gold IV is contra-indicated in patients with inborn errors of amino acids metabolism, irreversible liver damage and severe uremia when dialysis facilities are not available.

Side effects

Clinosol® Gold IV is usually well tolerated. Nausea occurs rarely. Vomiting flushing and sweating have been observed during infusion of **Clinosol® Gold IV** at rate exceeding the recommended maximal rate. The underlying disease and the components and their amount in the intravenous feeding regimens have been suggested. Hypersensitivity reactions have been reported. As with all hypertonic infusion solution, thrombophlebitis may occur when peripheral veins are used. The incidence may be reduced by the simultaneous infusion of 10% fat emulsion. If given to severely ill, premature infants, hyperphenylalaninemia may occur.

Use in pregnancy & lactation

Successful and safe administration of amino acid solution during pregnancy in the human has been reported. Animal reproduction studies have not been carried out with Amino acid IV infusion with 10% glucose and electrolytes.

Precautions

In hyperphenylalaninemia patients, monitoring of the phenylalanine levels is recommended and the infusion rate adjusted as needed. The solution should not be used if the solution is turbid or contains particles.

Drug interactions

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

Over dosage

There are no known symptoms of overdose in human.

Storage

Keep out of reach of children. Store in a dry place, below 25°C temperature and protected from light.

Packaging

Clinosol® Gold IV 500 ml: 500 ml sterile solution in clear glass bottle.



Manufactured by
Opsonin Pharma Limited
Rupatali, Barishal, Bangladesh.
® Registered Trade Mark.

0339-03