Nutrimin®

5 % Composite Amino Acid IV Infusion with
D-Sorbitol And Electrolytes

Description

This 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 pH lying in the range of 6.0 to 7.0.

Composition: Each 100 ml contains

Essential Amino Acids	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	USP	0.250 gm
L-Tyrosine	USP	0.025 gm

Non Essential Amino Acids	Specification	Quantity
L-Arginine	USP	0.500 gm
L-Aspartic Acid	USP	0.250 gm
L-Glutamic Acid	BP	0.075 gm
L-Alanine	USP	0.200 gm
L-Cystine	BP	0.010 gm
Glycine(Aminoacetic Acid)	USP	0.760 gm
L-Proline	USP	0.100 gm
L-Serine	USP	0.100 gm

Carbohydrate	Specification	Quantity
D-Sorbitol	BP	5.00 gm

Electrolytes	Quantity
Sodium(Na^+)	40.78 mmol/L
Potassium(K^+)	25 mmol/L
Magnesium(Mg^{++})	2.5 mmol/L
Chloride(Cl^-)	53.54 mmol/L
Acetate(CH_3COO^-)	25 mmol/L

Nitrogen content: 7.7 gm/L

Clinical Pharmacology

Nutrimin® contains all 18 essential and non-essential amino acid 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.

Indications

Amino Acid is indicated as a source of amino acids for protein synthesis in patients needing intravenous nutrition. This is particularly suitable for patients with basal amino acid requirements. Amino acid 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 0.10-0.15g nitrogen/kg/day (no or minor metabolic stress and normal nutritional state), 0.15-0.20g nitrogen/kg/day (moderate metabolic stress with or without malnutrition) and up to 0.20-0.25g nitrogen/kg/day (severe catabolism as in burns, sepsis and trauma). The dosage range 0.10-0.25g nitrogen/kg/day corresponds to 15-35 ml Nutrimin®/kg/day. In obese patients, the dose should be based on the estimated ideal weight. Depending upon patients requirements, 1000-2000 ml .It may be infused intravenously per 24 hours. It should be infused slowly, at rates 1.4-2.8 ml (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 step wise increase in the rate of administration during the first week.

Contraindications

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

Precautions

Hyperphenylaninemia 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.

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.

Adverse Effects

Nausea Occurs rarely. Vomiting, flushing and sweating have been observed during infusion of Amino acid at rates exceeding the recommended maximal rare. Transient increases liver test during intravenous nutrition have been reported. 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 given to severely ill, premature infants, hyperphenylalaninemia may occur.

Drug Interactions

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

Compatibility

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

Pharmaceutical Precaution

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

Commercial Pack

Nutrimin® is available in 500 ml glass bottle.

BEXIMCO PHARMA

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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