Travasol Important Risk Information

Indications

TRAVASOL (amino acid) Injection is indicated as a source of amino acids for patients requiring parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated. TRAVASOL may be used to treat negative nitrogen balance in patients.

Important Risk Information

- Contraindicated in patients with: known hypersensitivity to one or more amino acids; inborn errors of amino acid metabolism; and pulmonary edema or acidosis due to low cardiac output.
- This single use injection is for admixing use only, and not for direct intravenous infusion.
- Pulmonary vascular precipitates causing pulmonary vascular emboli and pulmonary distress have been reported in patients receiving PN, including TRAVASOL. In some cases, fatal outcomes due to pulmonary embolism have occurred. If signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation. Inspection of the solution, the infusion set, and catheter should periodically be checked for precipitates.
- Risk of infection is increased in patients with malnutrition-associated immunosuppression, hyperglycemia exacerbated by dextrose infusion, long-term use and poor maintenance of intravenous catheters, or immunosuppressive effects of other concomitant conditions, drugs or other components of the parenteral formulation.
- Refeeding severely undernourished patients may result in refeeding syndrome.
- Administration of PN solutions containing dextrose in patients with diabetes mellitus, impaired glucose tolerance may worsen hyperglycemia. Patients with underlying confusion and renal impairment who receive dextrose infusions, may be at greater risk of developing hyperosmolar hyperglycemic state.
- Solutions containing more than 5% dextrose or with an osmolarity of 900 mOsm/L or greater must be infused through a central catheter.
- Increase in blood ammonia levels and hyperammonemia may occur in patients receiving amino acid solutions, including TRAVASOL.
- With prolonged parenteral administration in patients with renal impairment, aluminum contained in TRAVASOL may reach toxic levels. Preterm infants are at a greater risk, and require large amounts of calcium and phosphate solutions which contain aluminum.
- Increased risk of Parenteral Nutrition Associated Liver Disease in patients who receive PN over extended periods of time, especially preterm infants. If liver function abnormalities occur, consider discontinuation or dosage reduction.
- Use with caution in patients with cardiac insufficiency or renal impairment; may require adjustment with specific attention to fluid, protein, and electrolyte content in these patients.
- Monitor fluid and electrolyte status, serum osmolarity, blood glucose, liver and kidney function, blood count and coagulation parameters throughout treatment. If electrolyte

levels are severely elevated, stop PN containing TRAVASOL until levels have been corrected.