15% CLINISOL sulfite-free (Amino Acid) Injection

Indications

15% CLINISOL sulfite-free (Amino Acid) Injection is indicated as an adjunct in the offsetting of nitrogen loss or in the treatment of negative nitrogen balance in patients where: (1) the alimentary tract cannot or should not be used, (2) gastrointestinal absorption of protein is impaired, or (3) metabolic requirements for protein are substantially increased, as with extensive burns.

Important Risk Information

- Contraindicated in patients with hypersensitivity to one or more amino acids, severe liver disease or hepatic coma, Anuria and Metabolic disorders involving impaired nitrogen utilization.
- Because of the potential for life threatening events, caution should be taken to ensure that precipitates have not formed in any parenteral nutrition admixture.
- **This injection is for compounding only, not for direct infusion.**
- Administration of amino acid solutions at excessive rates or to patients with hepatic insufficiency may result in plasma amino acid imbalances, hyperammonemia, prerenal azotemia, stupor and coma. If hyperammonemia develops, discontinue the amino acid administration and reevaluate the patient's clinical status.
- This product contains aluminum that may be toxic with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amount of calcium and phosphate solutions, which contain aluminum.
- The administration of 15% Clinisol Injection as part of the total parenteral nutrition with large volumes of hyperosmotic fluids requires periodic monitoring for signs of hyperosmolarity, hyperglycemia, glycosuria, hypertriglyceridemia and volume overload. Initiation and termination of TPN infusion must be gradual to permit adjustment of endogenous insulin release.
- During parenteral nutrition with concentrated dextrose and amino acid solutions, essential fatty acid deficiency syndrome may develop and therefore plasma lipids should be monitored. This syndrome may be prevented or corrected by treatment with intravenous fat emulsions.
- **Frequent clinical evaluations and laboratory determinations are necessary for proper monitoring during administration.**
- Total parenteral nutrition therapy may include multiple vitamins, trace elements and additional electrolytes. Potentially incompatible ions such as calcium and phosphate may be added to alternate infusate containers to avoid precipitation.
- Local adverse reactions consisting of a warm sensation, erythema, phlebitis and thrombosis at the infusion site have occurred with peripheral intravenous infusion of amino acids. Generalized flushing, fever and nausea have been reported during peripheral infusions of amino acid solutions.
- The following metabolic complications have been reported with administration of TPN: metabolic acidosis and alkalosis, hypophosphatemia, hypocalcemia, osteoporosis, glycosuria, hyperglycemia, hyperosmolar nonketotic states and dehydration, rebound hypoglycemia, osmotic diuresis and dehydration, elevated liver enzymes, hypo- and hypervitaminosis, electrolyte imbalances, hyperammonemia, coma and death.

Please see [accompanying/enclosed/Baxter representative] for a Package Insert for Full Prescribing Information.

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