PRODUCT MONOGRAPH

TRAVASOL Amino Acid Injections WITH ELECTROLYTES

TRAVASOL Amino Acid Injections WITHOUT ELECTROLYTES

TRAVASOL AMINO ACID INJECTIONS AND DEXTROSE

Intravenous Nutritive Supplements

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THERAPEUTIC CLASSIFICATION

Intravenous Nutritive Supplements

DESCRIPTION

Travasol Amino Acid Injections are sterile, hypertonic, non-pyrogenic solutions of essential and non-essential amino acids presented with or without electrolytes, for intravenous administration.

Each 100 mL of Travasol Amino Acid Injections with Electrolytes or without Electrolytes and Travasol Amino Acid Injections in double chamber bag contains:

	BLEND B			
	5%	**5.5%**	**8.5%**	**10%**
Amino Acids	5.0 g	5.5 g	8.5 g	10g
Total Nitrogen	844 mg	929 mg	1.44 g	1.69g
Approximate pH	6.0	6.0	6.0	6.0
Approximate milliosmols/ litre (With Electrolytes	657	722	1116	1305
and Without Electrolytes)	534	587	908	1047

	BLEND B			
Essential Amino Acids	**5%**	**5.5%**	**8.5%**	**10%**
L-Leucine	310 mg	340 mg	526 mg	620 mg
L-Phenylalanine	310 mg	340 mg	526 mg	620 mg
L-Methionine	290 mg	318 mg	492 mg	580 mg
L-Lysine (HCl)	290 mg	318 mg	492 mg	580 mg
L-Isoleucine	240 mg	263 mg	406 mg	480 mg
L-Valine	230 mg	252 mg	390 mg	460 mg
L-Histidine	220 mg	241 mg	372 mg	440 mg
L-Threonine	210 mg	230 mg	356 mg	420 mg
L-Tryptophan	90 mg	99 mg	152 mg	180 mg
Non-Essential Amino Acids	**5%**	**5.5%**	**8.5%**	**10%**
L-Alanine	1.04 g	1.14 g	1.76 g	2.08 g
Aminoacetic Acid	1.04 g	1.14 g	1.76 g	2.08 g
L-Arginine	520 mg	570 mg	880 mg	1.04 g
L-Proline	210 mg	231 mg	356 mg	420 mg
L-Tyrosine	20 mg	22 mg	34 mg	40 mg

BLEND C

	5%	5.5%	8.5%	10%
Amino Acids	5.0 g	5.5 g	8.5 g	10 g
Total Nitrogen	829 mg	912 mg	1.41 g	1.65 g
Approximate pH	6.0	6.0	6.0	6.0
Approximate milliosmols/ litre (With Electrolytes	637	701	1083	1274
and Without Electrolytes)	515	566	875	999

Essential Amino Acids	**5%**	**5.5%**	**8.5%**	**10%**
L-Leucine	365 mg	402 mg	620 mg	730 mg
L-Phenylalanine	280 mg	308 mg	476 mg	560 mg
L-Methionine	200 mg	220 mg	340 mg	400 mg
L-Lysine (HCl)	290 mg	319 mg	493 mg	580 mg
L-Isoleucine	300 mg	330 mg	510 mg	600 mg
L-Valine	290 mg	319 mg	493 mg	580 mg
L-Histidine	240 mg	264 mg	408 mg	480 mg
L-Threonine	210 mg	230 mg	357 mg	420 mg
L-Tryptophan	90 mg	99 mg	153 mg	180 mg

Non-Essential Amino Acids	**5%**	**5.5%**	**8.5%**	**10%**
L-Alanine	1.04 g	1.14 g	1.76 g	2.07 g
Aminoacetic Acid	0.52 g	566 mg	876 mg	1.03 g
L-Arginine	0.58 g	632 mg	978 mg	1.15 g
L-Proline	340 mg	374 mg	578 mg	680 mg
L-Tyrosine	20 mg	22 mg	34 mg	40 mg
L-Serine	250 mg	275 mg	425 mg	500 mg

Acetic acid is added for pH adjustment. In addition to the above, Travasol Amino Acid Injections with Electrolytes contain in each 100 mL the following electrolytes:

BLEND B AND C

Electrolyte	**5%**	**5.5%**	**8.5%**	**10%**
Sodium Acetate, Trihydrate USP	340 mg	431 mg	594 mg	680 mg
Dibasic Potassium Phosphate USP	261 mg	522 mg	522 mg	522 mg
Sodium Chloride, USP	58.5 mg	224 mg	154 mg	117 mg
Magnesium Chloride, Hexahydrate USP	51 mg	102 mg	102 mg	102 mg

Travasol Amino Acid Injections with Electrolytes contain the following electrolytes in approximate milliequivalents per liter*.

BLEND B AND C

Electrolyte	**5%**	**5.5%**	**8.5%**	**10%**
Sodium	35	70	70	70

Potassium	30	60	60	60
Magnesium	5	10	10	10
Acetate**	75	102	141	150
Chloride	35	70	70	70
Phosphate (as HPO_4=)	30	60	60	60

* Balanced by ions from amino acids

** Acetate is added as sodium acetate and as acetic acid used for pH adjustment.

Travasol Amino Acid Injections without Electrolytes contain the following anion profiles in mmol (mEq)/L.

Anion	**5%**	**5.5%**	**8.5%**	**10%**
Acetate (1)	44	48	73	87
Chloride (2)	20	22	34	40

(1) derived from pH adjustment with acetic acid
(2) contributed by the L-Lysine Hydrochloride

The dextrose chambers of Travasol Amino Acid with and without electrolytes and dextrose in the Clinimix dual chamber container contain the following per 100mL:

Ingredient	**10%**	**20%**	**33.3%**	**40%**	**50%**
Dextrose Hydrous USP	10.0 g	20.0g	33.3g	40.0g	50.0g
Water for Injection USP	qs	qs	qs	qs	qs

ACTION

When Travasol Amino Acid Injections are administered with an appropriate caloric source (e.g., dextrose, fructose, sorbitol), nitrogen balance is improved. Maximal nitrogen utilization is promoted by providing adequate calories to meet metabolic needs, usually at least 168 kJ/kg/day (40 kcal/kg/day).

INDICATIONS

Travasol Amino Acid Injections when administered with a caloric source, are indicated as a source of amino acids in a variety of clinical conditions in which the patient cannot absorb sufficient oral nutrition or in which it is inadvisable to use the oral route of nutrition.
Electrolytes must be added to the Travasol Amino Acid Injections without Electrolytes as dictated by the patient`s electrolyte profile.

CONTRAINDICATIONS

1. Patients with acute renal failure (for Travasol Amino Acid Injections with Electrolytes only).
2. Patients with severe liver disease or hepatic coma.
3. Hypersensitivity to one or more amino acids.
4. Hereditary fructose intolerance due to aldolase deficiency is a contraindication to the use of sorbitol or fructose injection.
5. Inborn errors of amino acid metabolism concerning one or more amino acid components.

WARNINGS

Proper administration of these injections 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.

Frequent clinical evaluation and laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, osmolarity, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation. Studies should include blood sugar, serum proteins, blood ammonia levels, kidney and liver function tests, electrolytes, hemogram, arterial blood gases, serum osmolarities and blood cultures.

The IV administration of these solutions can lead to fluid or solute overload resulting in hyper or hypoosmolal states. The risk of hypoosmolal states is especially present in conditions associated with ADH secretion and is proportional to the infusion rate.

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.

Administration of amino acid solutions to a patient with hepatic insufficiency may result in serum amino acid imbalances, hyperammonemia, stupor and coma.

Conservative doses of these injections should be given to patients with known or suspected hepatic dysfunction. Should symptoms of hyperammonemia develop, administration should be discontinued and the patients`s clinical status reevaluated.

Administration of amino acid solutions in the presence of impaired renal function presents special issues associated with retention of electrolytes.

A slight yellow color does not alter the quality and activity of the product.

These solutions should not be administered simultaneously with blood through the same infusion set because of the possibility of pseudoagglutination.

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 these injections 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 rebound hypoglycemia due to continued endogenous insulin production. Parenteral nutrition mixtures should be withdrawn slowly. In patients with myocardial infarction, infusion of amino acids should always be accompanied by dextrose since in anoxia, fatty acids cannot be properly utilized by myocardium.

Special care must be taken when giving hypertonic dextrose to patients with impaired glucose tolerance such as diabetics or prediabetics and uremic patients, especially when the latter are receiving peritoneal dialysis. To prevent severe hyperglycemia in such patients, insulin may be required.

Handling of glucose load is also frequently impaired in patients with liver failure.
Caution must be exercised when administering these injections to patients receiving corticosteroids or corticotropin.

Travasol Amino Acid Injections with Electrolytes contain sufficient electrolytes to provide for most parenteral nutritional needs with the possible exception of potassium where supplementation may be required. However, replacement of exceptional electrolyte loss due to nasogastric suction, fistula drainage, or unusual tissue exudation may be necessary. Particular attention should be given to monitoring serum potassium and phosphate levels.

Patients receiving Travasol Amino Acid Injections without Electrolytes should be carefully monitored and their electrolyte requirements individualized.

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 administration of carbohydrates.

During prolonged parenteral nutrition with concentrated dextrose and amino acid solutions, essential fatty acid deficiency syndrome may develop, but may not be clinically apparent. Early demonstration of this condition can only be accomplished by analysis of plasma lipids. The syndrome may be prevented or corrected by appropriate treatment with intravenous fat emulsions.

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.

Pregnancy. Animal reproduction studies have not been conducted with amino acid injections. It is also not known whether amino acid injections can cause fetal harm when

administered to a pregnant woman or can affect reproduction capacity. Amino acid injections should be given to a pregnant woman only if clearly needed.
Do not administer unless solution is clear.

SPECIAL PRECAUTIONS

Administration of amino acid solutions and other nutrients via central or peripheral venous catheter may be associated with complications which can be prevented or minimized 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**.

Although a detailed discussion of the complications is beyond the scope of this Product Monograph the following summary lists those based on current literature.

Technical: Strongly hypertonic nutrient solutions should be administered through an indwelling intravenous catheter with the tip located in the superior vena cava.

The placement of a central venous catheter should be regarded as a surgical procedure. The physician should be fully acquainted with various techniques of catheter insertion as well as recognition and treatment of complications. For details of techniques and placement sites consult the medical literature. X-ray is the best means of verifying catheter placement.

Complications known to occur from the placement of central venous catheters are pneumothorax, hemothorax, hydrothorax, artery puncture and transection, injury to the brachial plexus, malposition of the catheter, formation of arterio-venous fistula, phlebitis, thrombosis, cardiac arryhthmia and catheter embolus.

Septic: The constant risk of sepsis is present during administration of parenteral nutrition solution. Since contaminated solutions and infusion catheters are potential sources of infection, it is imperative that the preparation of the solution and the placement and care of catheters be accomplished under controlled aseptic conditions. If fever develops, the solution, its delivery system and the site of the indwelling catheter should be changed. Blood cultures should be taken and the remainder of fluid should be saved for examination when deemed necessary.

Extemporaneously prepared solutions should be used promptly after mixing. Any storage should be under refrigeration and limited to a brief period of time, preferably less than 24 hours. (See also Availability Section).

Metabolic: 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 day of therapy, to prevent or minimize these complications.

ADVERSE REACTIONS

See Warnings and Special Precautions.

OVERDOSE

In the event of hyperammonenia, over hydration and/or solute overload, discontinue infusion, re-evaluate the patient and institute appropriate corrective measures. See Warnings and Precautions.

DOSAGE AND ADMINISTRATION

The total daily dose of these solutions 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.

Travasol Amino Acid Injections with Electrolytes contains sufficient electrolytes to provide electrolyte balance for most parenteral nutrition needs. However, additional potassium ions may be required depending upon the amount of dextrose used as the caloric source.

Table 1 shows the nitrogen content and caloric values of some dosage forms packaged in individual containers and commonly used for the preparation of TPN solutions.

Table 1

Travasol Amino Acid Injections WITH ELECTROLYTES Blend B	**NITROGEN g**	**OSMOLARITY mOsmol/L**
5.5% Concentration, 500 mL	4.6	722
8.5% Concentration, 500 mL	7.2	1116
10% Concentration, 250 mL	4.2	1305
Travasol Amino Acid Injections WITHOUT ELECTROLYTES Blend B		
5.5% Concentrations, 500 mL	4.6	587
8.5% Concentrations, 500 mL	7.2	908
10% Concentrations, 250 mL	4.2	1047

	CALORIES kJ	CALORIES kcal	OSMOLARITY mOsm/L
10% Dextrose Injection, 1000 mL	1420	340	505
13.3% Dextrose Injection, 750 mL	1420	340	670
33.3% Dextrose Injection, 750 mL	3550	850	1680
50% Dextrose Injection, 500 mL	3550	850	2520

Recommended dietary allowances of protein range from approximately 0.8 g/kg of body weight for adults to 2.2 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 and 2 to 3 g/kg of body weight for infants with adequate calories are generally sufficient to satisfy protein needs and promote positive nitrogen balance.

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. 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 caloric 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 the electrolyte to these injections depending primarily on the amount of carbohydrate administered to and metabolized by the patient.

These injections provide a concentrated source of amino acids to meet the protein requirements of patients that are fluid restricted (e.g. renal failure). Typically 250 mL of these injections mixed with 500 mL of 70% Dextrose Injection is administered over a 12 hour period. 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.

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 day 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 rebound hypoglycemia 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, these injections can be diluted and infused by peripheral vein with or without fat emulsions.

Protein Sparing: For well nourished patients who require short-term parenteral support, these injections can be administered peripherally with or without carbohydrate calories. Infusates may also be prepared by dilution of these injections 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.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique.

Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

It is recommended that all intravenous administration apparatus be replaced per CDC guidelines.

Careful attention must be given to the proper care of the intravenous catheter to avoid contamination of the blood and consequent septicemia. If fever develops, therapy should be discontinued and the catheter removed. Blood cultures should be taken and the remainder of the fluid saved for examination when deemed necessary.

Directions for the Preparation of Travasol Amino Acid Injections and Dextrose Solutions

A. Travasol Amino Acid Injections Requiring Aseptic Transfer Procedures.
Use aseptic technique. Transfer procedure should be performed under a laminar flow hood. See directions accompanying transfer set for additional information.

Non-Air Dependent Containers

A type of flexible plastic non-air dependent system utilizing a final container which is initially empty. It is filled with both the amino acid and carbohydrate solutions in appropriate amounts to make the desired mixture. Filling methodology is dictated by the system selected for use. See individual directions.

NOTE:

The prepared amino acids / dextrose admixture should be administered immediately. If not, it should be stored under refrigeration (2˚ - 8˚ C) and used within 24 hours.

Stability data is available to substantiate stability of 2.75% -5.0% amino acids and 5- 35% dextrose for 28 days at room temperature and 112 days when stored under refrigeration 2˚C - 8˚C if admixtures are prepared using validated aseptic techniques for preparation of i.v. solutions Ref: Baxter (USA) study Protocol number R09D81013. 2/5/1982, Final report: "Evaluation of the stability of amino acid dextrose (TPN) solutions…". Note- from a microbial point of view, admixed solutions be used within 24 hours when warmed to room temperature (15-25°C)

b) It is recommended that all intravenous administration apparatus, including the needle, be replaced per CDC guidelines

WARNING: Do not use plastic container in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

B) Travasol Amino Acid Injections and Dextrose Injection container System not Requiring Aseptic Transfer Procedures

A flexible plastic, non-air dependent, closed transfer system consisting of a double-chambered container is illustrated in Figures 1 and 2.

The upper chamber contains Dextrose Injection USP. The lower chamber contains Travasol Amino Acid Injections with or without Electrolytes.

This container configuration is intended to:

(a) provide TRAVASOL Amino Acid Injections and Dextrose Injections as physically separate solutions within one individual container and to

(b) facilitate their admixture, in a closed system, immediately prior to administration (see Directions below).

NOTE: The double chamber container (unmixed solutions) should be stored at temperatures not exceeding 25°C protected from light and kept from freezing. The prepared solution should be administered immediately.

If not, it should be stored under refrigeration (2°C - 8°C) and used within 24 hours.

DIRECTIONS FOR USE OF Clinimix DUAL CHAMBER CONTAINER
TO OPEN

1. Do not remove unit from overwrap until ready for use. The overwrap is a moisture barrier. The inner bag maintains the sterility of the product.

2. Tear overwrap down side at strip and remove solution container. 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.

3. Check to ensure V seal is intact, i.e. solutions are contained in separate chambers. Check for minute leaks by separately squeezing each chamber. If external leaks or leakage between the top and bottom are found, discard the solution as sterility may be impaired.

TO MIX SOLUTIONS:

Hold the bag upright with the back of the bag facing you. Grasp the bag, towards the top with one hand. Then grasp the bag with the other hand so that the thumbs are crossed.

Apply pressure with both palms and the fluid in the top chamber to force the liquid downwards towards the internal seal. This downward fluid pressure will break the internal seal The seal will brake easily with minimal effort.

Picture here

WARNING: Do not use plastic container in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

Mixing Guidelines

Investigations have been conducted which demonstrate the compatibility of Intralipid 10% and 20% when properly mixed with either 8.5% Travasol or 10% Travasol Amino Acid Injections for use in Total Parenteral Nutrition (TPN) therapy. The proper mixing sequence assures that pH related problems are minimized by ensuring that typically acidic Dextrose Injections are not mixed with lipid emulsions alone.

A suggested mixing sequence follows below:

1. Transfer Dextrose Injection to the TPN Admixture Container
2. Transfer Travasol Amino Acid Injection
3. Transfer Intralipid (I.V. Fat Emulsion)

Note: Travasol Amino Acid Injection, Dextrose Injection and Intralipid may be simultaneously transferred to the admixture container. Admixing should be accompanied by gentle agitation to avoid localized concentration effects.

For Intralipid 10% 500ML solutions that following data has been generated:

	Travasol 8.5% with Electr. 500mL	Travasol 8.5% w/o Electr. 500mL	Travasol 10% with Electr. 500mL	Travasol 10% w/o Electr. 500mL
Dextrose 50%500mL	Compatible	Compatible	Compatible	Compatible

For Intralipid 20% 500ML solutions that following stability studies have been completed

	Travasol 8.5% with Electr. 1000mL
Dextrose 12.5%1000mL	Compatible
Dextrose 15%1000mL	Compatible

*Note: Due to the large number of potential combinations of admixture components, a matrix approach was employed to demonstrate stability over a broad range of concentrations.

Stability data is available to substantiate storage for 168 hours (7 days) at 5˚ ± 3˚C and 2 additional days at ambient temperature (22˚C - 25˚C) for the above combinations of Travasol with and without electrolytes, Intralipid, and dextrose admixed in Ethyl Vinyl Acetate (EVA) containers.

Special Precautions:

It is essential that the admixture be prepared using strict aseptic techniques as this nutrient mixture may support microorganisms.

Additives

Components other than Travasol and Intralipid may not be compatible. Complete information is not available. Supplemental electrolytes, trace metals or multivitamins may be required in accordance with the prescription of the attending physician. Additives known to be incompatible should not be used, consult with pharmacist. Use aseptic technique while compounding. Additives must not be added directly to Intralipid. It is suggested that additives be injected before lipid addition to facilitate visual inspection for incompatibility. Mix thoroughly when additives have been introduced.

The prime destabilizers of emulsions are excessive acidity (low pH) and inappropriate electrolyte concentration, particular divalent cations (Ca + + and Mg + +). Amino acid solutions exert a buffering effect protecting the emulsion. The concentration and ranges of all components should not exceed recommended guidelines.
The addition of the following additives resulted in admixtures stable for 7 days refrigerated plus an additional 2 days at room temperature.
Per litre of Travasol / Intralipid /Dextrose Admixture:

Electrolytes	Sodium	40 – 120 mmol
	Potassium	26.67 – 80 mmol
	Calcium	2 – 10 mmol
	Magnesium	3.33 – 10 mmol
	Phosphate	6.67 – 20 mmol
	Chloride	40 – 120 mmol
	Acetate	18 – 53.3 mmol
Trace Elements	Zinc	6.67 mg
	Copper	2.67 mg
	Manganese	0.67 mg
	Chromium	26.67 μg
	Selenium	0.133 mg
Vitamins	multivitamin preparation 6.67 mL (added to mixture on day 8)	

AVAILABILITY OF DOSAGE FORMS

Travasol Amino Acid Injection Blend B and Blend C, is available in **5.0%, 5.5%, 8.5% and 10% concentrations with Electrolytes** in glass containers as well as in Viaflex plastic containers.
Travasol Amino Acid Injection Blend B and Blend C, is available in **5.0%, 5.5%, 8.5% and 10% concentrations without Electrolytes** in glass containers as well as in Viaflex plastic containers.
Travasol Amino Acid Injections Blend B and Blend C with Electrolytes and Dextrose Injection are also available in a closed transfer system **(Clinimix™ Dual Chamber Viaflex plastic container)** in the following range of concentrations:

Travasol Amino Acid Injections

PRODUCT CODE	WITH ELECTROLYTES LOWER CHAMBER (VOL/%)	DEXTROSE INJECTION USP UPPER CHAMBER (VOL/%)
JB6761	500 mL/10%	500 mL/50%
JB6763	500 mL/10%	500 mL/40%
JB6767	500 mL/10%	500 mL/20%
JB6771	500 mL 10%	500 mL/33.3%
JB6751	500 mL/8.5%	500 mL/50%
JB6753	500 mL/8.5%	500 mL/40%
JB6757	500 mL/8.5%	500 mL/20%
JB6759	500 mL/8.5%	500 mL/10%
JB6741	500 mL/5.5%	500 mL/50%
JB6749	500 mL/5.5%	500 mL/10%
JB6731	500 mL/5%	500 mL/50%
JB6737	500 mL/5%	500 mL/20%

Travasol Amino Acid Injection Blend B and Blend C without Electrolytes and Dextrose Injection are available in a closed transfer system **(Clinimix™ Dual Chamber Viaflex plastic container)** in the following range of concentrations:

Travasol Amino Acid Injection

PRODUCT CODE	WITHOUT ELECTROLYTES DEXTROSE INJECTION USP LOWER CHAMBER (VOL/%)	UPPER CHAMBER (VOL/%)
JB6760	500 mL/10%	500 mL/50%
JB6762	500 mL/10%	500 mL/40%
JB6766	500 mL/10%	500 mL/20%
JB6770	500 mL 10%	500 mL/33.3%
JB6756	500 mL/8.5%	500 mL/20%
JB6750	500 mL/8.5%	500 mL/50%
JB6752	500 mL/8.5%	500 mL/40%
JB6758	500 mL/8.5%	500 mL 10%
JB6768	500 mL/10%	500 mL 10%
JB6736	500 mL/5%	500 mL/20%

STABILITY AND STORAGE RECOMMENDATIONS

The dosage forms packaged in glass, Viaflex bags, and double-chamber Viaflex plastic containers, should be stored at temperatures between 15°C and 25°C protected from light and kept from freezing.

The prepared amino acids / dextrose admixture should be administered immediately. If not, it should be stored under refrigeration (2˚ - 8˚ C) and used within 24 hours.

Stability data is available to substantiate stability of 2.75% -5.0% amino acids and 5- 35% dextrose for 28 days at room temperature and 112 days when stored under refrigeration 2˚C to 8˚C if admixtures are prepared using validated aseptic techniques for preparation of i.v. solutions Ref: Baxter (USA) study Protocol number R09D81013. 2/5/1982, Final report: "Evaluation of the stability of amino acid dextrose (TNP) solutions…". …". Note- from a microbial point of view, admixed solutions be used within 24 hours when warmed to room temperature (15-25°C)

Product of
Baxter Corporation, Clintec Division
Toronto, Ontario, Canada