

## 20% PROSOL sulfite-free (Amino Acid) Injection

### Indications

20% PROSOL 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. 20% PROSOL Injection can be used to reduce fluid intake in patients who require both fluid restriction and total parenteral nutrition (TPN). 20% PROSOL Injection is intended to be dosed on the basis of grams of amino acids/kg body weight/day. Therefore, this more concentrated amino acid provides the same nutritional value as in a more dilute form, but with the opportunity to limit fluid intake.

**Central Vein Administration:** 20% PROSOL sulfite-free (Amino Acid) Injection is intended for use in a pharmacy admixture program and as such is restricted to the preparation of admixtures for intravenous use. Central vein infusion should be considered when amino acid solutions are to be admixed with hypertonic dextrose to promote protein synthesis such as for hypercatabolic or depleted patients or those requiring long term parenteral nutrition. **20% PROSOL sulfite-free (Amino Acid) Injection should never be administered undiluted.**

**Peripheral Vein Administration:** For patients in whom the central vein route is not indicated, amino acid solutions diluted with low dextrose concentrations may be infused by peripheral vein with or without supplemented fat emulsion. In pediatric patients, the final solution should not exceed twice normal serum osmolarity (718 mOsmol/L). **20% PROSOL sulfite-free (Amino Acid) Injection should never be administered undiluted.**

**Protein Sparing:** Dilute amino acid solutions for **peripheral administration** may be used in patients who exhibit no clinically significant protein malnutrition. The purpose of the solution is to replace protein losses which occur in relation to an intercurrent phenomenon which is known or suspected to be productive of a protein loss condition for a short or moderate period of time. Protein-sparing can be achieved by peripheral infusion of dilute amino acid solutions with or without dextrose. 20% PROSOL sulfite-free (Amino Acid) Injection must be diluted below twice normal serum osmolarity (718 mOsmol/L).

### Important Risk Information

- Contraindicated in patients with hypersensitivity to one or more amino acids, severe liver disease or hepatic coma and anuria.
- **This injection is for compounding only, not for direct infusion and as such, should never be administered undiluted.**
- 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 of a final filter is recommended during administration of all parenteral solutions where possible. Caution should be exercised when admixing 20% PROSOL Injection and should be used promptly after admixing.
- Proper administration of this injection requires knowledge of fluid and electrolyte balance and nutrition as well as clinical expertise in recognition and treatment of the complications which may occur.
- Administration of amino acid solutions to a patient with hepatic insufficiency may result in serum amino acid imbalances, hyperammonemia, stupor and coma. Hyperammonemia is of **special significance in infants**. This reaction appears to be related to a deficiency of the urea cycle amino acids of genetic or product origin. It is essential that blood ammonia be measured frequently in infants.

- Conservative doses should be given to patients with known or suspected hepatic dysfunction. Should symptoms of hyperammonemia develop, administration should be discontinued and the patient's clinical status reevaluated.
- Administration of amino acid solutions in the presence of impaired renal function presents special issues associated with retention of electrolytes.
- This injection should not be administered simultaneously with blood through the same infusion set because of the possibility of pseudoagglutination.
- 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. Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 µg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.
- **Administration by central venous catheter should be used only by those familiar with this technique and its complications.**
- The administration of 20% PROSOL Injection in combination with highly concentrated dextrose solutions, hyperglycemia, glycosuria and hyperosmolar syndrome may result. Blood and urine glucose should be monitored on a routine basis in patients receiving this therapy. Sudden cessation in administration of a concentrated dextrose solution may result in insulin reaction due to high levels of endogenous insulin. Parenteral nutrition mixtures should be withdrawn slowly.
- Because of its antianabolic activity, concurrent administration of tetracycline may reduce the protein-sparing effect of infused amino acids.
- Care should be taken to avoid excess fluid accumulation, particularly in patients with renal disease, pulmonary insufficiency and heart disease.
- During protein-sparing therapy in the absence of supporting carbohydrate metabolism, an accumulation of ketone bodies in the blood often occurs. Correction of ketonemia usually can be accomplished by administering some carbohydrates. Protein-sparing therapy is useful for periods up to 10 to 12 days. Patients requiring nutritional support thereafter should be placed on oral or parenteral regimens that employ adequate non-protein calorie components.
- **Frequent clinical evaluations and laboratory determinations are necessary for proper monitoring during administration.** Laboratory tests should include blood glucose, serum electrolytes, liver and kidney function, serum osmolarity, blood ammonia, serum protein, pH, hematocrit, WBC, and urinary glucose. When infusing without adequate non-protein calories, monitoring of BUN is required.
- The following metabolic complications have been reported: metabolic acidosis, hypophosphatemia, alkalosis, hyperglycemia and glycosuria, osmotic diuresis and dehydration, rebound hypoglycemia, elevated liver enzymes, hypo and hypervitaminosis, electrolyte imbalances and hyperammonemia. Frequent clinical evaluation and laboratory determinations are necessary, especially during the first few days of therapy, to prevent or minimize these complications.
- Infusion of any hypertonic solution can result in local inflammatory reactions. Policies and procedures should be established for the recognition and management of such reactions.

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