POWERSOL IV

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

Presentation

POWERSOL: POWERSOL is a sterile aqueous solution of crystalline amino acids and D-Sorbitol with electrolytes. POWERSOL is necessary as the nitrogen source for parenteral nutrition in which nitrogen is provided in the form of essential and non-essential amino acids.

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 Monohydrochloride	USP	0.500 gm
L-Histidine Hydrochloride Monohydrate	BP	0.250 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 (2-Aminoacetic Acid)	BP	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 Injections	BP	q.s. to 100 ml
iii) Electrolytes	(mmol/L)	
Sodium(Na^+) :	65	
Potassium (K^+) :	31	
Magnesium (Mg^{++}) :	2.2	
Chloride (Cl^-) :	59	
Acetate (CH_3COO^-) :	25	

Clinical Pharmacology

POWERSOL 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.

Indications

POWERSOL is indicated as a source of amino acids for protein synthesis in patients needing intravenous nutrition. It is particularly suitable for a patient with basal amino acid requirements. POWERSOL 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 POWERSOL infusion/kg/day. In obese patients, the dose should be based on the estimated ideal weight. Depending upon patients requirements, 1000-2000 ml POWERSOL may be infused intravenously per 24 hours. POWERSOL infusion 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 wt/day is recommended, with a stepwise increment in the rate of administration during the first week of treatment.

Contraindications

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

Side Effects

POWERSOL is usually well tolerated. Yet nausea, vomiting, flushing and sweating have been observed during infusion of POWERSOL 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.

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 acid in POWERSOL solutions have no pharmacological effects and is not expected to interact with other medicaments.

Compatibility

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

Use in Pregnancy and Lactation

Successful and safe administration of amino acid solutions during pregnancy in the human has been reported.

Storage Conditions

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

Commercial Pack

POWERSOL: Each box contains 500 ml glass bottle of 5% Amino Acids Infusion with D-sorbitol and electrolytes sterile solution with one sterile infusion set, first aid bandage & alcohol pad.

Manufactured by :
GENERAL Pharmaceuticals Ltd.
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