Clinosol®

5% Composite Amino Acid Solution with D-Sorbitol

Description
Clinosol® is a sterile aqueous solution of crystalline amino acids and D-Sorbitol 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, colorless having a p^H lying in the range of 5.7 to 7.0.

Pharmacokinetics
Clinosol® contains all 18 essential and non-essential amino acids needed for protein synthesis. The amino acid composition is such that positive nitrogen balance can be achieved in the postoperative period and during extended periods of intravenous nutrition.

Composition
Each 100 ml contains:

i) Active ingredients	**Specification**	**Quantity**
L-Isoleucine	USP	0.352 gm
L-leucine	USP	0.490 gm
L-Lysine Hydrochloride	USP	0.430 gm
L-Methionine	USP	0.225 gm
L-Phenylalanine	USP	0.533 gm
L-Threonine	USP	0.250 gm
L-Tryptophan	USP	0.090 gm
L-Valine	USP	0.360 gm
L-Arginine Hydrochloride	USP	0.500 gm
L-Histidine Hydrochloride.H_20	USP	0.250 gm
L-Aspartic Acid	USP	0.250 gm
L-Glutamic Acid	USP	0.075 gm
L-Alanine	USP	0.200 gm
L-Cystine	USP	0.010 gm
Amino acetic Acid	USP	0.760 gm
L-Proline	USP	0.100 gm
L-Serine	USP	0.100 gm
L-Tyrosine	USP	0.025 gm
ii) Excipients		
D-Sorbitol	BP	5.000 gm
Water for Injection	BP	q.s

Electrolytes (mmol/L):

Sodium	40.0	Chloride	43.5
Potassium	25.0	Acetate	25.0
Magnesium	2.5		

Energy content : 1551 KJ / L (371.14 Kcal / L)
Nitrogen content: 7.2 gm / L

Indications
Clinosol® is indicated as a source of amino acids for protein synthesis in patients needing intravenous nutrition. **Clinosol®** is particularly suitable for a patient with basal amino acid nequirements. **Clinosol®** 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 patients 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®**/kg/day. In obese patients, the dose should be based on the estimated ideal weight. Depending upon patients requirements, 1000-200 ml **Clinosol®** may be infused intravenously per 24 hours. **Clinosol®** 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® 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® is usually well tolerated. Nausea occurs rarely. Vomiting, flushing and sweating have been observed during infusion of **Clinosol®** at rate exceeding the recommended maximal rate. The reasons are at present unclear. 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 give to severely ill, premature infants, hyperphenyialaninemia 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 **Clinosol®**.

Precautions
Hyperphenylalaninemia has been noted in severely ill, premature infants. In these patients, monitoring of the phenylalanine levels is recommended and the infusion rate adjusted as needed. Do not use if the solution is turbid or contains particles. Discard any unused portion.

Drug interactions
At the recommended dosage the amino acids in **Clinosol®** solution have no pharmacological effects and are not expected to interact with other medicaments.

Compatibility
Clinosol® containing amino acids should not be mixed with other preparations because of the increased risk of microbial contamination and incompatibility.

Storage
Protect from light and store between 15˚C~25˚C temperature avoid freezing. Keep medicaments out of reach of children.

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

Opsonin Pharma
Ideas for healthcare

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