

6% and 10% PREMASOL sulfite-free (Amino Acid) Injections

Indications

6% and 10% PREMASOL sulfite-free (Amino Acid) Injections are indicated for the nutrition support of Infants (including those of very low birth weight) and young children requiring TPN via central or peripheral infusion routes. Parenteral nutrition with PREMASOL injections is indicated to prevent nitrogen and weight loss or treat negative nitrogen balance in infants and young children where: (1) the alimentary tract, by the oral, gastrostomy, or jejunostomy route, cannot or should not be used or adequate protein intake is not feasible by these routes, (2) gastrointestinal absorption of protein is impaired, or (3) protein requirements are substantially increased, as with extensive burns. Dosage, route of administration, and concomitant infusion of non-protein calories are dependent on various factors, such as nutritional and metabolic status of the patient, anticipated duration of parenteral nutrition support, and vein tolerance.

Important Risk Information

- PREMASOL Injections are contraindicated in patients with untreated anuria, hepatic coma, inborn errors of amino acid metabolism, including those involving branched chain amino acid metabolism such as maple syrup urine disease and isovaleric acidemia, or hypersensitivity to one or more amino acids in the solution.
- **This injection is for compounding only, not for direct infusion**
- Safe, effective use of parenteral nutrition requires knowledge of nutrition as well as clinical expertise in recognition and treatment of the complications which can occur.
- **Frequent evaluation and laboratory determinations are necessary for proper monitoring of parenteral nutrition.** Depending on the patient's conditions or disease state, additional electrolyte supplementation may be required.
- Fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema can occur with IV administration.
- Administration of amino acids in patients with impaired renal function or gastrointestinal bleeding may augment an already elevated blood urea nitrogen. Do not infuse amino acids in patients with azotemia.
- Administration of amino acid solutions to a patient with hepatic insufficiency may result in plasma amino acid imbalances, hyperammonemia, prerenal azotemia, stupor and coma.
- It is essential that blood ammonia be measured frequently in infants. Hyperammonemia in the syndrome is caused by genetic metabolic defects and is sometimes associated, although not necessarily in a causal relationship, with mental retardation. This reaction appears to be dose related and is more likely to develop during prolonged therapy.
- 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 amounts of calcium and phosphate solutions, which contain aluminum.
- Strongly hypertonic nutrient solutions should be administered via an intravenous catheter placed in a central vein, preferably the superior vena cava.
- Special care must be taken when giving hypertonic dextrose to patients with diabetes or impaired glucose tolerance. To prevent hyperglycemia in such patients, insulin may be required.
- The final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration, and periodically during administration.
- Adverse reactions reported in clinical studies were: water weight gain, edema, increase in BUN, and mild acidosis. Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypovolemia. Phosphorus deficiency may lead to impaired tissue oxygenation and acute hemolytic anemia. Relative to calcium, excessive phosphorous intake can precipitate hypocalcemia with cramps, tetany, and muscular hyperexcitability. If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic counter measures and save the remainder of the fluid for examination, if deemed necessary.

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