Vigosol™ IV

Solution of 5% Composite Amino Acid with Electrolytes & D-Sorbitol

COMPOSITION

Vigosol™ IV: Each 100 ml solution contains-

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-Histidine Hydrochloride Monohydrate	EP	0.250 gm
L-Tyrosine	USP	0.025 gm
L-Arginine Hydrochloride	USP	0.500 gm
L-Aspartic Acid	USP	0.250 gm
L-Glutamic Acid	EP	0.075 gm
L-Alanine	USP	0.200 gm
L-Cysteine (as N-Acetyl-L-Cysteine)	USP	0.010 gm
Glycine (Aminoacetic Acid)	USP	0.760 gm
L-Proline	USP	0.100 gm
L-Serine	USP	0.100 gm
Excipients		
D-Sorbitol	BP	5.000 gm

Electrolytes	
Sodium (Na^+)	57 mmol/L
Potassium (K^+)	25 mmol/L
Magnesium (Mg^{++})	1.2 mmol/L
Chloride (Cl^-)	87 mmol/L
Acetate (CH_3COO^-)	25 mmol/L

Total Nitrogen Content: 7.25 gm/L
Total Energy Content: 1551 kj/L (371.14 Kcal/L)

PHARMACOLOGY

Vigosol™ IV is a sterile aqueous solution of crystalline Amino Acid and D-Sorbitol with electrolytes, which are necessary as the nitrogen source for parenteral nutrition. Nitrogen provided in the form of essential and non-essential amino acids. **Vigosol**™ IV 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. The solution is clear, colorless to pale yellow colored, having a pH lying in the range of 5.0 to 7.0.

INDICATION

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

DOSAGE AND ADMINISTRATION

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

PEDIATRIC USE

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

USE IN PREGNANCY AND LACTATION

Successful and safe administration of amino acid solutions during pregnancy in the human has been reported. Animal reproduction studies have not been carried out with Amino acid.

SIDE EFFECT

This preparation is usually well tolerated. Nausea occurs rarely. Vomiting, flushing and sweating have been observed during infusion of Amino acid at rates exceeding the recommended maximal rate. Transient increases liver test during intravenous nutrition have been reported. The reasons are at present unclear. 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.

CONTRAINDICATION

Contraindicated in patients with inborn errors of amino acids metabolism, irreversible liver damage and severe uremia when dialysis facilities are not available.

DRUG INTERACTION

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

PRECAUTION

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

COMPATIBILITY

Vigosol™ IV 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 to 25° C temperature. Avoid freezing. Keep out of reach of children.

HOW SUPPLIED

Vigosol™ IV: Each box contains sterile solution of 5% composite Amino Acid with electrolytes & D-Sorbitol for infusion in a glass bottle with Infusion set, Alcohol pad, First Aid Bandage & Plastic hanger.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
Kaliakoir, Bangladesh

TM- Trade Mark

2000016826