



Pediatric Parenteral Nutrition

Extensive portfolio of nutrition therapy for pediatric patients

Baxter



TRAVASOL (Amino Acid) Injections

TRAVASOL Injections for pediatric patients

- For patients \geq 1 year of age, adult amino acid formulations can be used.⁶
- TRAVASOL Injections is the source of amino acid in CLINIMIX Injections.

Essential Amino Acids*

Each 100 mL contains:	TRAVASOL Injections ⁷
Amino Acid Concentration	10%
Leucine	730 mg
Isoleucine	600 mg
Lysine (added as hydrochloride salt)	580 mg
Valine	580 mg
Histidine	480 mg
Phenylalanine	560 mg
Threonine	420 mg
Methionine	400 mg
Tryptophan	180 mg

*This product also contains nonessential amino acids. Please refer to enclosed prescribing information.



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 mOsm/L).

⁶ Forchielli ML, Miller SJ. The A.S.P.E.N. Nutrition Support Practice Manual. 2005:38-53.

⁷ TRAVASOL (Amino Acid) Injections package insert.

Indications

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.

Important Risk Information

- It is essential that a carefully prepared protocol based on current medical practices, be followed, preferably by an experienced team. Frequent clinical evaluation and laboratory determinations are necessary for proper monitoring during administration.
- TRAVASOL is contraindicated in patients with hypersensitivity to one or more amino acids, severe liver disease, hepatic coma, or anuria.
- TRAVASOL 10% is for compounding only, not for direct infusion.
- Proper administration 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, therefore conservative doses should be given to patients with known or suspected hepatic dysfunction. Hyperammonemia is of **special significance in infants**. It is essential that blood ammonia be measured frequently in infants.
- Administration of amino acid solutions in the presence of impaired renal function presents special issues associated with retention of electrolytes.
- Metabolic complications have been reported, such as acid-base, electrolyte, and blood glucose imbalances, elevated liver enzymes, osmotic diuresis and dehydration.
- This product contains aluminum that may be toxic with prolonged parenteral administration if kidney function is impaired.
- The infusion of any hypertonic solution into a peripheral vein may result in vein irritation, vein damage, and thrombosis. After mixing, strongly hypertonic nutrient solutions should only be administered through an indwelling intravenous catheter with the tip located in the superior vena cava.

Please see enclosed package inserts for complete prescribing information.

Baxter offers a broad Parenteral Nutrition (PN) portfolio for pediatric patients which include products that are:

Low in aluminum

Levels of aluminum marked on products for easy monitoring.

Sulfite-free

For those patients with sulfite sensitivities.

Non-Latex

To eliminate the concerns for latex allergic reactions.



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Please see enclosed package inserts for complete prescribing information.



INFUVITE PEDIatric Multiple Vitamins for Infusion

Infants and neonates are vulnerable to aluminum toxicity

- The safe limit of aluminum in PN has been set at 5 mcg/kg/day.⁸
- INFUVITE PEDIatric Multiple Vitamins for Infusion has the lowest aluminum content in the market.
 - Not more than 30 mcg/L for INFUVITE PEDIatric.
- INFUVITE PEDIatric Multiple Vitamins liquid injectible vs. powder formulations:
 - Requires fewer admixture steps.
 - Helps minimize contamination risks.
- The only preservative-free option available.
- Baxter offers the only Pharmacy Bulk-Package INFUVITE PEDIatric Multiple Vitamin.



⁸ Kumpf VJ, Mirtallo JM, Petersen C. The A.S.P.E.N. Nutrition Support Practice Manual. 2005:97-107.

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Indications

- INFUVITE Multiple Vitamins for Infusion are for intravenous infusion after dilution only.
- INFUVITE PEDIatric Multiple Vitamins for Infusion are indicated as a daily multivitamin maintenance dosage for infants and children up to 11 years of age receiving parenteral nutrition.

Important Risk Information

- INFUVITE Multiple Vitamins for Infusion are contraindicated where there is a pre-existing hypervitaminosis or known hypersensitivity to any of the vitamins or excipients in the product.
- Allergic reactions have been known to occur following intravenous administration of thiamine and vitamin K. The formulation is contraindicated prior to blood sampling for detection of megaloblastic anemia.

- **Caution should be exercised when administering INFUVITE Multiple Vitamins for Infusion to patients on warfarin sodium-type anticoagulation therapy. Periodic monitoring of prothrombin time/INR response is essential in determining the appropriate dosage of anticoagulant therapy.**
- If this formulation is the only source of vitamins for a long period of time, blood concentrations of each of the vitamins should be monitored, particularly vitamins A, C, D, and folic acid, to determine if deficiencies are occurring.
- There have been rare reports of anaphylactoid reactions following parenteral multivitamin administration. Rare reports of anaphylactoid reactions have also been reported following large intravenous doses of thiamine. However, the risk is negligible if thiamine is coadministered with other vitamins in the B group.
- INFUVITE Multiple Vitamins for Infusion contain aluminum that may be toxic.

Please see enclosed package inserts for complete prescribing information.

Supporting Pediatric Parenteral Nutrition

Baxter Healthcare Corporation has 75-plus years in developing Parenteral Nutrition solutions that work together to improve patient outcomes. Baxter offers clinicians and patients the broadest portfolio of Parenteral Nutrition in the industry and includes our innovative commercially manufactured multi-chamber bag of Parenteral Nutrition formulations. Baxter also offers Multiple Vitamins for infusion; IV fat emulsion for infusion and automated compounding equipment and software. Parenteral Nutrition Solutions from Baxter efficiently help you meet the nutritional goals of your patients.

Learn more about CLINIMIX Injections:

Clinimix.com • 888-229-0001 • Contact your Baxter representative



Medication Delivery

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TrophAmine is a trademark of B. Braun Medical, Inc.

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PREMASOL sulfite-free (Amino Acid) Injections

PREMASOL Injections for neonate patients or those pediatric patients who require a specialized amino acid

Equivalent essential amino acid profile to TROPHAMINE (6% and 10% Amino Acid Injections) but without sulfites.



Essential Amino Acids*

Each 100 mL contains:	PREMASOL Injections ⁴		TROPHAMINE Injections ⁵	
	6%	10%	6%	10%
Amino Acid Concentration				
Leucine	0.84 g	1.4 g	0.84 g	1.4 g
Isoleucine	0.49 g	0.82 g	0.49 g	0.82 g
Lysine (added as Lysine Acetate)	0.49 g	0.82 g	0.49 g	0.82 g
Valine	0.47 g	0.78 g	0.47 g	0.78 g
Histidine	0.29 g	0.48 g	0.29 g	0.48 g
Phenylalanine	0.29 g	0.48 g	0.29 g	0.48 g
Threonine	0.25 g	0.42 g	0.25 g	0.42 g
Methionine	0.20 g	0.34 g	0.20 g	0.34 g
Tyrosine (added as Tyrosine and N-Acetyl-L-Tyrosine)	0.14 g	0.24 g	0.14 g	0.24 g
Tryptophan	0.12 g	0.20 g	0.12 g	0.20 g
Cysteine	<0.014 g	<0.016 g	<0.014 g	<0.016 g

*This product also contains nonessential amino acids. Please refer to enclosed prescribing information.

⁴PREMASOL sulfite-free (Amino Acid) Injections package insert.

⁵TrophAmine® (Amino Acid Injections) package insert.

Indications and Usage

6% and 10% PREMASOL sulfite-free (Amino Acid) Injections are indicated for the nutritional support of infants (including those of low birth weight) and young children requiring TPN via either central or peripheral infusion routes. Parenteral nutrition with PREMASOL sulfite-free (Amino Acid) Injections is indicated to prevent nitrogen and weight loss or treat negative nitrogen balance in infants and young children where: (1) the alimentary tract, by the oral, gastrostomy, or jejunostomy route, cannot or should not be used, or adequate protein intake is not feasible by these routes; (2) gastrointestinal absorption of protein is impaired; or (3) protein requirements are substantially increased as with extensive burns. Dosage, route of administration, and concomitant infusion of nonprotein calories are dependent on various factors, such as nutritional and metabolic status of the patient, anticipated duration of parenteral nutritional support, and vein tolerance. See **Dosage and Administration** section of Prescribing Information for additional information.

Contraindications

PREMASOL sulfite-free (Amino Acid) Injections are contraindicated in patients with untreated anuria, hepatic coma, inborn errors of amino acid metabolism, including those involving branched chain amino acid metabolism such as maple syrup urine disease and isovaleric-acidemia, or hypersensitivity to one or more amino acids present in the solution.

Warnings

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

Safe, effective use of parenteral nutrition requires a knowledge of nutrition as well as clinical expertise in recognition and treatment of the complications which can occur.

Frequent evaluation and laboratory determinations are necessary for proper monitoring of parenteral nutrition.

Precautions

It is essential that a carefully prepared protocol, based on current medical practices, be followed, preferably by an experienced team.

Please see enclosed package inserts for complete prescribing information.



Baxter PN solutions align with A.S.P.E.N. recommendations.

A.S.P.E.N. suggests:

- Prescribing adult formulas of amino acid for patients ≥ 1 year of age.¹
- Obtaining products with the lowest aluminum contamination.²

Joint Commission urges using a manufacturer prepared product whenever possible.³

¹ Forchielli ML, Miller SJ. The A.S.P.E.N. Nutrition Support Practice Manual. 2005:38-53.

² Koo WWk, McLaughlin K, Saba M. The A.S.P.E.N. Nutrition Support Practice Manual. 2005:301-314.

³ http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_39.htm?print=yes



CLINIMIX & CLINIMIX E Injections

Innovative Multi-Chamber Bag Technology

- Multi-chamber bag (MCB) technology may reduce the risk of prescription and transcription errors versus compounding.
- May help reduce the potential of contamination during preparation.
- Immediately available to support early feed practices.
- Appropriate source of amino acids and dextrose for pediatric patients.

Pediatric Use

- Use of CLINIMIX and CLINIMIX E sulfite-free Injections 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.
- Solution administration by peripheral vein should not exceed twice normal serum osmolality (718 mOsm/L).

Pediatric Precautions

- Dextrose is safe and effective for the above indications in pediatric patients.
 - As reported in the literature, the dosage selection and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low birth weight infants, because of increased risk of hyperglycemia/hypoglycemia.
 - Frequent monitoring of serum glucose concentrations is required in these patient populations.
- Safety and effectiveness of CLINIMIX and CLINIMIX E Injections in pediatric patients have not been established by adequate and well-controlled studies.
 - However, use of amino acid injections in pediatric patients to help offset nitrogen loss or treat negative nitrogen balance is referenced in the medical literature.




CLINIMIX
sulfite-free (Amino Acid in Dextrose) Injections


CLINIMIX E
sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections

Nourish the Outcome

Indications

CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections and CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections are indicated as a caloric component in a parenteral nutrition regimen and as the protein (nitrogen) source for offsetting nitrogen loss or for 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.

Important Risk Information

- It is essential that a carefully prepared protocol based on current medical practices be followed, preferably by an experienced team. Frequent clinical evaluation and laboratory determinations are necessary for proper monitoring during administration.
- CLINIMIX and CLINIMIX E Injections are contraindicated in patients having intracranial or intraspinal hemorrhage, in patients who are severely dehydrated, in patients hypersensitive to one or more amino acids and in patients with severe liver disease or hepatic coma. Solutions containing corn-derived dextrose may be contraindicated in patients with known allergy to corn or corn products.

- Because of the potential for life-threatening events, caution should be taken to ensure that precipitates have not formed in any parenteral nutrient admixture.
- Use with caution when administering to patients with anuria or renal insufficiency, pulmonary insufficiency, or heart disease. The intravenous administration of these solutions can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema.
- Metabolic complications have been reported, such as acid-base, electrolyte, and blood glucose imbalances, elevated liver enzymes, and osmotic diuresis and dehydration.
- Other adverse reactions that may occur include febrile response, infection at the site of injection, extravasation, and hypervolemia. The infusion of hypertonic nutrient injections into a peripheral vein may result in vein irritation, vein damage, and thrombosis.
- This product contains aluminum that may be toxic with prolonged parenteral administration if kidney function is impaired.
- CLINIMIX and CLINIMIX E Injections **must be admixed** prior to infusion.

Please see enclosed package inserts for complete prescribing information.

Nourish the Outcome

CLINIMIX Injections

NDC Number	Baxter Code	Product Description	Size	AmeriSource Bergen	Cardinal	McKesson	Morris Dickson
00338113203	2B7725	CLINIMIX Inj. 2.75/5	1L	783783	3476421	1391325	546689
00338113303	2B7726	CLINIMIX Inj. 4.25/5	1L	783807	3476439	1393024	725267
00338108904	2B7704	CLINIMIX Inj. 4.25/5	2L	277319	2989150	1182369	764191
00338113403	2B7727	CLINIMIX Inj. 4.25/10	1L	702062	3449444	1115013	729459
00338109104	2B7705	CLINIMIX Inj. 4.25/10	2L	277269	2989176	1916162	862094
00338113503	2B7728	CLINIMIX Inj. 4.25/20	1L	783790	3483583	1395367	848200
00338109304	2B7706	CLINIMIX Inj. 4.25/20	2L	279208	2989184	1182716	752600
00338113603	2B7729	CLINIMIX Inj. 4.25/25	1L	702074	3444544	1114990	509950
00338109504	2B7707	CLINIMIX Inj. 4.25/25	2L	015917	2989192	1916196	509885
00338113703	2B7730	CLINIMIX Inj. 5/15	1L	783819	3483591	1397165	N/A
00338109904	2B7709	CLINIMIX Inj. 5/15	2L	278960	2989200	1183284	N/A
00338113803	2B7731	CLINIMIX Inj. 5/20	1L	783821	3483690	1329176	N/A
00338110104	2B7710	CLINIMIX Inj. 5/20	2L	278820	2989218	1183557	349852
00338113903	2B7732	CLINIMIX Inj. 5/25	1L	783833	3483708	1398890	N/A
00338110304	2B7711	CLINIMIX Inj. 5/25	2L	278788	2989226	1167253	674481

CLINIMIX E Injections

NDC Number	Baxter Code	Product Description	Size	AmeriSource Bergen	Cardinal	McKesson	Morris Dickson
00338114203	2B7735	CLINIMIX E Inj. 2.75/5	1L	702086	3450327	1401363	469668
00338110704	2B7713	CLINIMIX E Inj. 2.75/5	2L	012070	2989259	1181312	N/A
00338114303	2B7736	CLINIMIX E Inj. 2.75/10	1L	783865	3476447	1403419	N/A
00338110904	2B7714	CLINIMIX E Inj. 2.75/10	2L	012088	2989267	1180561	555656
00338114403	2B7737	CLINIMIX E Inj. 4.25/5	1L	702098	3444569	1114875	508234
00338111304	2B7716	CLINIMIX E Inj. 4.25/5	2L	278465	2989283	1174150	349845
00338114503	2B7738	CLINIMIX E Inj. 4.25/10	1L	702105	3450335	1114933	N/A
00338111504	2B7717	CLINIMIX E Inj. 4.25/10	2L	011437	2989291	1176726	449629
00338114603	2B7739	CLINIMIX E Inj. 4.25/25	1L	702112	3444585	1114958	469569
00338111904	2B7719	CLINIMIX E Inj. 4.25/25	2L	011452	2989325	1177591	N/A
00338114703	2B7740	CLINIMIX E Inj. 5/15	1L	783840	3483716	1406354	N/A
00338112304	2B7721	CLINIMIX E Inj. 5/15	2L	278218	2989333	1178581	N/A
00338114803	2B7741	CLINIMIX E Inj. 5/20	1L	783858	3476462	1410299	N/A
00338112504	2B7722	CLINIMIX E Inj. 5/20	2L	358770	2989358	1179175	N/A
00338114903	2B7742	CLINIMIX E Inj. 5/25	1L	771194	3483724	1413194	N/A
00338112704	2B7723	CLINIMIX E Inj. 5/25	2L	268417	2989366	1180033	N/A

TRAVASOL (Amino Acid) Injection

NDC Number	Baxter Code	Product Description	Size	AmeriSource Bergen	Cardinal	McKesson	Morris Dickson
00338064403	1B6623	10% TRAVASOL Inj.	500 mL	345389	2198679	1141613	382291
00338064404	1B6624	10% TRAVASOL Inj.	1000 mL	433979	2198653	1142157	180679
00338064406	1B6626P	10% TRAVASOL Inj.	2000 mL	020669	2733335	1785179	845685

INFUVITE PEDiatric Multiple Vitamins for Infusion

NDC Number	Baxter Code	Product Description	AmeriSource Bergen	Cardinal	McKesson	Morris Dickson
5464356461	2A9008	PEDiatric Single Dose (Box of 5 doses)	079297	3254760	2705234	401133
5464356470	2A9061	PEDiatric Pharmacy Bulk Package (Box of 10 doses)	974992	3561412	2136554	527176

PREMASOL sulfite-free (Amino Acid) Injections

NDC Number	Baxter Code	Product Description	Size	AmeriSource Bergen	Cardinal	McKesson	Morris Dickson
00338113103	2B0011	6% PREMASOL Inj.	500 mL	845952	3501558	1994227	499244
00338113003	2B0012	10% PREMASOL Inj.	500 mL	984447	3695293	1345172	638783
00338113004	2B0009	10% PREMASOL Inj.	1000 mL	845964	3501566	1994177	499285
00338113006	2B0010	10% PREMASOL Inj.	2000 mL	845976	3501574	1994193	499293



Medication Delivery