Xemocid

Solution of 5% Composite Amino Acid with electrolytes and D-Sorbitol

DESCRIPTION

Xemocid is a sterile aqueous solution of crystalline amino acids and electrolytes with D-sorbitol, 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.

COMPOSITION

Each 100 mL contains

Active ingredients	Specification	Quantity
Essential Amino Acids		
L-Isoleucine	USP	0.352 g
L-Leucine	USP	0.490 g
L-Lysine Hydrochloride	USP	0.430 g
L-Methionine	USP	0.225 g
L-Phenylalanine	USP	0.533 g
L-Threonine	USP	0.250 g
L-Tryptophan	USP	0.090 g
L-Valine	USP	0.360 g
L-Histidine Hydrochloride Monohydrate	BP	0.250 g
L-Tyrosine	USP	0.025 g
Non-Essential Amino Acids		
L-Arginine Hydrochloride	USP	0.500 g
L-Aspartic Acid	USP	0.250 g
L-Glutamic Acid	BP	0.075 g
L-Alanine	USP	0.200 g
L-Cysteine	BP	0.010 g
Glycine (Aminoacetic Acid)	USP	0.760 g
L-Proline	USP	0.100 g
L-Serine	USP	0.100 g
Carbohydrate		
D-Sorbitol	BP	5.000 g
Electrolytes		
Sodium (Na^+)		40.0 mmol
Potassium (K^+)		25.0 mmol
Magnesium (Mg^{++})		2.5 mmol
Chloride (Cl^-)		43.5 mmol
Acetate ($CH3COO^-$)		25.0 mmol

Energy Content : 371.14 Kcal/L

Total Nitrogen content : 7.2 gm/L

PHARMACOLOGICAL INFORMATION

Clinical Pharmacology

Xemocid consists of 18 essential and non-essential amino acids which are needed for protein synthesis as well as body build up. The amino acid composition is such that positive nitrogen balance can be achieved in the post-operative period and during extended periods of intravenous nutrition.

Therapeutic Indications

Xemocid is indicated as a source of amino acid for protein synthesis in patients needing intravenous nutrition. Xemocid is particularly suitable for patient with basal amino acid requirements. Xemocid is also indicated in faster recovery in surgery, burn, sarcopenia, malnutrition, hepatic insufficiency and effective management of cancer.

DOSAGE & ADMINISTRATION

Adults

The nitrogen requirement for maintenance of body protein mass depends on the patient's condition (nutritional state and degree of metabolic stress). No or minor metabolic stress and normal nutritional state: 0.10-0.15 g nitrogen/kg/day, Moderate metabolic stress with or without malnutrition: 0.15-0.20 g nitrogen/kg/day, Severe catabolism as in burns, sepsis and trauma: up to 0.20-0.25 g nitrogen/kg/day. The dosage range of 0.10-0.25 g nitrogen/kg/day corresponds to 15-35 ml Xemocid IV/kg/day.

In obese patients, the dose should be based on the estimated ideal weight. Depending upon patients requirements, 1000-2000 ml Xemocid may be infused intravenously per 24 hours. Xemocid IV 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/day is recommended, with a stepwise increment in the rate of administration during the first week of treatment.

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 Xemocid IV.

SIDE EFFECTS

Xemocid IV is usually well tolerated. But nausea, vomiting, flushing and sweating have been observed during infusion of Xemocid IV at rates exceeding the recommended maximal rate. Hypersensitivity reactions have been reported. Like 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 it is infused to severely ill patients, premature infants, hyperphenylalaninemia may occur.

Contraindications

Xemocid IV is contraindicated in patients with inborn errors of amino acids metabolism. Moreover, Xemocid IV should not be used in patients with hepatic coma or metabolic disorders involving impaired nitrogen utilization.

Precaution

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 acid in Xemocid solution have no pharmacological effects and is not expected to interact with other medication.

PHARMACEUTICAL INFORMATION

Storage conditions

Protect from light and store between 15^{0}C to 25^{0}C temperature. Avoid freezing and keep out of the reach of children.

Presentation & Packaging

Each box contains 500 mL of 5% composite amino acid with electrolytes and D-Sorbitol in glass bottle along with infusion set.

Manufactured By
BEACON®
Pharmaceuticals PLC
Bhaluka, Mymensingh, Bangladesh

1300003547