20% ProSol - sulfite-free (Amino Acid) Injection

Pharmacy Bulk Package
Not for Direct Infusion

in VIAFLEX Plastic Container

Description
20% ProSol - sulfite-free (Amino Acid) Injection is a sterile, nonpyrogenic, hypertonic solution of essential and nonessential amino acids provided in a Pharmacy Bulk Package. A Pharmacy Bulk Package is a container of a single parenteral product that contains many single doses. The content is intended for use in a pharmacy administration program and is restricted to the preparation of admixtures for intravenous use.

The VIAFLEX Plastic Container is fabricated from a specially formulated polyvinyl chloride (PVC-Free Plastic). The amount of water that can permeate inside the container into the product results in 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 within the expiration period, e.g., 0.2-4.5% aminophylline, up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

Each 100 mL of 20% ProSol - sulfite-free (Amino Acid) Injection contains:

- Arginine-HCl (NH₂CH₂COOH) 30.0 g
- Total Nitrogen 3.21 g
- pH 6.0 (5.5-6.5) (pH adjusted with glacial acetic acid)

Essential Amino Acids
- Lysine-HCl (C₆H₁₂NO₄) 1.44 g
- Methionine-HCl (CH₃CH₂SHCOOH) 1.35 g
- Phenylalanine-HCl (C₈H₁₀NO₂) 1.09 g
- Threonine-HCl (CH₃CH(OH)CH₂COOH) 1.18 g
- Isoleucine-C₅H₁₁NO₂ (CH₂)₃COOH 1.08 g
- Histidine-HCl (C₇H₁₂NO₄) 1.09 g
- Lysine-HCl (C₆H₁₂NO₄) 1.09 g
- Tryptophan-C₉H₁₁NO₂ 0.90 g
- Methionine-HCl (CH₃CH₂SHCOOH) 1.35 g
- Tryptophan-C₉H₁₁NO₂ 140 μmol

Nonessential Amino Acids
- Alanine-C₃H₇NO₂ 2.76 g
- Glycine-H₂NCH₂COOH 2.09 g
- Proline-H₂NCH(OH)CH₂COOH 1.99 g
- Glutamic acid (L)-L-glutamic acid 1.34 g
- Serine-H₂NCH₂CH₂COOH 1.02 g
- Asparagine-H₂NCH₂COOH 0.90 g
- Glutamine-H₂NCH₂CONHCH₃ 0.90 g
- Threonine-HCl (CH₃CH(OH)CH₂COOH) 50 μg

Amine profiles by litmus

Acids from the 20% ProSol - sulfite-free (Amino Acid) Injection are balanced by bases from amino acids.

Osmonality (calc.)
1850 mosM/mL

Clinical Pharmacology

20% ProSol - sulfite-free (Amino Acid) Injection administered via central vein, after appropriate dilution, will provide biologically usable material for protein synthesis when used with concurrent products such as vitamins, minerals, electrolytes, vitamins and minerals. Administered parenterally after appropriate dilution or with minimal calories, the product may be expected to have a renal concentrating potential (RCP) of 25-30 mOsm/kg H2O. It is concomitantly will support protein synthesis in concentrations up to 250 mOsm/kg H2O.

Indications and Usage
20% ProSol - sulfite-free (Amino Acid) Injection is indicated as an adjunct in the treatment of negative nitrogen balance in patients where (1) the anabolic tract cannot or should not be used, (2) protein supplementation is of impaired, or (3) protein requirements of the patient are substantially increased, with an excessive burn rate.

20% ProSol - sulfite-free (Amino Acid) Injection can be used to reduce fluid intake in patients with limited fluid restrictions and/or the parenteral nutrition (TPN). 20% ProSol - sulfite-free (Amino Acid) Injection is intended to be dosed on the basis of grams of amino acids body weight.

Precautions

Central Vein Administration: 20% ProSol - sulfite-free (Amino Acid) Injection is intended for use in central veins that are patent and are devoid of any significant protein precipitation. The purpose of the solution is to replace protein lost, and as such is intended for the prevention of admixtures for intravenous use. Central venous infusion should be administered when amino acid solutions are to be used in high concentrations, to promote protein synthesis than for hyperalimentation or depalpated patients or those requiring long-term parenteral nutrition. 20% ProSol - sulfite-free (Amino Acid) Injection should never be administered by peripheral vein.

Peripheral Vein Administration: For patients in whom the central venous route is not indicated, amino acid solutions may be given by peripheral vein, without supplemental fluid intake. In pediatric patients, the total solution should not exceed twice normal serum concentration limits. 20% ProSol - sulfite-free (Amino Acid) Injection should never be administered by peripheral vein.

Protein Storage: Dry amino acid solutions for peripheral administration may be used in patients with normal renal function. The major indication for the use of protein solutions is to produce a protein loss in patients for a short or moderate period of time. Protein storage should be performed in an aseptic environment in a 10% to 15% Defatted dextrose solution with or without defatted defatted. 20% ProSol - sulfite-free (Amino Acid) Injection must be diluted before use to normal serum concentration (118 mosM/L).

Contraindications
Hypersensitivity to one or more amino acids
Severe liver disease or hepatic coma

Warnings
This injection is for compounding only, not for direct infusion.

Adverse reactions may be incompatible. Consult with pharmacist, if available. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Because of the potential for life-threatening events, caution should be taken to ensure that premedications have not been formulated in any parenteral nutrient admixture.

Caution should be exercised when administering 20% ProSol - sulfite-free (Amino Acid) Injection.

This solution should be used promptly after admixing. Any storage should be under refrigeration and limited to a period of time, preferably less than 24 hours. Reference should be made to the USP labels on the sterile kit for instructions. Use of the IV. Fat Emulsion Package itself and high concentration dextrose injection from Baxter Healthcare Corporation (RTP-15) is contraindicated.

Proper administration of this injection requires a 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 intolerance, hyperammonemia, hyperkalemia, and oliguria.

Hyperammonemia is of special significance in infants. This reaction appears to be related to a deficiency of the urea cycle amino acids of genes or protein origin. It is essential that blood ammonia be measured frequently in infants.

Conservative doses of this injection 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 reassessed.

Administration of amino acids 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 pseudomembranous enterocolitis.

WARNING: The product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidney is immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive more than 4 mEq/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 not be used by those familiar with this technique and its complications.

Precautions

20% ProSol - sulfite-free (Amino Acid) Injection is a highly concentrated amino acid solution used for the treatment of patients with parenteral nutrition admixture (see Dosage and Administration). Some of the amino acids in 20% ProSol - sulfite-free (Amino Acid) Injection are close to their toxic level of intake and, in such a small volume of amino acids may form upon storage.

If amino acids are present, they will readily dissolve during administration compounding. Do not use unless solution is free of visible particles. Use of a final filter is recommended during administration of all parenteral solutions where possible.

It is essential to provide adequate saline concurrently if parenterally administered amino acids are to be retained by the body and utilized for protein synthesis. Concentrated dextrose solutions are an effective source of such calories.

Sudden cessation in administration of a concentrated dextrose solution may result in high levels of Capillary insulin. Parenteral nutrition mixtures should be withdrawn slowly.

The metabolizable amino acid and amino acid profile in this injection were designed to minimize or prevent occurrence of hyperosmolar metabolic acidosis and hyperammonemia. However, the physician should be aware of appropriate countermoves if these become necessary. The physician should be aware of appropriate countermoves if these become necessary.

Strongly hyperammonemia solutions should be administered through an indwelling intravenous catheter with the tip located in the superior vena cava. Because of its amniotic activity, concurrent administration of tetracycline may reduce the protein-blocking effect of refined amino acids.

Cautions should be observed when administering in combination, particularly in patients with renal disease. Pulmonary insufficiency and heart disease

During maintenance 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-therapy option is useful for periods up to 10 to 12 days. Patients requiring nutritional support should be placed on oral or parenteral regimens that employ adequate nonprotein calorie components.

20% ProSol - sulfite-free (Amino Acid) Injection is not intended for direct infusion, and, as such, never should be administered undiluted.

Drug product contains no more than 25 μg of aluminum.
Laboratory Tests
Phenotyping and laboratory determinations are necessary for proper monitoring of the patient.

- Blood tests should include blood glucose, serum electrolytes, ion and acid-base evaluations, serum creatinine, blood urea nitrogen, BUN, and urinalysis. Additional tests may be needed, such as liver function tests for patients with liver disease, electrolyte evaluations for patients with renal disease, and coagulation studies for patients with bleeding disorders.
- Serum electrolytes should be monitored daily. When 20% PROSUL-fluoro-4-Acetamido) injection is infused without adequate non-protein calories, vomiting, and diarrhea should be treated with appropriate therapy. No further action is required.
- Carcinogenesis, Mutagens, Impairment of Fertility: Studies with 20% PROSUL-fluoro-4-Acetamido) injection have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.
- Pregnancy: Teratogenic Effects
- Pregnancy Category C. Animal production studies have not been conducted with 20% PROSUL-fluoro-4-Acetamido) injection. It is not known whether 20% PROSUL-fluoro-4-Acetamido) injection and its metabolites may cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. 20% PROSUL-fluoro-4-Acetamido) injection should be avoided in pregnant women only if clearly needed.

- Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, precautions should be taken when administering this medication to a nursing woman, especially if the patient has a known reaction to this drug or if the patient is allergic to the drug. The potential benefits of the medication should be weighed against the potential risks to the nursing infant.

- Pediatric Use: Safety and effectiveness of 20% PROSUL-fluoro-4-Acetamido) injection have not been established in children. If appropriate, the benefits of the medication should be weighed against the potential risks to the child. The potential benefits of the medication should be weighed against the potential risks to the child.

- Geriatric Use: Clinical studies of 20% PROSUL-fluoro-4-Acetamido) injection have not included sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger patients. This drug should generally be used with caution in the aged patients, especially those with poor renal function. Any change in the dosage schedule should be adjusted to achieve the daily requirements of increased hydration, renal, or cardic function, and of constipating disease or Drug Therapy.

Special Precautions
Administration of 20% PROSUL-fluoro-4-Acetamido) injection and other nutrients via central or peripheral venous catheter may be associated with complications which can be prevented or remedied by careful attention to all aspects of the procedure. This includes attention to solution preparation, administration, and patient monitoring. It is essential that a carefully prepared protocol, based on current medical practices, be followed, preferably by an experienced team.

- A physician should be available throughout the administration of this medication to deal with any complications that may arise. The physician should be immediately available for consultation in the event of any complications.

- The patient should be monitored closely to ensure that the medication is being administered correctly. The patient should be monitored closely to ensure that the medication is being administered correctly.

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