

Indications

CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections and CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections are indicated as a caloric component in a parenteral nutrition regimen and as the protein (nitrogen) source for offsetting nitrogen loss or for 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

- **It is essential that a carefully prepared protocol based on current medical practices be followed, preferably by an experienced team. Frequent clinical evaluation and laboratory determinations are necessary for proper monitoring during administration.**
- CLINIMIX and CLINIMIX E Injections are contraindicated in patients having intracranial or intraspinal hemorrhage, in patients who are severely dehydrated, in patients hypersensitive to one or more amino acids and in patients with severe liver disease or hepatic coma. Solutions containing corn-derived dextrose may be contraindicated in patients with known allergy to corn or corn products.
- Because of the potential for life-threatening events, caution should be taken to ensure that precipitates have not formed in any parenteral nutrient admixture.
- Use with caution when administering to patients with anuria or renal insufficiency, pulmonary insufficiency, or heart disease. The intravenous administration of these solutions can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema.
- Metabolic complications have been reported, such as acid-base, electrolyte, and blood glucose imbalances, elevated liver enzymes, and osmotic diuresis and dehydration.
- Other adverse reactions that may occur include febrile response, infection at the site of injection, extravasation, and hypervolemia. The infusion of hypertonic nutrient injections into a peripheral vein may result in vein irritation, vein damage, and thrombosis.
- This product contains aluminum that may be toxic with prolonged parenteral administration if kidney function is impaired. CLINIMIX and CLINIMIX E Injections **must be** admixed prior to infusion.

Please refer to Full Prescribing Information