Description

10% TRAVASOL (Amino Acid) Injection is a sterile, nontoxic hypertonic solution of essential amino acids for injection in a Pharmacy Bulk Package. A Pharmacy Bulk Package is a container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of pharmaceutical admixtures for intravenous infusion.

The VIAFLEX plastic container is fabricated from a specially formulated polyvinyl chloride (PVC) plastic and is designed to maintain a high solution-specific gravity (1.077) during transport and storage and to resist minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period. The amount of water lost can permeate from inside the container into the environment is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts while in the expiration period. e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million; however, the safety of the plastic has been confirmed in tests in animals according to US biological test for plastic materials as well as in those culture toxicity studies.

10% TRAVASOL (Amino Acid) Injection contains:

- Amino acids
- pH 6.0 (5.0 to 7.0)
- Total sugars 1.8 g
- Total choline 0.0 g

In VIAFLEX Plastic Container

- 10% TRAVASOL (Amino Acid) Injection contains:
  - Alanine - C3H7NO2 2.07 g
  - Aspartic acid - C4H7NO4 1.83 g
  - Glutamic acid - C5H9NO4 1.68 g
  - Glutamine - C5H12NO4 1.50 g
  - Glycine - C2H5NO2 1.03 g
  - Histidine - C6H9N3O2 480 mg
  - Methionine - C5H11NO2S 440 mg
  - Phenylalanine - C9H11NO2 560 mg
  - Threonine - C4H9NO3 420 mg
  - Tryptophan - C11H12N2O2 160 mg
  - Tyrosine - C9H11NO3 40 mg
  - Lysine - C6H14N2O2 1140 mg
  - Leucine - C6H13NO2 920 mg
  - Valine - C6H12NO2 900 mg
  - Isoleucine - C6H13NO2 880 mg
  - Taurine - C2H7NO3 460 mg
  - Arginine - C6H14N4O2 920 mg
  - Proline - C5H9NO2 880 mg
  - Serine - C3H7NO3 580 mg

- 998 mOsmol/L

2. Balanced by ions from amino acids.
3. Contributed by the lysine hydrochloride.

Clinical Pharmacology

10% TRAVASOL (Amino Acid) Injection administered via central vein will provide biologically utilizable source of protein when used with concentrated calorie sources. When parenteral amino acids are used peripherally after appropriate dilution or with minimal calorie supplementation (such as 5% dextrose), it supports the conservation of body protein.

Indications and Uses

10% TRAVASOL (Amino Acid) Injection is indicated for use in the offsetting of nitrogen loss in patients whose alimentary tract cannot absorb or should not be used, (2) gastrointestinal absorption of protein is impaired, or (3) metabolic support thereafter should be placed on oral or parenteral regimens that employ adequate nonprotein calorie sources. Protein-sparing effects of infused amino acids.

Because of its antianabolic activity, concurrent administration of tetracycline may reduce the protein-sparing effects of infused amino acids. This reaction appears to be related to a deficiency of the area amino acids as genetic or product aneuploidy. It is essential to provide adequate calories in the presence of impaired renal function to prevent or prevent occurrences of hyperchloremic metabolic acidosis and hyperammonemia. However, the physician should be aware of appropriate countermeasures if they become necessary.

Studies with 10% TRAVASOL (Amino Acid) 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 combination.

10% TRAVASOL (Amino Acid) Injection is indicated as an adjunct in the offsetting of nitrogen loss in patients where: (1) the alimentary tract cannot absorb or should not be used, (2) gastrointestinal absorption of protein is impaired, or (3) metabolic support thereafter should be placed on oral or parenteral regimens that employ adequate nonprotein calorie sources. Protein-sparing effects of infused amino acids.

Drug product contains no more than 25 µg/L of aluminum. This reaction appears to be related to a deficiency of the area amino acids as genetic or product aneuploidy. It is essential to provide adequate calories in the presence of impaired renal function to prevent or prevent occurrences of hyperchloremic metabolic acidosis and hyperammonemia. However, the physician should be aware of appropriate countermeasures if they become necessary.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Studies should include blood sugar, serum proteins, kidney and liver function tests, electrolytes, and coagulation studies.

Intravenous Fat Emulsion injection and high concentration dextrose injection (10 to 70%), from Baxter Healthcare Corporations, are stable over short periods of time. These solutions should be used promptly after admixture. Any changes should be noted, and if noted they should be noted before infusion administration. As with all amino acids, use of parenteral amino acids in combination with intravenous fat emulsion and high concentration dextrose injection from Baxter Healthcare Corporation packages means for dictated information on each component. Proper administration of this injection requires knowledge of fluid and electrolyte balance and surface as well as clinical expertise in recognition and treatment of the complications which may occur.

Contraindications

Anuria

Central Vein Administration:

Contraindications for parenteral administration may be used in patients who exemplify 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 to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts while in the expiration period. e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million; however, the safety of the plastic has been confirmed in tests in animals according to US biological test for plastic materials as well as in those culture toxicity studies.

Anuria

Contraindications

Central Vein Administration:

Necrosis, Phlebitis, Impairment of Fertility:

Proofreading Approval/Released Artwork

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P1 07-MAY-2014 JMC
Patients that are fluid restricted (e.g., renal failure). Acceptable total daily administration volumes. This injection provides a concentrated source of amino acids to meet the protein requirements of individualized.

Supplements with noncarbohydrate or carbohydrate-containing electrolyte solutions. Frequent and careful laboratory evaluation.

The key factor in their preparation is careful aseptic technique to avoid inadvertent touch contamination during reconstituting of solutions and addition of other nutrients. Metabolites. The following metabolic complications have been reported: metabolic acidosis, hypophosphatemia, alkalosis, hyperglycemia and glycosuria, amino acid depletions and electrolyte imbalances, elevated liver enzymes, hypophosphatemia, electrolyte imbalances and hyperglycemia. Frequent clinical evaluation and laboratory determinations are necessary, especially during the first two days of therapy, to prevent or minimize these complications.

**BRIDGE POSITION ONLY**

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Maintenance of nitrogen balance and accurate daily body weight response. Use of 10% TRAVASOL (Amino Acid) Injection in pediatric patients is not recommended. See Warnings.

**BAR CODE POSITION ONLY

Pregnancy: Teratogenic Effects

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. 1B6626 2000 mL NDC 0338-0644-06

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**BRIDGE POSITION ONLY**

Intravenous fat emulsions provide approximately 1.1 kcal/mL (10%) or 2.0 kcal/mL (20%) and contribute approximately 10% of the total daily caloric requirements. The amount administered is dosed on the basis of grams of amino acids/kg of body weight/day. Maintenance of nitrogen balance and accurate daily body weight responses. Parenteral nutrition should be reconstituted no more than 24 hours.

10% TRAVASOL (Amino Acid) Injection. The fluid balance requirements of the patient, prior to and during administration of parenteral nutrition solutions. Since contaminated solutions and intravenous line placements are potential sources of infection, it is essential that the preparation of the solution and the placement of care is handled under aseptic (sterile) conditions. This basic technique, manipulation of the catheter, formation of amino-acid solutions, phlebitis, phlebitis, thrombosis, catheter site infections.

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The following is a summary list of those based on current literature:

The total dose of 10% TRAVASOL (Amino Acid) Injection depends on the patient's metabolic requirement and clinical response. The determination of nitrogen balance and accurate daily body weight responses. In these circumstances, patient's body weight, the amount of body water needed, the maintenance fluid balances, or the concentration of amino acids in the blood will be necessary. The calculation of amino-acid requirements is based on the total nitrogen intake and the patient's metabolic need.