VITALIPID N- vitamin a palmitate, ergocalciferol, .alpha.-tocopherol, dl-, phytonadione emulsion
Fresenius Kabi USA, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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September 1, 2023

IMPORTANT PRESCRIBING INFORMATION

Subject:	Temporary importation of Vitalipid N ADULT and Vitalipid N INFANT to address drug shortage. The product is also labeled as Vitlipid N ADULT and Vitlipid N INFANT.

Dear Healthcare Professional,

Due to the critical shortage of parenteral multivitamins in the U.S. market, Fresenius Kabi USA, LLC (Fresenius Kabi USA) is coordinating with the U.S. Food and Drug Administration (FDA) to provide an alternative treatment option during this time. Fresenius Kabi USA has initiated temporary importation of Vitalipid Injection 10 mL Single Dose Glass Ampule into the U.S. market. The products imported into the U.S. may also be labeled with a slight variation of the proprietary name, Vitlipid N ADULT and Vitlipid N INFANT, depending on which country the product was originally intended. Other than the slight variation in the proprietary name, the products are identical, and the products will be referred to as Vitalipid N ADULT and Vitalipid N INFANT for the remainder of this letter. Vitalipid N ADULT and Vitalipid N INFANT are sterile oil-in-water emulsions containing fat-soluble vitamins in the oil phase. This product is marketed in Europe and is manufactured in the Fresenius Kabi Uppsala, Sweden plant.

At this time, no other entity except Fresenius Kabi USA is authorized by the FDA to import or distribute Vitalipid Injection 10 mL Single Dose Glass Ampules (One Point Cut) in the U.S. The FDA has not approved Fresenius Kabi's Vitalipid product for marketing in the United States.

This communication and product information is available on the Fresenius Kabi USA web site http://products.fresenius-kabi.us/product-323.html as well as on the FDA Drug Shortage web site. http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm.

IMPORTANT DRUG INFORMATION

It is important to note the following **key differences** between the Vitalipid and Infuvite:

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
Indication	For prevention	Indicated in adult	For the	Indicated in infants

	of vitamin deficiency in adults and children aged 11 and older receiving parenteral nutrition	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.	prevention of vitamin deficiency in pediatric patients up to 11 years of age receiving parenteral nutrition	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.
Product ingredients present	13 vitamins present (water and fat soluble)	Only 4 fat-soluble vitamins	13 vitamins present (water and fat soluble)	Only 4 fat-soluble vitamins
Contraindications	Existing hypervitaminosis or history of hypersensitivity due to any vitamins or excipients contained in the formulation	Egg, soy, peanut allergy, hypersensitivity to ingredient/excipient	Existing hypervitaminosis or history of hypersensitivity due to any vitamins or excipients contained in the formulation	Egg, soy, peanut allergy, hypersensitivity to ingredient/excipient
Storage	Minimize exposure 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 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
Bar code/NDC	54643-5649-1	NDC (Finished Product): 6521933381; 6521933582 NDC (Unit of Use): 6521933310; 6521933510	54643-5646-1	NDC (Finished Product): 6521933762; 6521933964 NDC (Unit of Use): 6521933710; 6521933910

- Vitalipid is packaged in glass ampules, so filter needles must always be used in conjunction with a regular (nonfilter) needle during compounding to reduce the risk of introducing glass particles during administration
- Vitalipid provides fat-soluble vitamins (A, D, E, K) only; Infuvite contains fat-soluble vitamins as well as 9 water-soluble vitamins (see Product Comparison Table below)
- Vitalipid N ADULT and INFANT are contraindicated in patients with known hypersensitivity to any of the components (i.e., egg, soy, peanut protein, or any active substance or excipient)
- Any barcodes on the Vitalipid N ADULT or Vitalipid N INFANT products will not be appropriately recognized by scanning systems used in the United States and should NOT be used. 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 prepared and administered to individual patients.
- Vitalipid N ADULT and Vitalipid N INFANT are available only by prescription in the U.S.

However, the imported lots do not have the statement “Rx only” on their labeling.

Effective immediately, and during this temporary period, Fresenius Kabi USA will offer the following presentation of adult and pediatric multivitamins:

Product Description

Vitalipid/Vitlipid N ADULT 10 mL[2,3]		
Description	Concentrated Emulsion for Injection	
Dosage Form:	10 mL Single Dose Glass Ampule	
Package size	Box contains 10 units of 10 mL	
Finished Product NDC	6521933582	
Unit of Use NDC	6521933510	
Lot Numbers/(Expiration Date)	10SC1307/(2025.02.28); 10SD2190 (2025.03.31)	
Vitamin	**Active Ingredients (per 1 mL)**	**Active Ingredients (per 10 mL)**
Retinol palmitate (Vitamin A)	**99 mcg (330 IU)**	**990 mcg (3300 IU)**
Ergocalciferol (Vitamin D_2)	**0.5 mcg (20 IU)**	**5 mcg (200 IU)**
All-rac-alpha-tocopherol (Vitamin E)	**0.91 mg (1IU)**	**9.1 mg (10 IU)**
Phytomenadione (Vitamin K_1)	**15 mcg**	**150 mcg**
	Excipients (per 1 mL)	**Excipients (per 10 mL)**
Purified egg phospholipids	**12 mg**	**120 mg**
Glycerol anhydrous	**22 mg**	**220 mg**
Purified soybean oil	**100 mg**	**1000 mg**
Sodium hydroxide	**N/A**	**To pH 8**
Water for injection	**N/A**	**To 1 mL**

Vitalipid/Vitlipid N INFANT 10 mL[5,6]		
Description	Concentrated Emulsion for Injection	
Dosage Form:	Single Dose Glass Ampule	
Package Size:	Box contains 10 units of 10 mL	
Finished Product NDC:	6521933762; 6521933964	
Unit of Use NDC:	6521933710; 6521933910	
Lot Numbers/(Expiration Date)	10SB9030/(2025.01.31); 10SB9028/(2025.03.31)	
Vitamin	**Active Ingredients (per 1 mL)**	**Active Ingredients (per 10 mL)**
Retinol palmitate (Vitamin A)	**69 mcg (230 IU)**	**690 mcg (2300 IU)**
Ergocalciferol (Vitamin D_2)	**1 mcg (40 IU)**	**10 mcg (400 IU)**
All-rac-alpha-tocopherol (Vitamin E)	**0.64 mg (0.7 IU)**	**6.4 mg (7 IU)**
Phytomenadione (Vitamin K_1)	**20 mcg**	**200 mcg**
	Excipients (per 1 mL)	**Excipients (per 10 mL)**
Purified egg phospholipids	**12 mg**	**120 mg**
Glycerol anhydrous	**22 mg**	**220 mg**
Purified soybean oil	**100 mg**	**1000 mg**
Sodium hydroxide	**N/A**	**To pH 8**
Water for injection	**N/A**	**To 1 mL**

Preparation/Administration

- Vitalipid N ADULT must be diluted before use and strict aseptic technique must always be maintained during handling. Because Vitalipid N ADULT is packaged in a glass ampule, a filter needle must always be used in conjunction with a regular (nonfilter) needle during compounding to reduce the risk of introducing glass particulates during administration.
- Both Vitalipid N ADULT and Vitalipid N INFANT are packaged in One Point Cut (OPC) ampules. OPC ampules are manufactured with a colored dot on the bulbous part of the ampule indicating the position where the ampule should be broken. Please follow the recommended instructions below to open the OPC ampule easily and safely:
  - Before an ampule is opened, any solution visible in the top portion (i.e., the head) should be moved to the bottom (i.e., body) by swirling the ampule in an upright position, tapping the ampule with one's finger, or inverting the ampule and then quickly swinging it into an upright position.
  - To open an ampule properly, the head should be cleansed with an alcohol swab. The alcohol swab can be left in place or a new alcohol-soaked gauze pad can be applied to prevent accidental cuts to the fingers as well as shattering of glass particles and aerosolized drug.
  - Pick up the ampule and hold its lower part (body) between your thumb and index finger and position the ampule so that the colored dot faces you.
  - Grasp the top of the ampule with your other hand. Place your thumb over the colored dot and index finger on the opposite side (back) of the bulbous part of the ampule.
  - Hold the bottom of the ampule firmly in an upright position and push away from oneself in a quick motion to “snap” open the ampule at the neck.
  - Ampules should NOT be opened toward the HEPA filter in the compounding work area (to prevent spraying of liquid) or toward other sterile preparation within the hood.
- A regular needle should be used to withdraw 10 mL from one ampule. The regular needle should be removed from the syringe and replaced with a new **filter** needle to inject the 10 mL of Vitalipid into 500 mL of Intralipid (Fresenius Kabi). To ensure a homogeneous admixture, the bag should be inverted a couple of times immediately before the infusion. Vitalipid N ADULT is also used as a complement in parenteral nutrition (PN) formulations. Questions about compatibility may be directed to Fresenius Kabi USA, LLC Medical Affairs.
- Vitalipid N ADULT should be added to an infusion within one hour of administration and the infusion should be completed within 24 hours from preparation to prevent microbiological contamination. Any remaining contents of opened ampules should be discarded.
- Vitalipid N ADULT has been tested in PN formulations available outside of the U.S. containing lipid injectable emulsions under European standards and demonstrated compatibility with non-U.S. approved amino acids and other PN products. Branded U.S. PN products tested that have shown compatibility are SMOFlipid and Kabiven. Similar tests have not been conducted using U.S. amino acid products, thus caution should be taken when adding Vitalipid N ADULT to adult PN formulations. Vitalipid has also demonstrated compatibility when added to Kabiven in combination with some US amino acid branded products (e.g., Travasol 10% [Baxter Healthcare], Aminosyn II 15% [Hospira, Inc], Clinisol 15% [Baxter Healthcare], Prosol 20% [Baxter Healthcare]).
- Vitalipid N INFANT must be diluted before use in Intralipid 20% (Fresenius Kabi). The daily dose must not exceed 10 mL. Because Vitalipid N INFANT is packaged in a glass ampule, a filter needle must always be used in conjunction with a regular (nonfilter) needle during compounding to reduce the risk of introducing glass particulates during administration. A regular needle should be used to withdraw up to 10 mL from 1 ampule. The regular needle should be removed from the syringe and replaced with a new **filter** needle to inject up to 10 mL of Vitalipid N INFANT into Intralipid 20% (Fresenius Kabi). To ensure a homogeneous admixture, the bag should be inverted a

couple of times immediately before the infusion. After mixing by gentle agitation, the emulsion is infused as described for Intralipid (Fresenius Kabi). Any remaining contents of opened ampules should be discarded.

- Vitalipid N INFANT has been tested in PN formulations available outside of the U.S. containing lipid injectable emulsions under European standards and demonstrated compatibility with non-U.S. approved pediatric amino acids and other PN products. Similar tests have not been conducted using U.S. amino acid products, thus caution should be taken when adding Vitalipid N INFANT to pediatric PN formulations. Branded U.S. PN products that have been tested and demonstrate compatibility include SMOFlipid, Intralipid (Fresenius Kabi).
- Results from stability studies show that unopened ampules of Vitalipid N ADULT and Vitalipid N INFANT can be stored both at +5±3°C and at +25°C/60 % RH for 24 months. Based on available data, the product is proposed to be stored between 2°C – 25°C with a shelf life of 24 months. Do not freeze. Protect the product from light
- Storage with dilution and admixture: The admixing of Vitalipid N ADULT and Vitalipid N INFANT in PN formulations has been investigated according to standard methods, documenting the physicochemical stability of admixtures after storage times up to 7 days. Vitalipid N ADULT and Vitalipid N INFANT have been tested with a variety of PN products marketed in the US, including Kabiven, PeriKabiven, and Intralipid 20% (Fresenius Kabi). The storage time and conditions specifically investigated compatibility of these products for 7 days, i.e., 6 days storage at 2°C -8°C followed by 24 hours at 20°C-25°C (i.e., 6+1 conditions). The methods employed are measurement of mean droplet size, droplet size distribution, pH, visual inspection and investigations aiming to determine precipitation in the aqueous phase. The latter have been carried out by comparisons with the corresponding aqueous systems without added lipid emulsion. The experimental results demonstrate that all tested compositions are stable and compatible under 6+1 conditions. It is important to note that there is variability in the U.S. use of different PN components which may not have been tested. If HCPs 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)	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)	Only fat-soluble vitamins These include: Retinol palmitate (vitamin A) Ergocalciferol (Vitamin D_2) All-rac-Alpha-tocopherol (Vitamin E) Phytomenadione (Vitamin K_1)

	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		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	
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 Vitamin B_{12}: 0.5 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 Vitamin B_{12}: 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 Vitamin B_{12}: 0.2 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 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-	Between 2- 25°C (36-77°F). Protect from light. Do not freeze

			8°C (36-46°F).	
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
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	**Vitalipid N Adult[2,3]**	**Infuvite Adult[1]**

	Recommendations[7]	(10 mL dose)	(10 mL dose)
Thiamine (B_1)	6 mg		6 mg
Riboflavin (B_2)	3.6 mg		3.6 mg
Niacin (B_3)	40 mg		40 mg
Pantothenic Acid (B_5)	5 mg		15 mg
Pyridoxine (B_6)	6 mg		6 mg
Biotin	60 mcg		60 mcg
Folate	600 mcg		600 mcg
Cyanocobalamin (B_{12})	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

Daily Pediatric ASPEN Guideline Recommendations for Parenteral Multivitamins and amount in Vitalipid N Infant and Infuvite Pediatric Products

	Preterm Neonates: Guideline Recommendations	Infants: Guideline Recommendations[7]	Children: Guideline Recommendations[7]	Vitalipid N Infant[5,6] (10 mL)	Infuvite Pediatric (4 mL+ 1 mL)[4]
Pediatric Dosing	Amounts/kg/d	Amounts/kg/d	Amounts/d	Preterm and <2.5 kg: 4 mL/kg >2.5 kg to 11 years: 10 mL	< 1 kg: 1.5 mL 1 kg - <3 kg: 3.25 mL ≥ 3 kg: 5 mL
Thiamine (B_1), mg	200–350 mcg	0.35 -0.5	1.2		1.2 mg
Riboflavin (B_2, mg)	50–200 mcg	0.15 – 0.2	1.4		1.4 mg
Niacin (B_3), mg	4–6.8	4 – 6.8	17		17 mg
Pantothenic Acid (B_5), mg	1–2	1 – 2	5		5 mg
Pyridoxine (B_6), mg	150–200 mcg	0.15 – 0.2	1		1 mg
Biotin , mg	5-8 mcg	5 – 8	20		20 mcg
Folate, mcg	56 mcg	56	140		140 mcg
Cyanocobalamin (B_{12}), mcg	0.3	0.3	1		1 mcg
Vitamin C (ascorbic acid), mg	15-25	15 – 25	80		80 mg
Vitamin A , mcg (IU)	700-1500 IU	150-300 (500 – 1000 IU)	150 (500 IU)	690 (2300 IU)	700 mcg (2300 IU)
Vitamin D, mcg (IU)	40-160 IU	0.8 (32 IU)	10 (400 IU)	10 mcg (400 IU)	10 mcg (400 IU)
Vitamin E , mg	2.8-3.5 IU	2.8 – 3.5	7	6.4 mg (7 IU)	7 mg (7 IU)

Vitamin K_1 , mcg	10	10	200	200 mcg	200 mcg

Refer to the Vitalipid N package insert for full prescribing information

REPORTING ADVERSE EVENTS

To report adverse events experienced with the use of this product, call Fresenius Kabi USA Vigilance at 1-800-551-7176, Monday – Friday, between the hours of 8 a.m. and 5 p.m. (CST), or e-mail adverse.events.USA@fresenius-kabi.com

To report a product complaint with the use of this product, call (800) 551- 7176 or e-mail productcomplaint.USA@fresenius-kabi.com.

Fresenius Kabi USA CONTACT NUMBERS: Please use the following contact numbers as appropriate:

Reason To Call	Department	Number
ADE Reporting	Vigilance Department	1-800-551-7176
Clinical/Technical Info. Or Product Complaint	Medical Affairs Department	
Product Availability & Ordering	Customer Service Department	1-888-386-1300

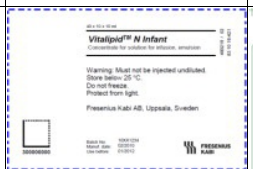
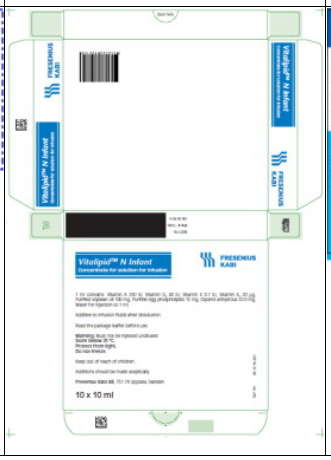
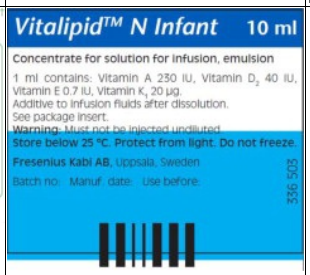
Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

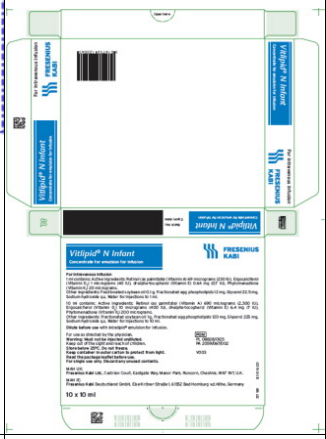
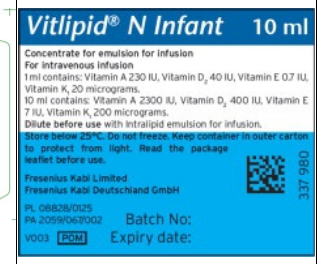
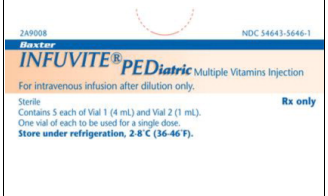
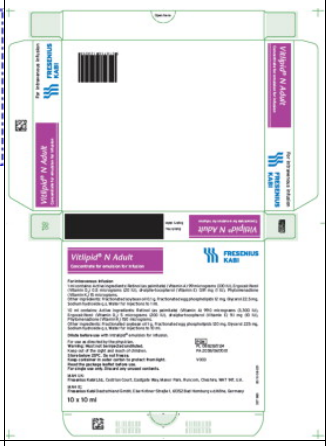
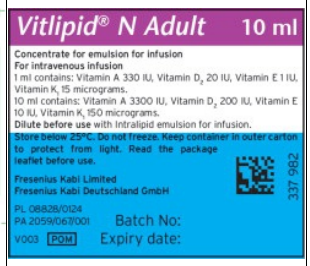
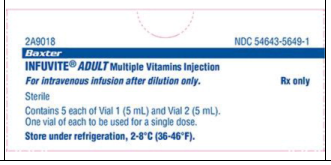
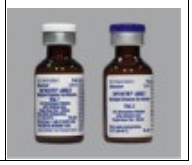
- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/medwatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (1-800-332-0178).

Sincerely,

Gordon S. Sacks, PharmD, BCNSP, FASPEN, FCCP
Senior Director, Medical Affairs
Fresenius Kabi USA, LLC

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

Product	Shipper label	Box Label	Ampule/Vial label	Ampule/Vial picture
Vitalipid N Infant				

Vitlipid N Infant				Not available
Infuvite Pediatric (Baxter Healthcare)	Not available		Not available	
Vitlipid N Adult				Not available
Infuvite Adult (Baxter Healthcare)	Not available			

References:

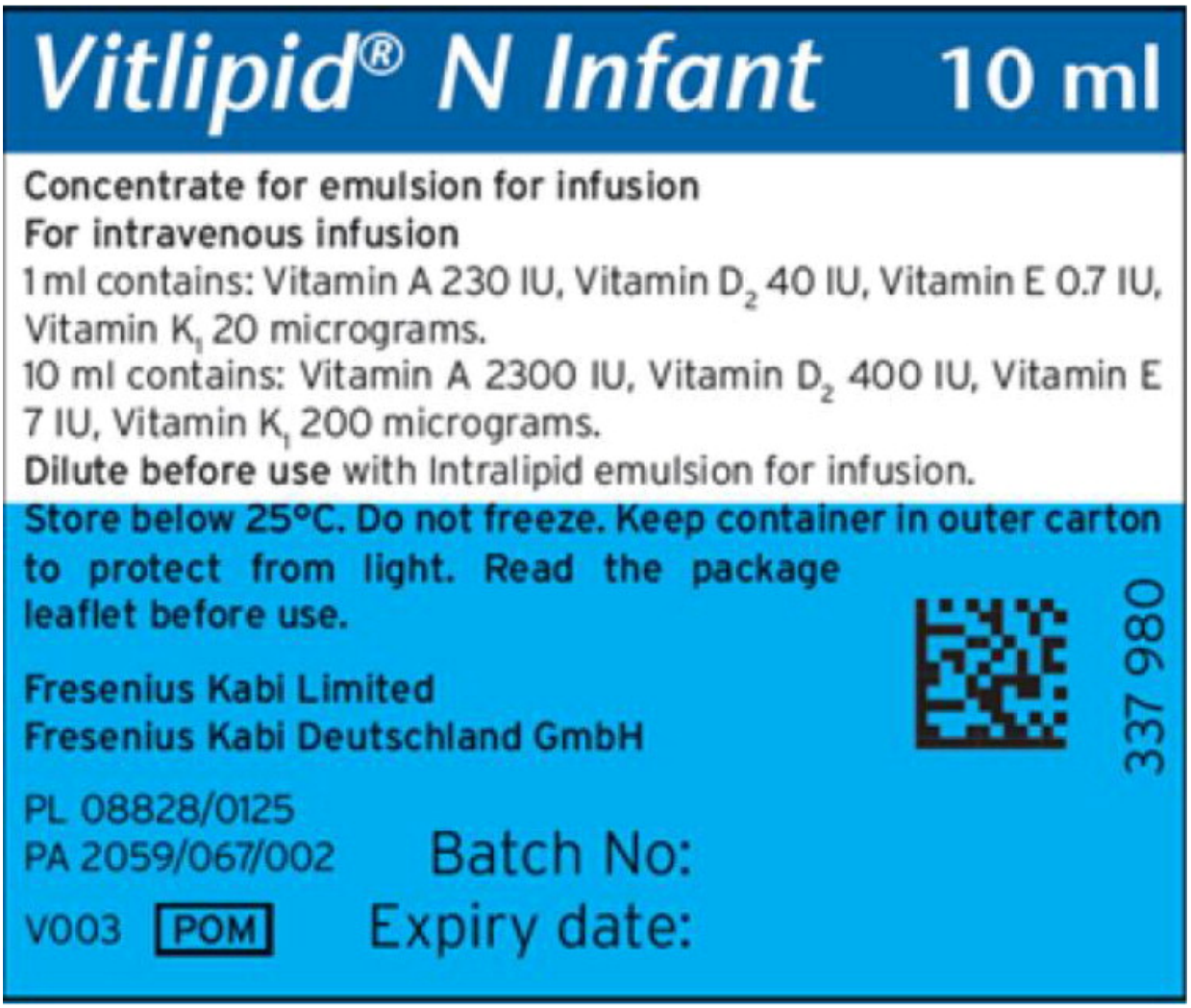
1. Infuvite Adult. Prescribing Information. Baxter Healthcare Corporation. Deerfield IL. October 2016.
2. Vitalipid N Adult Summary of Product Characteristics. Fresenius Kabi 2008
3. Vitalipid N Adult Prescribing Information, Fresenius Kabi AB. Uppsala, Sweden
4. Infuvite Pediatric. Prescribing Information. 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.

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – VITALIPID® N Infant 10 mL Ampule Label

***Vitalipid® N Infant* 10 ml**

Concentrate for emulsion for infusion

For intravenous infusion

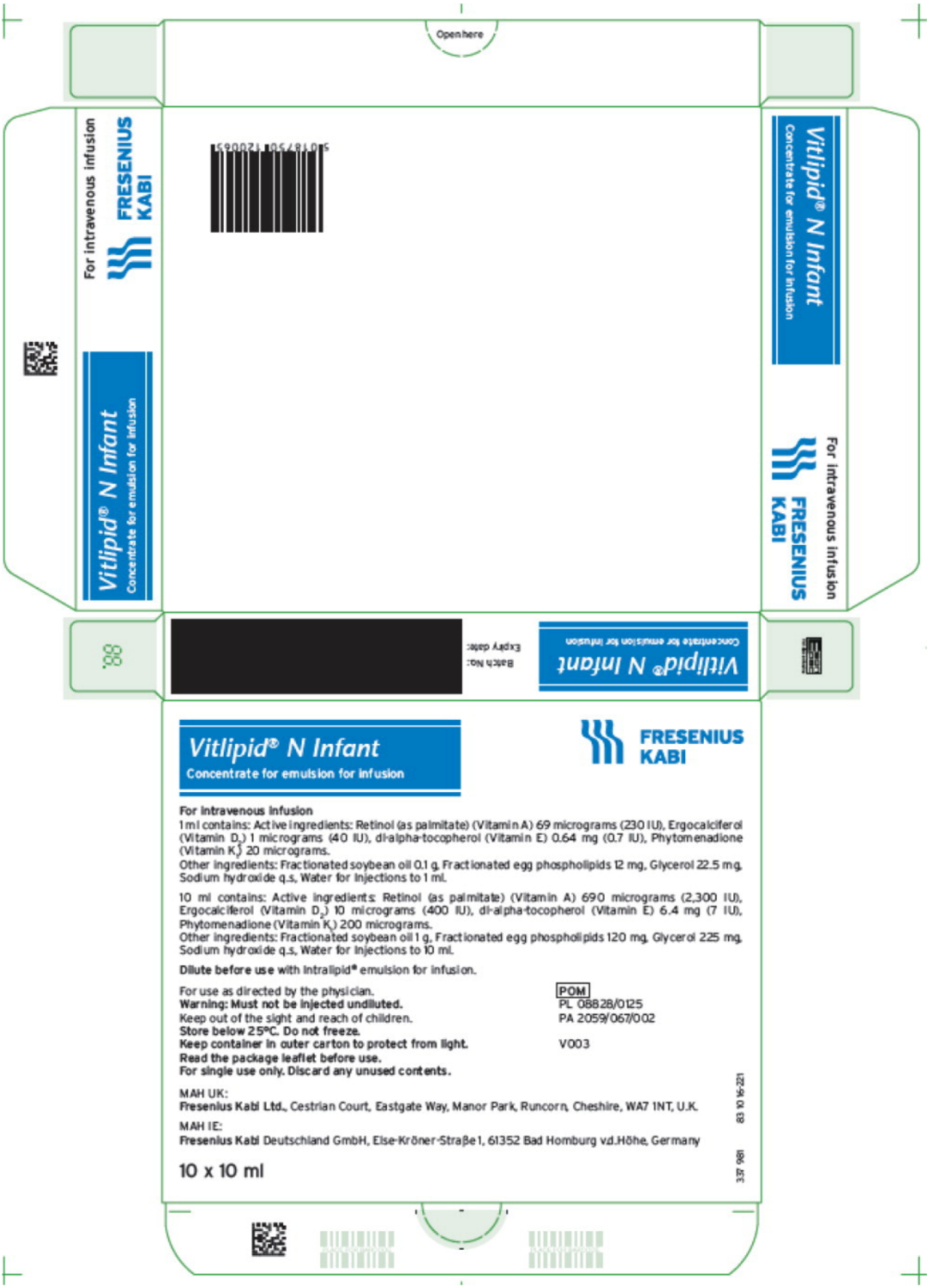


PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – VITALIPID® N Infant 10 mL Ampule Carton Panel

Vitalipid® N Infant

Concentrate for emulsion for infusion

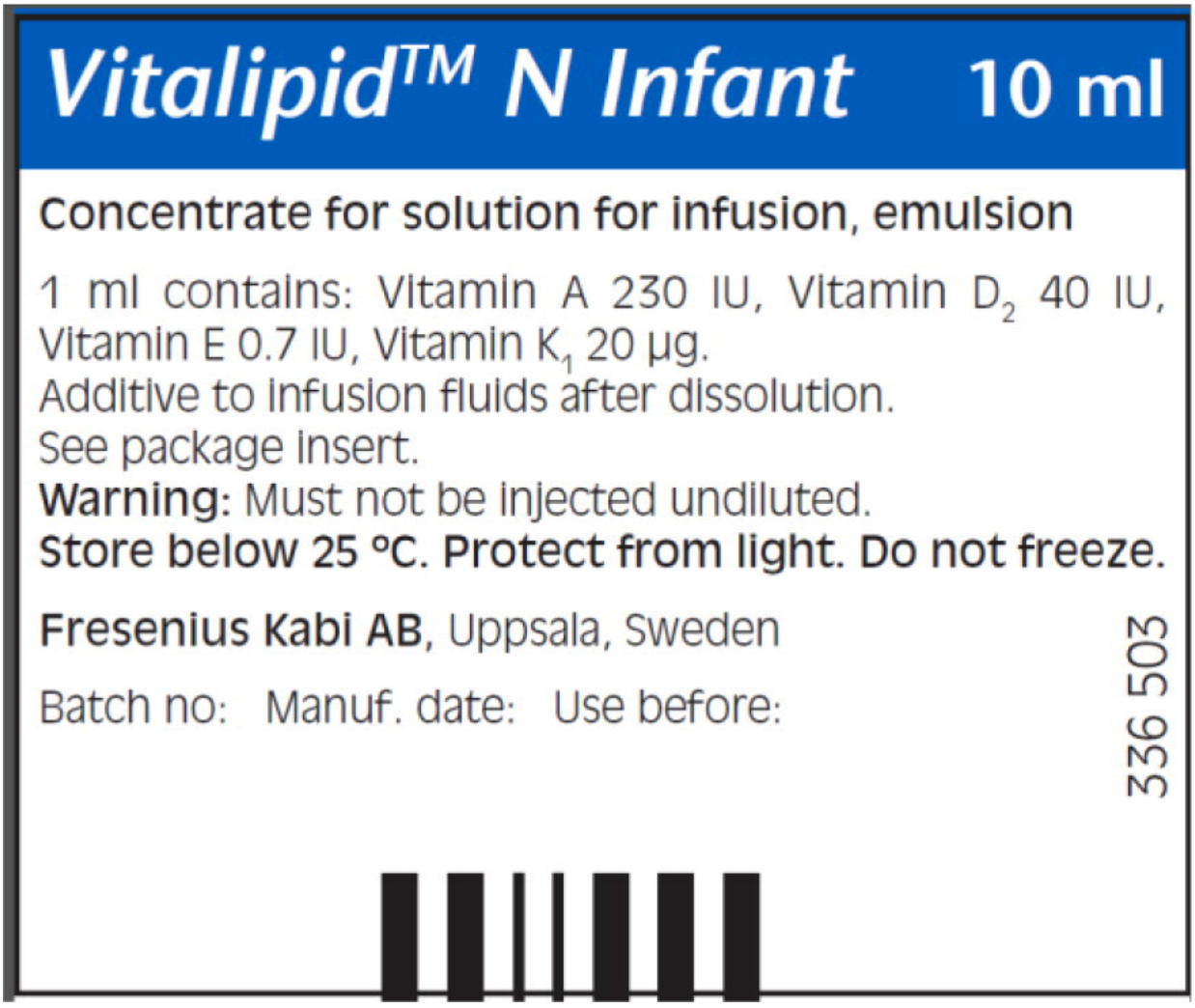
For intravenous infusion



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – VITALIPID™ N Infant 10 mL Ampule Label

***Vitalipid™ N Infant* 10 ml**

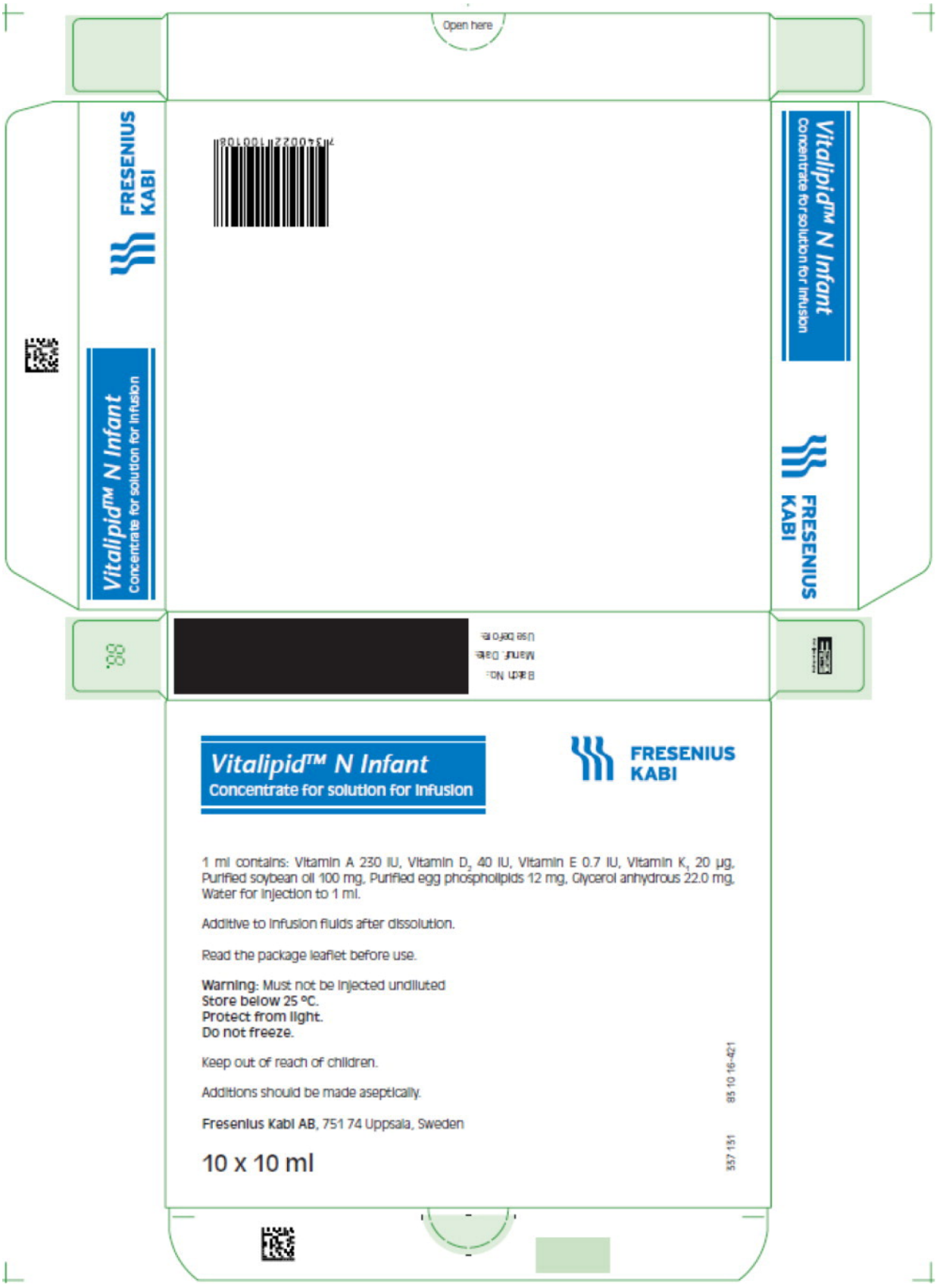
Concentrate for solution for infusion, emulsion



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – VITALIPID™ N Infant 10 mL Ampule Carton Panel

Vitalipid™ N Infant

Concentrate for solution for infusion

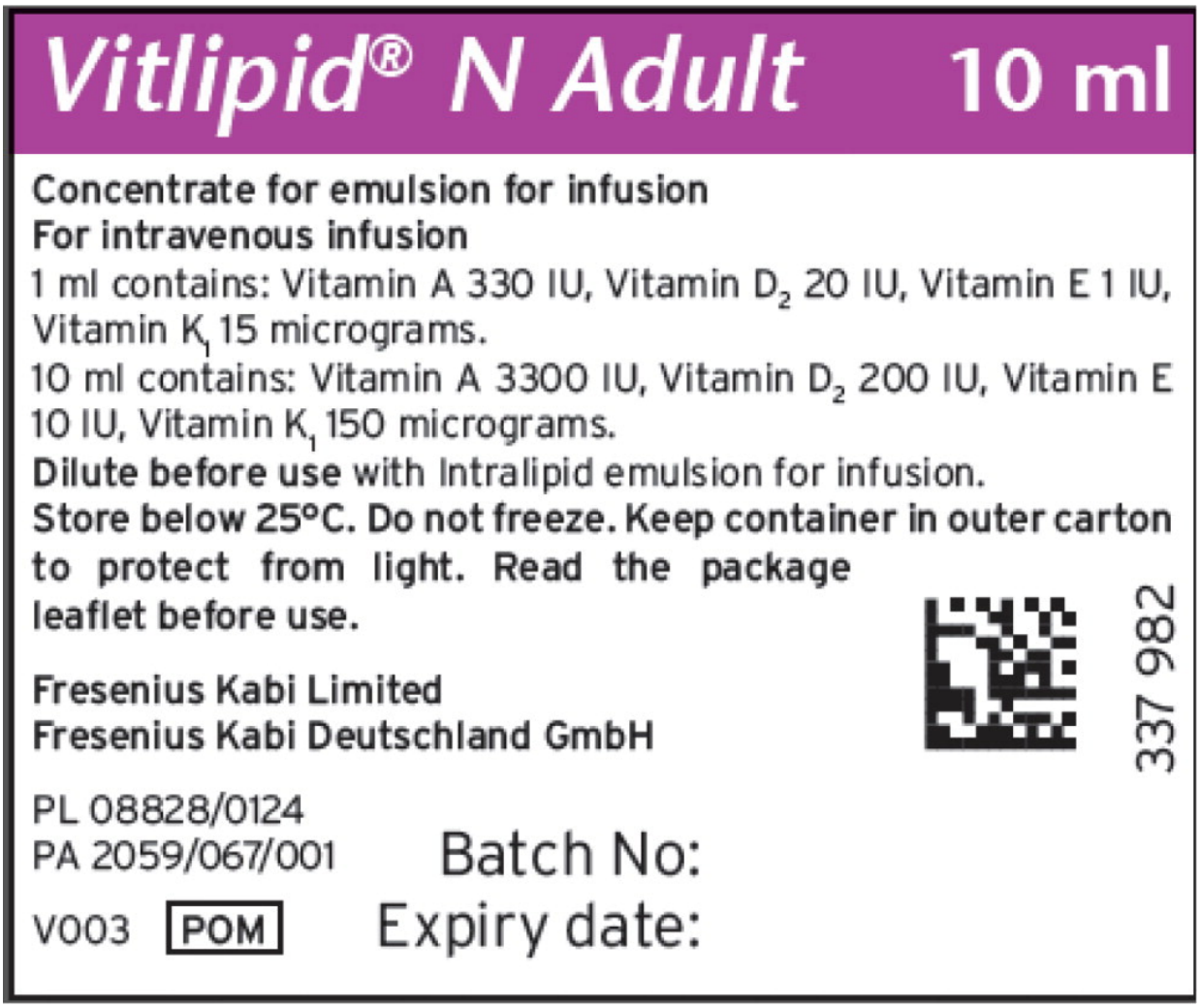


PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – VITALIPID® N Adult 10 mL Ampule Label

***Vitalipid® N Adult* 10 ml**

Concentrate for emulsion for infusion

For intravenous infusion

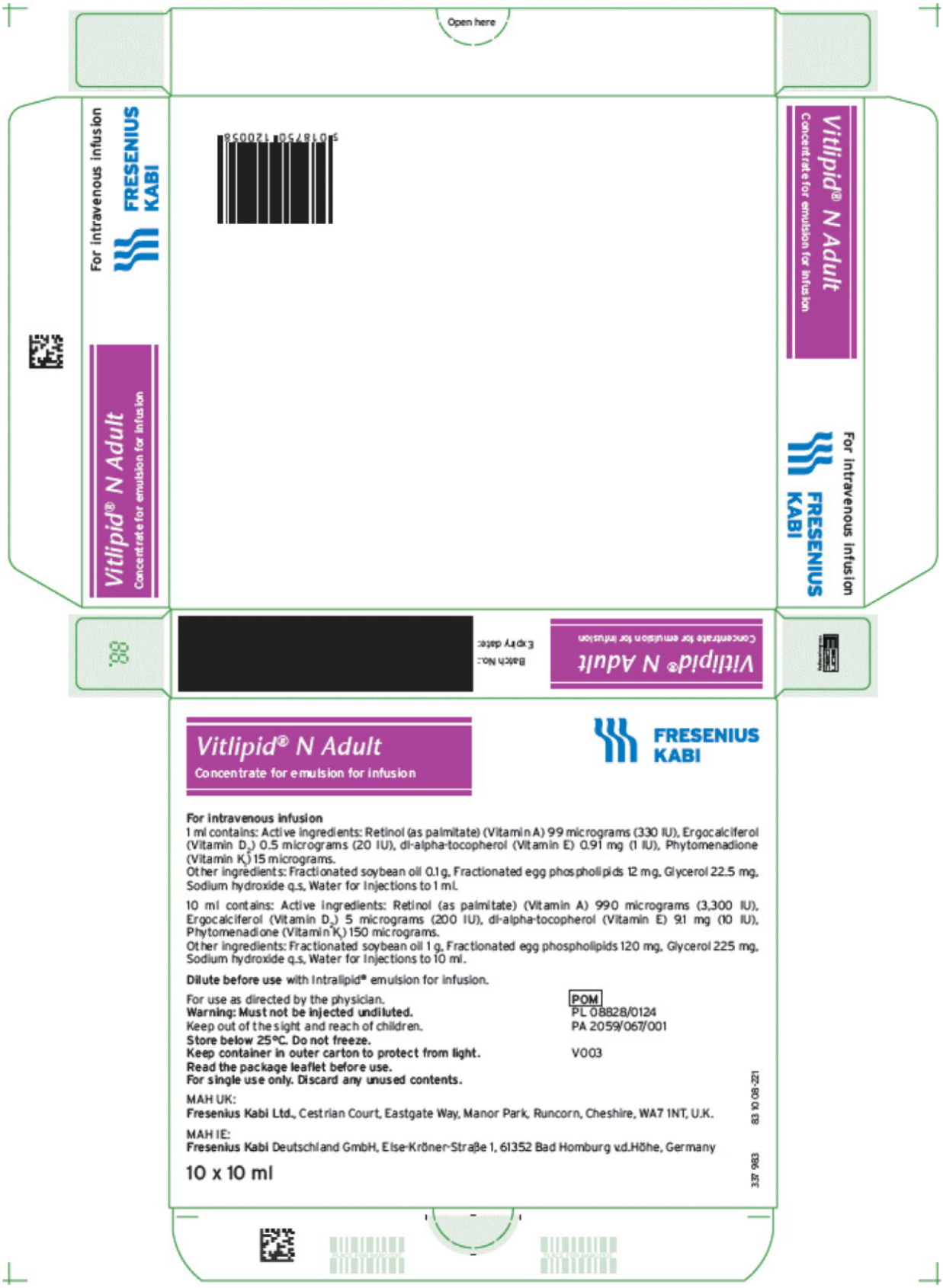


PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – VITALIPID® N Adult 10 mL Ampule Carton Panel

Vitalipid® N Adult

Concentrate for emulsion for infusion

For intravenous infusion



VITALIPID N

vitamin a palmitate, ergocalciferol, .alpha.-tocopherol, dl-, phytonadione emulsion

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65219-337

Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	230 [iU] in 1 mL
Ergocalciferol (UNII: VS041H42XC) (Ergocalciferol - UNII:VS041H42XC)	Ergocalciferol	40 [iU] in 1 mL
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	0.7 [iU] in 1 mL
PHYTONADIONE (UNII: A034SE7857) (PHYTONADIONE - UNII:A034SE7857)	PHYTONADIONE	20 ug in 1 mL

Inactive Ingredients

Ingredient Name	Strength
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
SOYBEAN OIL (UNII: 241ATL177A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65219-337-62	10 in 1 CARTON	08/18/2023	
1	NDC:65219-337-10	10 mL in 1 AMPULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		08/18/2023	

VITALIPID N

vitamin a palmitate, ergocalciferol, .alpha.-tocopherol, dl-, phytonadione emulsion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65219-339
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	230 [iU] in 1 mL
Ergocalciferol (UNII: VS041H42XC) (Ergocalciferol - UNII:VS041H42XC)	Ergocalciferol	40 [iU] in 1 mL
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01) (.ALPHA.-TOCOPHEROL, DL- -	.ALPHA.-	0.7 [iU]

UNII:7QWA1RIO01)	TOCOPHEROL, DL-	in 1 mL
PHYTONADIONE (UNII: A034SE7857) (PHYTONADIONE - UNII:A034SE7857)	PHYTONADIONE	20 ug in 1 mL

Inactive Ingredients

Ingredient Name	Strength
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
SOYBEAN OIL (UNII: 241ATL177A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65219-339-64	10 in 1 CARTON	08/18/2023	
1	NDC:65219-339-10	10 mL in 1 AMPULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		08/18/2023	

VITALIPID N

vitamin a palmitate, ergocalciferol, .alpha.-tocopherol, dl-, phytonadione emulsion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65219-335
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	330 [iU] in 1 mL
Ergocalciferol (UNII: VS041H42XC) (Ergocalciferol - UNII:VS041H42XC)	Ergocalciferol	20 [iU] in 1 mL
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	1 [iU] in 1 mL
PHYTONADIONE (UNII: A034SE7857) (PHYTONADIONE - UNII:A034SE7857)	PHYTONADIONE	15 ug in 1 mL

Inactive Ingredients

Ingredient Name	Strength
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
GLYCERIN (UNII: PDC6A3C0OX)	
SOYBEAN OIL (UNII: 241ATL177A)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65219-335-82	10 in 1 CARTON	08/18/2023	
1	NDC:65219-335-10	10 mL in 1 AMPULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		08/18/2023	

Labeler - Fresenius Kabi USA, LLC (013547657)

Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi AB		559785113	ANALYSIS(65219-337, 65219-339, 65219-335) , API MANUFACTURE(65219-337, 65219-339, 65219-335) , MANUFACTURE(65219-337, 65219-339, 65219-335)

Revised: 9/2023 Fresenius Kabi USA, LLC