Important Prescribing Information

November 3, 2017

Subject: Temporary importation of intravenous drug products to address drug shortages

Dear Healthcare Professional,

Due to the critical shortage of drug products resulting from Hurricane Maria, Baxter Healthcare Corporation (Baxter) is coordinating with the U.S. Food and Drug Administration (FDA) to increase the availability of products from Baxter manufacturing facility in the United Kingdom (UK).

Baxter has initiated temporary importation of SYNTHAMIN 17 without Electrolytes 10% Amino Acid Intravenous Infusion. This product is manufactured by Baxter's manufacturing facility in the UK and marketed in the UK. At this time, no other entity except Baxter is authorized by the FDA to import or distribute these products in the United States. FDA has not approved the listed products manufactured by Baxter's manufacturing facility in the UK.

Effective immediately, and during this temporary period, Baxter will offer the following:

Product name and description	Size	Product code	Pack Factor	NDC
SYNTHAMIN 17 without Electrolytes 10% Amino Acid Intravenous Infusion	3000 mL	FKB6642	3	0338-9575-03

It is important to note the following:

- The imported SYNTHAMIN 17, 10% Amino Acid and TRAVSOL 10% contain the same amino acid profile and are therapeutically equivalent formulations.
- **This product has not been tested for aluminum content and this should be taken into consideration, especially when administering to preterm and term infants less than 1 month of age and patients with renal impairment.**
- The imported Synthamin 17, 10% Amino Acid product does not contain added sulfites and is considered sulfite-free.
- For SYNTHAMIN 17, 10% Amino Acid Intravenous Infusion product supplied in a clear overpouch, **keep container in the outer carton in order to protect from light**.
- **Prior to use, it is important to check for leaks** by squeezing the inner bag firmly. If leaks are found, discard solution as sterility may be impaired. Additionally, check to see that solution is clear and free of foreign matter. Discard the solution if solution is not clear.

- **The barcode may not register accurately on the U.S. scanning systems.** Institutions should manually input the product into their systems to confirm that barcode systems do not provide incorrect information when the product is scanned. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.

There are some key differences in the labeling between the U.S. marketed products and the imported products. Please see the product comparison tables at the end of this letter for the key differences between TRAVASOL 10% and SYNTHAMIN 17, 10% Amino Acid products. Refer to Table 2 (below) for a comparison.

Please refer to the FDA-approved package insert for the full prescribing information of TRAVASOL 10% (Amino Acids) Injection at:
https://www.dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=8543b5be-0f43-4891-9e56-d7c39fe839b5&type=pdf&name=8543b5be-0f43-4891-9e56-d7c39fe839b5

If you have any questions about the information contained in this letter or the use of the imported products, please contact Baxter's Medical Information Service at 1-800-933-0303.

To place an order, please contact Baxter's Center for Service by calling 1-888-229-0001.

To report product quality issues please contact Baxter Product Surveillance at 1-800-437-5176.

To report adverse events associated with these imported products, please call Baxter at 1-866-888-2472, or fax: 1-800-759-1801. Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

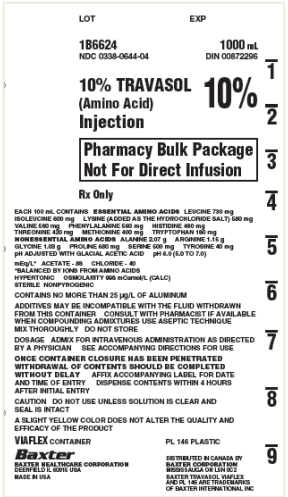
- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Sincerely,

Dennis Vaughn
Vice President, Marketing Operations
Baxter Healthcare Corporation

Product Comparison Tables

Table 1: Key Differences between 10% TRAVASOL and SYNTHAMIN Injections

	US FDA approved product	Import Product
	10% TRAVASOL (Amino Acids) Injection	**SYNTHAMIN 17 without Electrolytes 10% Amino Acid Intravenous Infusion**
		
Description	10% TRAVASOL (Amino Acid) Injection is a sterile, nonpyrogenic hypertonic solution of essential and nonessential amino acids 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 admixtures for intravenous infusion. The VIAFLEX plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). Exposure to temperatures above 25ºC/77ºF during transport and storage will lead to 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 that can permeate from inside the container into the overwrap 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 within 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 USP biological test for plastic containers as well as by tissue culture toxicity studies.	Synthamin 17, 10.0% Amino Acid Intravenous Infusion without Electrolytes is a sterile, nonpyrogenic hypertonic solution of essential and nonessential amino acids in a Pharmacy Bulk Package. The products are supplied in poly (vinyl chloride) Viaflex containers which are sealed in a plastic laminated overpouch, or in dual bag containers sealed in a plastic laminated overpouch. The container is sealed with a closure made from poly (vinyl chloride).
Indication for Use	10% TRAVASOL (Amino Acid) 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. **Central Vein Administration:** 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. **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 when supplemented with or without fat emulsion. **Protein-Sparing:** Dilute amino acid solutions for **peripheral 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 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 amino acid solutions with or without dextrose.	Synthamin 17, 10.0% Amino Acid Intravenous Infusion without Electrolytes provides a biologically available source of nitrogen (L-amino acids) for amino acids synthesis. When administered with an adequate source of energy such as concentrated carbohydrate solutions, minerals and vitamins, the mixture provides (with the exception of essential fatty acids) sufficient parenteral nutrition for patients unable to absorb adequate oral nutrition.
Dosage and Administration	If a patient is unable to take enteral nourishment for a prolonged period of time, institution of total parenteral nutrition (TPN) with exogenous calories should be considered. The total daily 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 weights, corrected for fluid balance, are probably the best means of assessing individual nitrogen requirements. Recommended Dietary Allowances of protein range from approximately 0.75 g/kg of body weight for adults to 1.68 g/kg for infants. It must be recognized, however, that protein as well as caloric requirements in traumatized or malnourished patients may be increased substantially. Daily amino acid doses of approximately 1.0 to 1.5 g/kg of body weight for adults with adequate calories are generally sufficient to satisfy protein needs and promote positive nitrogen balance.	The solution is for administration by intravenous infusion through a central venous catheter with the tip located in the central vena cava. The total daily dose of the solution depends upon the patient's metabolic requirement and clinical response. The determination of nitrogen balance and accurate daily body weights, corrected for fluid balance, are probably the best means of assessing individual nitrogen requirements. In addition to meeting nitrogen needs, the rate of administration is governed, especially during the first few days of therapy, by the patient's ability to tolerate glucose. Daily intake of amino acids, electrolytes and glucose should be increased gradually to the maximum required dose as indicated by frequent determination of urine and blood sugar levels. Recommended daily dietary allowances for protein range from 2.2g/kg of body weight for infants to 56g of protein per day for adults weighing 70kg. An associated source of non-protein energy should be

	US FDA approved product	Import Product
	10% TRAVASOL (Amino Acids) Injection	**SYNTHAMIN 17 without Electrolytes 10% Amino Acid Intravenous Infusion**
	For the initial treatment of trauma or protein calorie malnutrition, higher doses of protein with corresponding quantities of carbohydrate will be necessary to promote adequate patient response to therapy. The severity of the illness being treated is the primary consideration in determining proper dose level. Such higher doses, especially in infants, must be accompanied by more frequent laboratory evaluation. For protein-sparing in well-nourished patients not receiving significant additional calories, amino acid dosages of 1.0 to 1.7 g/kg/day reduce nitrogen losses and spare body protein. If daily increases in BUN in the range of 10 to 15 mg% for more than three days should occur, then protein-sparing therapy should be discontinued and a regimen with full nonprotein calorie substrates should be adopted. Care should be exercised to insure the maintenance of proper levels of serum potassium. Quantities of 60 to 180 mEq of potassium per day have been used with adequate clinical effect. It may be necessary to add quantities of this electrolyte to this injection, depending primarily on the amount of carbohydrate administered to and metabolized by the patient. This injection provides a concentrated source of amino acids to meet the protein requirements of patients that are fluid restricted (e.g., renal failure). Acceptable total daily administration volumes are dependent upon the fluid balance requirements of the patient. Extreme care should be given to prevent fluctuations of blood osmolarity and serum electrolyte concentrations. Frequent and careful monitoring is mandatory when fluid restricted patients are receiving intravenous nutrition. Patients receiving this injection should be monitored (carefully) and their electrolyte requirements individualized. Total daily fluid requirements can be met beyond the volume of amino acid solutions by supplementing with noncarbohydrate or carbohydrate-containing electrolyte solutions. *Food and Nutrition Board National Academy of Sciences – National Research Council (Revised 1989) Maintenance vitamins, additional electrolytes and trace elements should be administered as required. Fat emulsion coadministration should be considered when prolonged parenteral nutrition (more than 5 days) is required in order to prevent essential fatty acid deficiency (EFAD). Serum lipids should be monitored for evidence of EFAD in patients maintained on fat free total parenteral nutrition. **Pediatric Use:** Use of 10% TRAVASOL (Amino Acid) Injection in pediatric patients is governed by the same considerations that affect the use of any amino acid solution in pediatrics. The amount administered is dosed on the basis of grams of amino acids/kg of body weight/day. Two to three g/kg of body weight for infants with adequate calories are generally sufficient to satisfy protein needs and promote positive nitrogen balance. Solutions administered by peripheral vein should not exceed twice normal serum osmolarity (718 mOsmol/L). **Central Vein Administration:** Hypertonic mixtures of amino acids and dextrose may be administered safely by continuous infusion through a central vein catheter with the tip located in the vena cava. In addition to meeting nitrogen needs, the administration rate is governed, especially during the first few days of therapy, by the patient's tolerance to dextrose. Daily intake of amino acids and dextrose should be increased gradually to the maximum required dose as indicated by frequent determinations of urine and blood sugar levels. In many patients, provision of adequate calories in the form of hypertonic dextrose may require the administration of exogenous insulin to prevent hyperglycemia and glycosuria. Parenteral nutrition may be started with infusates containing lower concentrations of dextrose; dextrose content may be gradually increased to estimated caloric needs as the patient's glucose tolerance increases. Sudden cessation in administration of concentrated dextrose solution may result in insulin reaction due to continued endogenous insulin production. Such solutions should be withdrawn slowly. **Peripheral Vein Administration:** For patients requiring parenteral nutrition in whom the central vein route is not indicated, this injection can be mixed with low concentration dextrose solutions and administered by peripheral vein in conjunction with or without fat emulsions. In pediatric patients, the final solution should not exceed twice normal serum osmolarity (718 mOsmol/L). Intravenous fat emulsions provide approximately 1.1 kcal/mL (10%) or 2.0 kcal/mL (20%) and may be administered along with amino acid-dextrose solutions by means of a short Y-connector near the infusion site to supplement caloric intake. Fat, however, should not be the sole caloric intake since studies have indicated that glucose is more nitrogen sparing in the stressed patient. **Protein-Sparing:** For well-nourished patients who require short-term parenteral support, 10% TRAVASOL (Amino Acid) Injection can be administered peripherally with or without carbohydrate calories. Such infusates can be prepared by dilution of this injection with Sterile Water for Injection or 5% Dextrose Injection to prepare isotonic or slightly hypertonic solutions which may be administered by peripheral vein. Depending upon the clinical condition of the patient, approximately 3 liters of solution may be administered per 24 hour period. When used postoperatively, the therapy should begin with 1000 mL on the first postoperative day. Thereafter, the dose may be increased to 3000 mL per day. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Use of a final filter is recommended during administration of all parenteral solutions where possible. Do not administer unless solution is clear and seal is intact. A slight yellow color does not alter the quality and efficacy of the product. 10% TRAVASOL (Amino Acid) Injection in the Pharmacy Bulk Package is intended for use in the preparation of sterile, intravenous admixtures. Additives may be incompatible with the fluid withdrawn from this container. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. When compounding admixtures, use aseptic technique. Mix thoroughly. Do not store any unused portion of 10% TRAVASOL (Amino Acid) Injection. Any storage should be under refrigeration and limited to a brief period of time, preferably less than 24 hours.	administered in a quantity not less than 0.75 megajoules (180 kcal) per gram of nitrogen. In the initial treatment of severe trauma or in the presence of marked malnutrition, higher doses of amino acids with correspondingly larger quantities of carbohydrate will be necessary to promote adequate patient response to therapy. The degree of negative nitrogen balance being treated is the primary consideration in determining replacement therapy. Electrolyte supplementation may be indicated according to the clinical needs of the patient. Fat emulsion co-administration should be considered when prolonged parenteral nutrition is required in order to prevent essential fatty acid deficiency (EFAD). As indicated on an individual basis, vitamins and trace elements and other components (including glucose and lipids) can be added to the parenteral nutrition regimen to meet nutrient needs and prevent deficiencies and complications from developing. The osmolarity of a specific infusion solution must be taken into account when peripheral administration is considered. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. The flow rate should be increased gradually during the first hour. The flow rate must be adjusted taking into account the dose being administered, the daily volume intake, and the duration of the infusion. Use of a final filter is recommended during administration of all parenteral nutrition solutions. **Paediatric population** In children, the dosage of parenteral nutrition should be individually tailored to the amino acid, electrolyte and energy requirements of the patient.
Contraindica-tions	• Hypersensitivity to one or more amino acids • Severe liver disease or hepatic coma • Anuria	Synthamin is contraindicated in patients with: • Known hypersensitivity to any of the active substances or excipients, or to components of the container • Congenital abnormality of amino acid metabolism

	US FDA approved product	Import Product
	10% TRAVASOL (Amino Acids) Injection	**SYNTHAMIN 17 without Electrolytes 10% Amino Acid Intravenous Infusion**
Warnings and Precautions	**WARNINGS - This injection is for compounding only, not for direct infusion.** Caution should be exercised when admixing 10% TRAVASOL (Amino Acid) Injection. Studies have shown that admixtures of TRAVASOL (Amino Acid) Injection, 10% and 20% TRAVAMULSION Intravenous Fat Emulsion injection and high concentration dextrose injection (10 to 70%), from Baxter Healthcare Corporation, are stable over short periods of time. These solutions should be used promptly after admixing. Any storage should be under refrigeration and limited to a brief period of time, preferably less than 24 hours. Reference should be made to TRAVAMULSION injection and high concentration dextrose injection from Baxter Healthcare Corporation package inserts for detailed information on each component. 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 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 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. WARNING: This 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 kidneys are 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 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.** **PRECAUTIONS** It is essential to provide adequate calories 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. With the administration of 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 therapy. Sudden cessation in administration of a concentrated dextrose solution may result in insulin reaction due to continued endogenous insulin production. Parenteral nutrition mixtures should be withdrawn slowly. Electrolytes may be added to this injection as dictated by the patient's electrolyte profile. The metabolizable acetate anion and amino acid profile in this injection were designed to minimize or prevent occurrences of hyperchloremic metabolic acidosis and hyperammonemia. However, the physician should be aware of appropriate countermeasures if they become necessary. Strongly hypertonic nutrient solutions should be administered through an indwelling intravenous catheter with the tip located in the superior vena cava. Because of its antianabolic activity, concurrent administration of tetracycline may reduce the protein sparing effects 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 nonprotein calorie components. Drug product contains no more than 25 µg/L of aluminum.	**WARNINGS** Anaphylactic/anaphylactoid reactions and other hypersensitivity/infusion reactions have been reported with Synthamin administered as a component of parenteral nutrition. The infusion must be stopped immediately if any signs or symptoms of a reaction develop. Pulmonary vascular precipitates causing pulmonary vascular emboli and pulmonary distress have been reported in patients receiving parenteral nutrition. In some cases, fatal outcomes have occurred. Excessive addition of calcium and phosphate increases the risk of the formation of calcium phosphate precipitates. Precipitates have been reported even in the absence of phosphate salt in the solution. Precipitation distal to the in-line filter and suspected in vivo precipitate formation has also been reported. Pulmonary vascular precipitates have also been reported with Synthamin. If signs of pulmonary distress occur, the infusion should be stopped and medical evaluation initiated. In addition to inspection of the solution, the infusion set and catheter should also periodically be checked for precipitates. Infection and sepsis may occur as a result of the use of intravenous catheters to administer parenteral formulations, poor maintenance of catheters or contaminated solutions. Immunosuppression and other factors such as hyperglycaemia, malnutrition and/or their underlying disease state may predispose patients to infectious complications. Careful symptomatic and laboratory monitoring for fever/chills, leukocytosis, technical complications with the access device, and hyperglycaemia can help recognize early infections. The occurrence of septic complications can be decreased with heightened emphasis on aseptic technique in catheter placement, maintenance, as well as aseptic technique in nutritional formula preparation. Refeeding severely undernourished patients may result in the refeeding syndrome that is characterized by the shift of potassium, phosphorus, and magnesium intracellularly as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. Careful monitoring and slowly increasing nutrient intakes while avoiding overfeeding can prevent these complications. Hypertonic infusion solutions may cause irritation of the vein when administered into a peripheral vein. **PRECAUTIONS** Monitoring should be appropriate to the patient's clinical situation and condition, and should include determinations of water and electrolyte balance, serum osmolarity, acid/base balance, blood glucose, liver and kidney function. Metabolic complications may occur if the nutrient intake is not adapted to the patient's requirements, or the metabolic capacity of any given dietary component is not accurately assessed. Adverse metabolic effects may arise from administration of inadequate or excessive nutrients or from inappropriate composition of an admixture for a particular patient's needs. Amino acid solutions should be used with caution in patients with preexisting liver disease or liver insufficiency. Liver function parameters should be closely monitored in these patients, and they should be monitored for possible symptoms of hyperammonemia (see below). Patients on parenteral nutrition may experience hepatic complications (including cholestasis, hepatic steatosis, fibrosis and cirrhosis, possibly leading to hepatic failure, as well as cholecystitis and cholelithiasis) and should be monitored accordingly. The etiology of these disorders is thought to be multifactorial and may differ between patients. Patients developing abnormal laboratory parameters or other signs of hepatobiliary disorders should be assessed by a clinician knowledgeable in liver diseases in order to identify possible causative and contributory factors, and possible therapeutic and prophylactic interventions. Increase in blood ammonia levels and hyperammonemia may occur in patients receiving amino acid solutions. In some patients this may indicate the presence of a congenital disorder of amino acid metabolism or hepatic insufficiency. Blood ammonia should be measured frequently in newborns and infants to detect hyperammonemia, which may indicate the presence of a congenital abnormality of amino acid metabolism. Depending on extent and etiology, hyperammonemia may require immediate intervention. Should symptoms of hyperammonemia develop, administration should be discontinued and the patient's clinical status reevaluated. Azotemia has been reported with parenteral administration of solutions containing amino acids, and may occur in particular in the presence of renal impairment. Use with caution in patients with pulmonary oedema or heart failure. Fluid status should be closely monitored. Use with caution in patients with renal insufficiency. Fluid and electrolyte status should be closely monitored in these patients. Severe water and electrolyte disorders, severe fluid overload states, and severe metabolic disorders should be corrected before starting the infusion. Mixtures containing amino acids may precipitate acute folate deficiency and folic acid should be administered daily. It is essential to provide an adequate source of non-protein energy concurrently if

	US FDA approved product	Import Product
	10% TRAVASOL (Amino Acids) Injection	**SYNTHAMIN 17 without Electrolytes 10% Amino Acid Intravenous Infusion**
		parenterally administered amino acids are to be retained by the body and utilised for protein synthesis. Concentrated glucose solutions are an effective source of such energy. The infusion of Synthamin with highly concentrated glucose solutions may result in hyperglycaemia, glycosuria and hyperosmolar syndrome. Blood and urine glucose should be monitored on a routine basis in patients receiving this treatment
Usage in Specific Population	**Pregnancy:** Teratogenic Effects *Pregnancy Category C* - Animal reproduction studies have not been conducted with 10% TRAVASOL (Amino Acid) Injection. It is also not known whether 10% TRAVASOL (Amino Acid) Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. 10% TRAVASOL (Amino Acid) Injection should be given to a pregnant woman only if clearly needed. **Nursing Mothers:** Caution should be exercised when 10% TRAVASOL (Amino Acid) Injection is administered to a nursing woman. **Pediatric Us e:** Safety and effectiveness of 10% TRAVASOL (Amino Acid) Injection in pediatric patients have not been established by adequate and well-controlled studies. However, the use of amino acid injections in pediatric patients as an adjunct in the offsetting of nitrogen loss or in the treatment of negative nitrogen balance is referenced in the medical literature. See Dosage and Administration	**Paediatric use** There have been no studies performed by Baxter Healthcare Corporation in the paediatric population. See above regarding monitoring for hyperammonemia in paediatric patients. **Geriatric use** In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.
Adverse Events	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.	The following adverse reactions have been reported in the post-marketing experience. Frequency is defined as very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1000 to < 1/100): rare (≥ 1/10,000 to < 1/1000); very rare (< 1/10,000); and not known (cannot be estimated from the available data).Other adverse reactions reported with parenteral amino acid products include: **Tabulated list of adverse reactions** **System Organ Class** / **Preferred MedDRA Term** / **Frequency** Immune system disorders / Anaphylactic/anaphylactoid reactions* / Not known Hypersensitivity** / Not known Vascular disorders / Pulmonary vascular precipitate / Not known
Overdosage	See Contradictions	In the event of inappropriate administration (overdose, and/or infusion rate higher than recommended), hypervolemia, electrolyte disturbances, acidosis and/or azotemia may occur. In such situations, the infusion must be stopped immediately. If medically appropriate, further intervention may be indicated to prevent clinical complications. There is no specific antidote for overdose. Emergency procedures should include appropriate corrective measures.
Storage Conditions	Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. It is recommended the product be stored at room temperature (25ºC/77ºF). Do not remove container from overpouch until ready to use. Do not use if overpouch has been previously opened or damaged.	Storage temperature should not exceed 25°C. Product supplied in a clear overpouch should be protected from light during storage.
Directions for use	**Directions for us e of VIAFLEX plastic Pharmacy Bulk Package container** **To Open** Tear overpouch down side at slit and remove solution container. Visually inspect the container. If the outlet port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. **For compounding only, not for direct infusion. -** Preparation for Admixing 1. The Pharmacy Bulk Package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area). 2. Suspend container from eyelet support. 3. Remove plastic protector from outlet port at bottom of container. 4. Attach solution transfer set. Refer to complete directions accompanying set. Note: The closure shall be penetrated only one time with a suitable sterile transfer device or dispensing set which allows measured dispensing of the contents. 5. VIAFLEX containers should not be written on directly since ink migration has not been investigated. Affix accompanying label for date and time of entry. 6. Once container closure has been penetrated, withdrawal of contents should be completed without delay. After initial entry, maintain contents at room temperature (25ºC/77ºF) and dispense within 4 hours.	2 litre and 3 litre containers are bulk source containers for pharmacy use and should not be used for direct intravenous infusion. Do not administer unless the solution is clear and colourless or slightly yellow, and the container undamaged. **To open** Do not remove from overpouch until ready to use. Remove the protective overpouch. Check bag for leaks. **If additions to the bag are made** Aseptic conditions must be observed. Ensure stability and compatibility of additives. Prepare the injection site of the bag. Puncture the injection site and inject the additives using an injection needle or a reconstitution device. Mix content of the bag and the additives thoroughly. Inspect final solution for discoloration and particulate matter. Check bag for leaks. Ensure proper storage requirements of additives are followed. **Administration of the infusion** Do not be administered simultaneously with, before or after an administration of blood through the same infusion equipment, because of the possibility of pseudo-agglutination. Do not connect bags in series in order to avoid air embolism due to possible residual air contained in the primary bag. For single use only. Discard all equipment after use. Discard any unused portion. Do not reconnect partially used bags.
How Supplied	10% TRAVASOL (Amino Acid) Injection is available in VIAFLEX plastic Pharmacy Bulk Package containers. Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. It is recommended the product be stored at room temperature (25ºC/77ºF). Do not remove container from overpouch until ready to use. Do not use if overpouch has been previously opened or damaged.	Storage temperature should not exceed 25°C. Product supplied in a clear overpouch should be protected from light during storage.

Table 2. Comparison of TRAVASOL and SYNTHAMIN Ingredients

US FDA approved product			Import Product			
10% TRAVASOL (Amino Acids) Injection			**SYNTHAMIN 17 without Electrolytes 10% Amino Acid Intravenous Infusion**			
Ingredients - 10% TRAVASOL		**mg/100 mL**	**Ingredients – SYNTHAMIN 17 10% Amino Acid Intravenous Infusion**		**g/L**	**mg/100 mL**
Essential Amino Acids	Leucine	730	Active Ingredients	L- Leucine	7.30	730
	Isoleucine	600		L-Isoleucine	6.00	600
	Valine	580		L-Valine	5.80	580
	Lysine (added as hydrochloride)	580		L-Lysine (as hydrochloride salt)	5.80	580
	phenylalanine	560		L-Phenylalanine	5.60	560
	Histidine	480		L-Histidine	4.80	480
	Threonine	420		L-Threonine	4.20	420
	Methionine	400		L-Methionine	4.00	400
	Tryptophan	180		L-Tryptophan	1.80	180
Nonessential Amino Acids	Alanine	2.07 g/100 mL		L-Alanine	20.70	2.07 g/100 mL
	Arginine	1.15 g/100 mL		L-Arginine	11.50	1.15 g/100 mL
	Glycine	1.03 g/100 mL		Amino acetic Acid (Glycine)	10.30	1.03 g/100 mL
	Proline	680		L-Proline	6.80	680
	Serine	500		L-Serine	5.00	500
	Tyrosine	40		L-Tyrosine	400 mg	40
Other	Acetate*	88 mEq/L	Other	Acetate*	82 mmol/L	
	Chloride*	40 mEq/L		Chloride*	40mmol/L	
	pH	6.0 (5.0 to 7.0)		pH	6.0	
	Osmolarity (calculated)	998 mOsm/L		Osmolarity (calculated)	1000 mOsm/L	

* For monovalent ions, the numeric value of the millimole and milliequivalent are identical.