

have specific questions based on their PN admixtures, the Fresenius Kabi Medical Information department can provide them with the information on the specific admixtures tested.

- Consult Fresenius Kabi for further information on complete and balanced intravenous nutrition regimens.

Product Comparison Table

Product Name	U.S. FDA-Approved Product (Infuvite Adult)¹	Imported Product (Vitalipid N Adult)^{2,3}	U.S. FDA-Approved Product (Infuvite Pediatric)⁴	Imported Product (Vitalipid N Infant)^{5,6}
Manufacturer	Baxter	Fresenius Kabi	Baxter	Fresenius Kabi
Multivitamins & active ingredient salt forms present	13 vitamins present (water and fat soluble) These include: Thiamine (Vitamin B ₁) Riboflavin (Vitamin B ₂) Niacinamide (Vitamin B ₃) Dexpanthenol (Vitamin B ₅) Pyridoxine HCl (Vitamin B ₆) Biotin Folate Cyanocobalamin (Vitamin B ₁₂) Ascorbic acid (Vitamin C) Vitamin A (as palmitate) cholecalciferol (Vitamin D ₃) dl-Alpha-tocopherol acetate (Vitamin E) Vitamin K ₁	Only fat-soluble vitamins These include: Retinol palmitate (vitamin A) Ergocalciferol (Vitamin D ₂) All-rac-Alpha-tocopherol (Vitamin E) Phytomenadione (Vitamin K ₁)	13 vitamins present (water and fat soluble) These include: Thiamine (vitamin B1) Riboflavin (vitamin B2) Niacinamide (vitamin B3) Dexpanthenol (vitamin B5) Pyridoxine (vitamin B6) Biotin (B7) Folate (B9) Cyanocobalamin (B12) Ascorbic acid (Vitamin C) Vitamin A (as palmitate) cholecalciferol (Vitamin D ₃) dl-Alpha-tocopherol acetate (Vitamin E) Vitamin K ₁	Only fat-soluble vitamins These include: Retinol palmitate (vitamin A) Ergocalciferol (Vitamin D ₂) All-rac-Alpha-tocopherol (Vitamin E) Phytomenadione (Vitamin K ₁)
Differences in the amount of vitamins present in each 1 mL	Ascorbic acid: 20 mg Vitamin A: 330 IU Vitamin D ₃ : 20 IU Thiamine (vitamin B ₁): 0.6 mg Riboflavin (Vitamin B ₂): 0.36 mg Pyridoxine (vitamin B ₆): 0.6 mg Niacinamide: 4 mg Dexpanthenol: 1.5 mg Vitamin E: 1 IU Vitamin K ₁ : 15 mcg Folic Acid: 60 mcg Biotin: 6 mcg	Ascorbic acid: 0 Vitamin A: 330 IU Vitamin D ₂ : 20 IU Thiamine: 0 Riboflavin: 0 Pyridoxine: 0 Niacinamide: 0 Dexpanthenol: 0 Vitamin E: 1 IU Vitamin K ₁ : 15 mcg Folic Acid: 0 Biotin: 0	Ascorbic acid: 16 mg Vitamin A: 460 IU Vitamin D ₃ : 80 IU Thiamine: 0.24 mg Riboflavin: 0.28 mg Pyridoxine: 0.2 mg Niacinamide: 3.4 mg Dexpanthenol: 1 mg Vitamin E: 1.4 IU Vitamin K ₁ : 40 mcg Folic Acid: 28 mcg Biotin: 4 mcg	Ascorbic acid: 0 Vitamin A: 230 IU Vitamin D ₂ : 40 IU Thiamine: 0 Riboflavin: 0 Pyridoxine: 0 Niacinamide: 0 Dexpanthenol: 0 Vitamin E: 0.7 IU Vitamin K ₁ : 20 mcg Folic Acid: 0 Biotin: 0

Product Name	U.S. FDA-Approved Product (Infuvite Adult)¹	Imported Product (Vitalipid N Adult)^{2,3}	U.S. FDA-Approved Product (Infuvite Pediatric)⁴	Imported Product (Vitalipid N Infant)^{5,6}
	Vitamin B ₁₂ : 0.5 mcg	Vitamin B ₁₂ : 0	Vitamin B ₁₂ : 0.2 mcg	Vitamin B ₁₂ : 0
Package & Container Size	Single dose Vial 1: 5 mL, Vial 2: 5 mL Pharmacy Bulk: Vial 1 – 50 mL, Vial 2 – 50 mL	10 mL glass ampule, concentrated emulsion for injection	Single dose: Vial 1: 5 mL, Vial 2: 5 mL Pharmacy Bulk: Vial 1 (40 mL Fill in 50 mL Vial) and Vial 2 (10 mL).	10 mL glass ampule, concentrated emulsion for injection
Storage	Minimize exposure of INFUVITE ADULT to light because vitamins A, D and riboflavin are light sensitive. Store under refrigeration, 2-8°C (36-46°F).	Between 2-25°C (36-77°F). Protect from light. Do not freeze	Minimize exposure of INFUVITE PEDIATRIC to light because vitamins A, D and riboflavin are light sensitive. Store under refrigeration 2-8°C (36-46°F).	Between 2- 25°C (36-77°F). Protect from light. Do not freeze
Shelf Life	Not reported	24 months	Not reported	24 months
Excipients	Vial 1: polysorbate 80, sodium hydroxide and/or hydrochloric acid for pH adjustment, water for injection Vial 2: Propylene glycol, citric acid ± sodium citrate for pH, water for injection	Soya oil Egg lecithin Glycerol SWFI NaOH for pH	polysorbate 80, sodium hydroxide and/or hydrochloric acid for pH adjustment, and water for injection. Vial 2: mannitol, citric acid and/or sodium citrate for pH adjustment and water for injection.	Soya oil Egg lecithin Glycerol SWFI NaOH for pH
Aluminum	≤ 70 mcg/L (vials 1+2)	Not reported	≤ 30 mcg/L (Vials 1 + 2).	Not reported
Indication	For prevention of vitamin deficiency in adults and children aged 11 and older receiving parenteral nutrition	Indicated in adult patients and children from 11 years of age as a supplement in intravenous nutrition to meet the daily requirements of the fat-soluble vitamins A, D ₂ , E and K ₁ .	For the prevention of vitamin deficiency in pediatric patients up to 11 years of age receiving parenteral nutrition	Indicated in infants and children up to 11 years of age as a supplement in intravenous nutrition to meet the daily requirements of the fat-soluble vitamins A, D ₂ , E and K ₁ .
Dose	10 mL	10 mL	<1 kg: 1.5 mL 1 to <3 kg: 3.25 mL ≥3 kg: 5 mL	Preterm and infants below 2.5 kg: 4 mL/kg/d Infants and children >2.5 kg and up to 11 years: 10 mL/d


Product Name	U.S. FDA-Approved Product (Infuvite Adult)¹	Imported Product (Vitalipid N Adult)^{2,3}	U.S. FDA-Approved Product (Infuvite Pediatric)⁴	Imported Product (Vitalipid N Infant)^{5,6}
Contraindications	An existing hypervitaminosis, or A history of hypersensitivity due to any vitamins or excipients contained in this formulation.	Egg, soy, peanut allergy, hypersensitivity to ingredient/excipient	An existing hypervitaminosis, or A history of hypersensitivity to any vitamins or excipients contained in this formulation.	Egg, soy, peanut allergy, hypersensitivity to ingredient/excipient


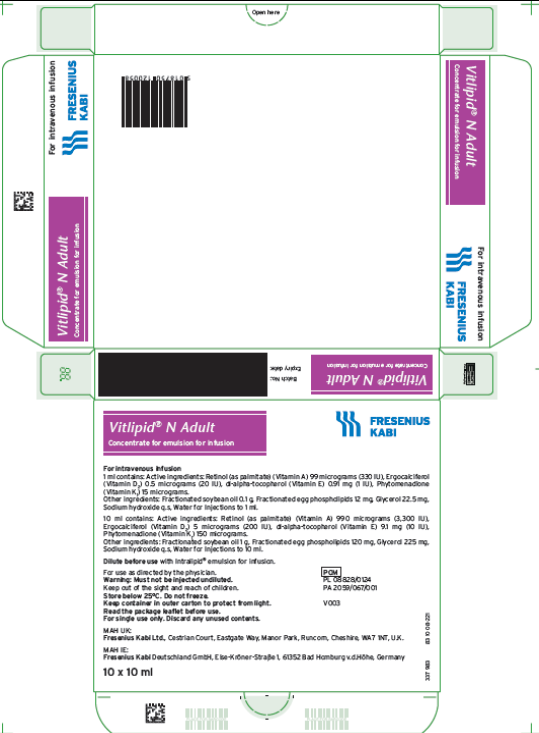
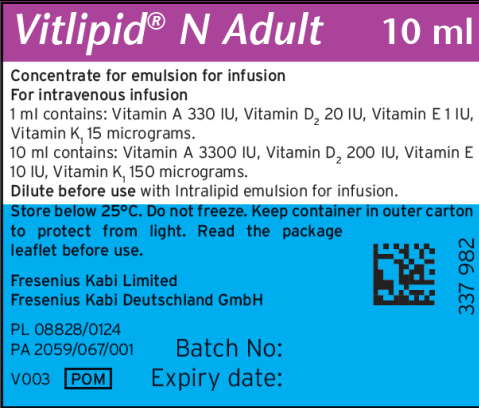



The following 2 tables compare the content of Infuvite, Vitalipid N and ASPEN Vitamin Recommendations for adult and pediatric patients.

Daily Adult ASPEN Guideline Recommendations for Multivitamins and amount in Vitalipid N Adult and Infuvite Adult Products

	Adult: Guideline Recommendations⁷	Vitalipid N Adult^{2,3} (10 mL dose)	Infuvite Adult¹ (10 mL dose)
Thiamine (B₁)	6 mg		6 mg
Riboflavin (B₂)	3.6 mg		3.6 mg
Niacin (B₃)	40 mg		40 mg
Pantothenic Acid (B₅)	5 mg		15 mg
Pyridoxine (B₆)	6 mg		6 mg
Biotin	60 mcg		60 mcg
Folate	600 mcg		600 mcg
Cyanocobalamin (B₁₂)	5 mcg		5 mcg
Vitamin C (ascorbic acid)	200 mg		200 mg
Vitamin A	990 mcg (3300 IU)	990 mcg (3300 IU)	3300 IU (1 mg)
Vitamin D	5 mcg (200 IU)	5 mcg (200 IU)	200 IU (5 mcg)
Vitamin E	10 mg (10 IU)	9.1 mg (10 IU)	10 IU (10 mg)
Vitamin K	150 mcg	150 mcg	150 mcg

Vitalipid N and Vitlipid N, Infuvite Pediatric and Infuvite Adult Product Labels

Product	Shipper label	Box Label	Ampule/Vial label	Ampule/Vial picture
<p>Vitalipid N Infant</p>	<p>40 x 10 x 10 ml</p> <p>Vitalipid™ N Infant Concentrate for solution for infusion, emulsion</p> <p>Warning: Must not be injected undiluted. Store below 25 °C. Do not freeze. Protect from light.</p> <p>Fresenius Kabi AB, Uppsala, Sweden</p> <p>300000000</p> <p>Batch No: 10XX1234 Manuf. date: 02/2010 Use before: 01/2012</p> <p>FRESENIUS KABI</p>	<p>Open here</p> <p>Vitalipid™ N Infant Concentrate for solution for infusion</p> <p>FRESENIUS KABI</p> <p>Vitalipid™ N Infant Concentrate for solution for infusion</p> <p>FRESENIUS KABI</p> <p>Vitalipid™ N Infant Concentrate for solution for infusion</p> <p>1 ml contains: Vitamin A 230 IU, Vitamin D₂ 40 IU, Vitamin E 0.7 IU, Vitamin K₁ 20 µg, Purified soybean oil 100 mg, Purified egg phospholipids 12 mg, Glycerol amprouse 220 mg, Water for injection to 1 ml.</p> <p>Additive to infusion fluids after dissolution.</p> <p>Read the package leaflet before use.</p> <p>Warning: Must not be injected undiluted Store below 25 °C. Protect from light. Do not freeze.</p> <p>Keep out of reach of children. Additions should be made aseptically.</p> <p>Fresenius Kabi AB, 751 74 Uppsala, Sweden</p> <p>10 x 10 ml</p>	<p>Vitalipid™ N Infant 10 ml</p> <p>Concentrate for solution for infusion, emulsion</p> <p>1 ml contains: Vitamin A 230 IU, Vitamin D₂ 40 IU, Vitamin E 0.7 IU, Vitamin K₁ 20 µg. Additive to infusion fluids after dissolution. See package insert.</p> <p>Warning: Must not be injected undiluted. Store below 25 °C. Protect from light. Do not freeze.</p> <p>Fresenius Kabi AB, Uppsala, Sweden</p> <p>Batch no: Manuf. date: Use before:</p> <p>336 503</p>	 <p>Vitalipid™ N Infant Concentrate for solution for infusion, emulsion</p> <p>1 ml contains: Vitamin A 230 IU, Vitamin D₂ 40 IU, Vitamin E 0.7 IU, Vitamin K₁ 20 µg. Additive to infusion fluids after dissolution. Warning: Must not be injected undiluted. Store below 25 °C. Protect from light. Fresenius Kabi AB, Uppsala, Sweden Batch no: Manuf. date: Use before:</p>

Product	Shipper label	Box Label	Ampule/Vial label	Ampule/Vial picture
Vitlipid N Adult	 <p>Vitlipid® N Adult Concentrate for emulsion for infusion</p> <p>Store below 25°C. Do not freeze. Keep container in outer carton to protect from light. Read the package leaflet before use.</p> <p>PL 08828/0124 PA2059/067/001</p> <p>Fresenius Kabi Ltd., Cedrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, U.K. Fresenius Kabi Deutschland GmbH, Elise-Köhner-Straße 1, 61352 Bad Homburg v.d.Höhe, Germany</p> <p>V004 Batch no: 100X1234 Expiry date: 01/2012</p>	 <p>Vitlipid® N Adult Concentrate for emulsion for infusion</p> <p>Vitlipid® N Adult Concentrate for emulsion for infusion</p> <p>Vitlipid® N Adult Concentrate for emulsion for infusion</p> <p>For intravenous infusion 1 ml contains: Active ingredients: Retinol (as palmitate) (Vitamin A) 99 micrograms (200 IU), Ergocaliferol (Vitamin D₂) 0.5 micrograms (20 IU), alpha-tocopherol (Vitamin E) 0.9 mg (6 IU), Phylloquinone (Vitamin K₁) 15 micrograms. Other ingredients: Fractionated soybean oil 1 g, Fractionated egg phospholipids 12 mg, Glycerol 22.5 mg, Sodium hydroxide q.s. Water for injections to 1 ml.</p> <p>10 ml contains: Active ingredients: Retinol (as palmitate) (Vitamin A) 990 micrograms (2,000 IU), Ergocaliferol (Vitamin D₂) 5 micrograms (200 IU), alpha-tocopherol (Vitamin E) 9 mg (60 IU), Phylloquinone (Vitamin K₁) 150 micrograms. Other ingredients: Fractionated soybean oil 1 g, Fractionated egg phospholipids 120 mg, Glycerol 225 mg, Sodium hydroxide q.s. Water for injections to 10 ml.</p> <p>Dilute before use with Intralipid® emulsion for infusion.</p> <p>For use as directed by the physician. Warnings: Must not be injected undiluted. Keep out of the sight and reach of children. Store below 25°C. Do not freeze. Keep container in outer carton to protect from light. Read the package leaflet before use. For single use only. Discard any unused contents.</p> <p>MAH UK: Fresenius Kabi Ltd., Cedrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, U.K. MAH DE: Fresenius Kabi Deutschland GmbH, Elise-Köhner-Straße 1, 61352 Bad Homburg v.d.Höhe, Germany</p> <p>10 x 10 ml</p>	 <p>Vitlipid® N Adult 10 ml</p> <p>Concentrate for emulsion for infusion For intravenous infusion 1 ml contains: Vitamin A 330 IU, Vitamin D₂ 20 IU, Vitamin E 1 IU, Vitamin K₁ 15 micrograms. 10 ml contains: Vitamin A 3300 IU, Vitamin D₂ 200 IU, Vitamin E 10 IU, Vitamin K₁ 150 micrograms. Dilute before use with Intralipid emulsion for infusion.</p> <p>Store below 25°C. Do not freeze. Keep container in outer carton to protect from light. Read the package leaflet before use.</p> <p>Fresenius Kabi Limited Fresenius Kabi Deutschland GmbH</p> <p>PL 08828/0124 PA 2059/067/001 Batch No: V003 POM Expiry date:</p>	<p>Not available</p>
Infuvite Adult (Baxter Healthcare)	<p>Not available</p>	 <p>2A9018 Baxter INFUVITE® ADULT Multiple Vitamins Injection For intravenous infusion after dilution only. Sterile Contains 5 each of Vial 1 (5 mL) and Vial 2 (5 mL) One vial of each to be used for a single dose. Store under refrigeration, 2-8°C (36-46°F).</p>		

References:

1. Infuvite Adult. Prescribing Information. Baxter Healthcare Corporation. Deerfield IL. October 2016.
2. Vitalipid N Adult Summary of Product Characteristics. Fresenius Kabi 2008
3. Vitalipid N Adult Prescribing Information, Fresenius Kabi AB. Uppsala, Sweden
4. Infuvite Pediatric. Prescribing Information. Baxter Healthcare Corporation. Deerfield IL. October 2016.
5. Vitalipid N Infant Prescribing Information, Fresenius Kabi AB. Uppsala, Sweden
6. Vitalipid N Infant Summary of Product Characteristics. Fresenius Kabi 2008
7. Vanek VW, Borum P, Buchman A, et al. A.S.P.E.N. Position Paper: Recommendations for changes in commercially available parenteral multivitamin and multi-trace element products. *Nutr Clin Pract.* 2012;27(4):440-491.