PROTINEX®

5% Composite Amino Acid IV Nutrition
with D-Sorbitol and Electrolytes

DESCRIPTION

PROTINEX® 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.

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	USP	0.250 g
Non-Essential Amino Acids		
L-Arginine	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-Cystine	BP	0.010 g
Glycine (Aminoacetic Acid)	USP	0.760 g
L-Proline	USP	0.100 g
L-Serine	USP	0.100 g
L-Tyrosine	USP	0.025 g
Carbohydrate		
D-Sorbitol	BP	5.000 g
Electrolytes (mmol/L)		
Sodium (Na^+)		35.5
Potassium (K^+)		25.0
Magnesium (Mg^{++})		2.5
Chloride (Cl^-)		53.4
Acetate (CH_3COO^-)		25.0

CLINICAL PHARMACOLOGY

PROTINEX® 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.

INDICATIONS

- Faster recovery after surgery
- Burns
- Hepatic insufficiency
- Renal insufficiency
- Effective management of cancer
- Severe Malnutrition

DOSAGE AND ADMINISTRATION

Adults: The nitrogen requirement for maintenance of body protein mass depends on the patients condition (nutritional state and degree of metabolic stress). The requirements are 0.10-0.15 gm nitrogen/kg/day (no or minor metabolic stress and normal state), 0.15-0.20 gm nitrogen/kg/day (moderate metabolic stress with or without malnutrition), 0.20-0.25 gm nitrogen/kg/day (severe catabolism as in burns, sepsis and trauma).

The dosage range 0.10-0.25 gm nitrogen/kg/day corresponds to 15-30 ml PROTINEX®/kg/day.

In obese patients, the dose should be based on the estimated ideal weight. Depending upon patients' requirements, 500-2000 ml PROTINEX® may be infused intravenously per 24 hours. PROTINEX® should be infused slowly at rates 20-30 drops/minute initially followed by 30-60 drops per minute.

Infants and children:

In children and Infants, the rate of infusion is 0.20-0.25 gm/kg/day. PROTINEX® should be infused slowly at rates 15-20 drops/minute initially followed by 30-40 drops/minute.

USE IN PREGNANCY AND LACTATION

There are published reports of successful and safe administration of amino acid solutions during pregnancy.

CONTRAINDICATIONS

PROTINEX® is contraindicated in patients with inborn errors of Amino Acids metabolism, irreversible liver damage and severe uremia when dialysis facilities are not available.

ADVERSE EFFECTS

PROTINEX® is usually well tolerated. Nausea occurs rarely. Vomiting, flushing and sweating have been observed during infusion of PROTINEX® at rates exceeding the recommended maximal rate. Transient increases in 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 INTERACTION

At the recommended dosage the amino acids in PROTINEX® solutions have no pharmacological effects and is not exceed to interact with other medications.

COMPATIBILITY

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

CAUTION

Hyperphenylalaninemia has been noted in severely ill, premature infants. In these patients monitoring of the phenylalanine level is recommended and the infusion rate adjusted as needed. Do not use if the solution is turbid or contains particle. Discard any unused portion.
Use immediately after piercing first time. A slight yellow color does not alter the quality and efficacy of the product.

PHARMACEUTICAL PRECAUTIONS

Store below 30 °C temperature. Protect from sunlight. Avoid freezing. Keep out of reach of children.

PACKAGING

PROTINEX® is available in 500 ml glass bottle.

SK+F

Manufactured by
ESKAYEF BANGLADESH LIMITED
GAZIPUR, BANGLADESH

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