FRESENIUS KABI

Y-Site Drug Compatibility Reference Guide

The information presented within was obtained from the Medical Affairs Department at Fresenius Kabi USA.

This guide is intended for US audiences only.

DISCLAIMERS: 1. This compatibility reference guide is not intended as a substitute for independent clinical judgment or your institution's policies and procedures. **2.** This is not a full list of medications. The list contains only drugs that have been tested.

For additional information about the testing results, and for more insights into how to use this information for your parenteral nutrition (PN) patients, please contact Fresenius Kabi Medical Affairs via phone at 1-800-551-7176, option 4, or email Nutrition.MedInfo.USA@fresenius-kabi.com

SMOFlipid®
(lipid injectable emulsion), for intravenous use

Omegaven®
(fish oil triglycerides) injectable emulsion, for intravenous use

Y-Site Drug Compatibility Reference Guide

SMOFlipid Compatibility and Stability

- Internal compatibility and stability studies were conducted in March 2023 to evaluate medication compatibility with SMOFlipid administered via Y-site with both pediatric and adult PN formulations containing Premasol® 10%, TrophAmine® 10%, Travasol® 10%, Clinisol® 15%, and Plenamine™ 15%.
- A series of PN formulations were designed based on the following weight categories: 500 g, 2 kg, 29 kg, and 70 kg. Each medication was tested with PN formulations containing the maximum electrolyte content as per ASPEN dosing guidelines.[1] After mixing PN formulations with medications, the samples were tested as soon as possible (i.e., within 1 hour) and again after 4 hours at room temperature from 20°C to 25°C [68°F to 77°F]. Medications were mixed at a 1-to-1 ratio with the PN formulations.
- Table 1 outlines testing methods. No microbiological or chemical tests were conducted on the PN formulations or medications. The presence of lipid injectable emulsion (i.e., SMOFlipid) prohibits the direct assessment of potential precipitation. Therefore, sample preparation and the subsequent analyses were divided into two parts: assessment of potential precipitate (lipid-free PN) and analysis of emulsion stability (all constituents of PN present). Results are only valid for the branded products listed at the time of testing. Additions to the PN admixtures should be evaluated by a pharmacist for compatibility. If it is deemed advisable to introduce additives, use strict aseptic technique to avoid microbial contamination.

Admixing Instructions[2]

- Prepare the admixture in PN containers using strict aseptic techniques to avoid microbial contamination.
- Additions to the PN admixture should be evaluated by a pharmacist for compatibility. Questions about compatibility may be directed to Fresenius Kabi USA.
- Infuse admixtures containing SMOFlipid immediately. If not used immediately, store admixtures under refrigeration at 2°C to 8°C [36°F to 46°F] for no longer than 24 hours. Infusion must be complete within 24 hours after removal from refrigeration. Discard any remaining admixture.

References: 1. ASPEN. Appropriate Dosing for Parenteral Nutrition: ASPEN Recommendations. http://www.nutritioncare.org/PNDosing. Published 2020. Accessed March 6, 2026. **2.** SMOFlipid. Prescribing information. Fresenius Kabi USA, LLC; 2025.

Please see IMPORTANT SAFETY INFORMATION for SMOFlipid at the end of this Section.

Table 1. Testing Methods and Criteria for Admixtures[1]

Method	Description
Visual inspection of lipid phase	No free oil droplets on the admixture surface, white emulsion with no visual signs of discoloration[a]
pH of lipid/aqueous phase	A change in pH of not more than ± 0.5 during the testing period for formulations with and without lipids
Lipid globule distribution[2]	MDD < 500 nm Percentage of fat globules > 5 micron < 0.4%
Visual inspection of aqueous phase	Observation of cloudiness, discoloration, visible particles (unaided eye), and clarity. The liquid should be clear and practically free from particles, and only colors of the components in the mix.
Subvisible particles in aqueous phase	Limits in accordance with USP Chapter <788> for LVP (≥ 100 mL) products: NMT 25 particles/mL ≥ 10 microns NMT 3 particles/mL ≥ 25 microns
Turbidity[3]	Change of 0.5 NTU or more over the baseline turbidity value

LVP = large volume parenterals; MDD = mean droplet diameter; NMT = no more than; NTU = nephelometric turbidity units
[a] Addition of vitamins causes discoloration of the admixture (light yellow-yellow/cream color depending on the concentration). If vitamins are added, the acceptance criterion "white emulsion" cannot be met, and the results of the discoloration parameter are only for information.

References: 1. Staven V, Wang S, Grønlie I, Tho I. Development and evaluation of a test program for Y-site compatibility testing of total parenteral nutrition and intravenous drugs. *Nutr J*. 2016;15:29. **2.** Driscoll DF, Bhargava HN, Li L, Zaim RH, Babayan VK, Bistrian BR. Physicochemical stability of total nutrient admixtures. *Am J Health Syst Pharm*. 1995;52(6):623-634. **3.** Trissel LA, Bready BB. Turbidimetric assessment of the compatibility of taxol with selected other drugs during simulated Y-site injection. *Am J Hosp Pharm*. 1992;49(7):1716-1719.

Only the PN formulations listed in Table 2 below have been tested and shown to be physically stable. Tables 3-7 list the compatible and incompatible medications tested via Y-site. ***Note that only the components in the specific amounts listed below were tested and no ranges were included.***

Table 2. Admixtures Tested With SMOFlipid

Admixture		1	2	3	4	5	6
Patient Weight (kg)		0.5	2	2	29	70	70
Final Concentrations (%)							
SMOFlipid 20%		2.2	2.4	2.4	2.4	4.3	4.3
TrophAmine® 10%		3	3.2	–	–	–	–
Premasol® 10%		–	–	3.2	–	–	–
Travasol® 10%		–	–	–	4	–	–
Clinisol® 15%		–	–	–	–	6.5	–
Plenamine™ 15%		–	–	–	–	–	6.5
Dextrose 70%		8.6	16.2	16	23.2	12.3	12.3
Volume (mL)		50	250	250	1800	1620	1620
Micronutrients							
Sodium[a]	mEq/kg/day (mEq/L)	7 (67)	8 (61)	8 (61)	8 (123)	3.4 (145)	3.4 (145)
Potassium Acetate	mEq/kg/day (mEq/L)	4 (40)	4 (32)	4 (32)	4 (64)	3.4 (145)	3.4 (145)
Calcium Gluconate	mEq/kg/day (mEq/L)	4 (40)	4 (32)	4 (32)	1 (16)	0.2 (10)	0.2 (10)
Magnesium Sulfate	mEq/kg/day (mEq/L)	0.5 (5)	0.5 (4)	0.5 (4)	0.5 (8)	0.4 (15)	0.4 (15)
(Inorganic) Phosphate[b]	mmol/kg/day (mmol/L)	2 (20)	2 (16)	2 (16)	2 (32)	0.3 (15)	0.3 (15)
INFUVITE® PEDIATRIC Multivitamin (mL/day) (Sandoz Inc.)		1.5	3.25	3.25	5	–	–
INFUVITE® ADULT Multivitamin (mL/day) (Sandoz Inc.)		–	–	–	–	10	10
Tralement® (mL/day) (American Regent, Inc.)		–	–	–	–	1	1
Zinc Sulfate (mcg/kg/day) (American Regent, Inc.)		400	400	400	50	–	–
Selenium (selenious acid) (mcg/kg/day) (American Regent, Inc.)		2	2	2	2	–	–
Copper (cupric chloride) (mcg/kg/day) (Hospira)		20	20	20	20	–	–
Cysteine Hydrochloride (mg/kg/day) (Exela® Pharma Sciences)		160	160	160	–	–	–

[a]The total sodium content includes sodium chloride and sodium phosphates.
[b]The phosphate content is entirely provided as sodium phosphate.
– = Not applicable.
Any significant change in pH from additives not listed compared to what has been evaluated in this study may affect compatibility.

Table 3: Medication Compatibility Tested With SMOFlipid and TrophAmine 10% via Simulated Y-Site

Reference Table 2 for complete PN admixtures tested with each medication.

Drug Infusion Via Y-Site		
Admixture	**1**	**2**
Patient Weight (kg)	0.5	2
Drug Compounded Concentration (Manufacturer)	**Compatible/Incompatible (C/I)**	
Ampicillin 10 mg/mL (Fresenius Kabi)	C	C
Cefepime 20 mg/mL (B. Braun)	I	I
Cisatracurium Besylate 0.1 mg/mL (Fresenius Kabi)	I	C
Dexmedetomidine 4 mcg/mL (Fresenius Kabi)	C	C
Dopamine HCl 1600 mcg/mL (Hospira/Pfizer)	C	C
Famotidine 0.4 mg/mL (Baxter)	C	C
Fluconazole 2 mg/mL (Hospira/Pfizer)	C	C
Gentamicin 2 mg/mL (Baxter)	C	C
Meropenem 20 mg/mL (B. Braun)	I	I
Metronidazole 5 mg/mL (Hospira/Pfizer)	C	I
Micafungin 1 mg/mL (Fresenius Kabi)	I	I
Norepinephrine 16 mcg/mL (Baxter)	C	C
Vancomycin 5 mg/mL (Hospira/Pfizer)	I	C

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

Table 4: Medication Compatibility Tested With SMOFlipid and Premasol 10% via Simulated Y-Site

Reference Table 2 for complete PN admixtures tested with each medication.

Drug Infusion Via Y-Site	
Admixture	**3**
Patient Weight (kg)	2
Drug Compounded Concentration (Manufacturer)	**Compatible/Incompatible (C/I)**
Ampicillin 10 mg/mL (Fresenius Kabi)	C
Cefepime 20 mg/mL (B. Braun)	C
Cisatracurium Besylate 0.1 mg/mL (Fresenius Kabi)	C
Dexmedetomidine 4 mcg/mL (Fresenius Kabi)	C
Dopamine HCl 1600 mcg/mL (Hospira/Pfizer)	C
Famotidine 0.4 mg/mL (Baxter)	C
Fluconazole 2 mg/mL (Hospira/Pfizer)	C
Gentamicin 2 mg/mL (Baxter)	C
Meropenem 20 mg/mL (B. Braun)	I
Metronidazole 5 mg/mL (Hospira/Pfizer)	I
Micafungin 1 mg/mL (Fresenius Kabi)	I
Norepinephrine 16 mcg/mL (Baxter)	C
Vancomycin 5 mg/mL (Hospira/Pfizer)	C

Table 5: Medication Compatibility Tested With SMOFlipid and Travasol 10% via Simulated Y-Site

Reference Table 2 for complete PN admixtures tested with each medication.

Drug Infusion Via Y-Site	
Admixture	**4**
Patient Weight (kg)	29
Drug Compounded Concentration (Manufacturer)	**Compatible/Incompatible (C/I)**
Ampicillin 10 mg/mL (Fresenius Kabi)	C
Cefepime 20 mg/mL (B. Braun)	C
Cisatracurium Besylate 0.1 mg/mL (Fresenius Kabi)	C
Dexmedetomidine 4 mcg/mL (Fresenius Kabi)	C
Dopamine HCl 1600 mcg/mL (Hospira/Pfizer)	C
Famotidine 0.4 mg/mL (Baxter)	I
Fluconazole 2 mg/mL (Hospira/Pfizer)	C
Gentamicin 2 mg/mL (Baxter)	C
Meropenem 20 mg/mL (B. Braun)	I
Metronidazole 5 mg/mL (Hospira/Pfizer)	C
Micafungin 1 mg/mL (Fresenius Kabi)	I
Norepinephrine 16 mcg/mL (Baxter)	C
Vancomycin 5 mg/mL (Hospira/Pfizer)	C

Table 6: Medication Compatibility Tested With SMOFlipid and Clinisol 15% via Simulated Y-Site

Reference Table 2 for complete PN admixtures tested with each medication.

Drug Infusion Via Y-Site	
Admixture	**5**
Patient Weight (kg)	70
Drug Compounded Concentration (Manufacturer)	**Compatible/Incompatible (C/I)**
Ampicillin 10 mg/mL (Fresenius Kabi)	C
Cefepime 20 mg/mL (B. Braun)	C
Cisatracurium Besylate 0.1 mg/mL (Fresenius Kabi)	C
Dexmedetomidine 4 mcg/mL (Fresenius Kabi)	C
Dopamine HCl 1600 mcg/mL (Hospira/Pfizer)	C
Famotidine 0.4 mg/mL (Baxter)	C
Fluconazole 2 mg/mL (Hospira/Pfizer)	C
Gentamicin 2 mg/mL (Baxter)	C
Meropenem 20 mg/mL (B. Braun)	I
Metronidazole 5 mg/mL (Hospira/Pfizer)	C
Micafungin 1 mg/mL (Fresenius Kabi)	I
Norepinephrine 16 mcg/mL (Baxter)	C
Vancomycin 5 mg/mL (Hospira/Pfizer)	I

Table 7: Medication Compatibility Tested With SMOFlipid and Plenamine 15% via Simulated Y-Site

Reference Table 2 for complete PN admixtures tested with each medication.

Drug Infusion Via Y-Site	
Admixture	**6**
Patient Weight (kg)	70
Drug Compounded Concentration (Manufacturer)	**Compatible/Incompatible (C/I)**
Ampicillin 10 mg/mL (Fresenius Kabi)	C
Cefepime 20 mg/mL (B. Braun)	I
Cisatracurium Besylate 0.1 mg/mL (Fresenius Kabi)	C
Dexmedetomidine 4 mcg/mL (Fresenius Kabi)	C
Dopamine HCl 1600 mcg/mL (Hospira/Pfizer)	C
Famotidine 0.4 mg/mL (Baxter)	C
Fluconazole 2 mg/mL (Hospira/Pfizer)	C
Gentamicin 2 mg/mL (Baxter)	I
Meropenem 20 mg/mL (B. Braun)	I
Metronidazole 5 mg/mL (Hospira/Pfizer)	C
Micafungin 1 mg/mL (Fresenius Kabi)	I
Norepinephrine 16 mcg/mL (Baxter)	C
Vancomycin 5 mg/mL (Hospira/Pfizer)	C

Plenamine is a registered trademark of B. Braun Medical Inc.

SMOFlipid®

(lipid injectable emulsion),
for intravenous use

The information presented in this document is not a substitute for clinical or professional judgment. Please review the Full Prescribing Information before administering SMOFlipid.

INDICATIONS AND USAGE

SMOFlipid is indicated in adult and pediatric patients, including term and preterm neonates, as a source of calories and essential fatty acids for parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated.

IMPORTANT SAFETY INFORMATION

For intravenous infusion only into a central or peripheral vein. Use a non-vented non-DEHP 1.2 micron in-line filter set during administration. Recommended dosage depends on age, energy expenditure, clinical status, body weight, tolerance, ability to metabolize and eliminate lipids, and consideration of additional energy given to the patient. The recommended dose for adults and pediatrics is shown in Table 1. For information on age-appropriate infusion rate, see the full prescribing information. SMOFlipid Pharmacy Bulk Package is only indicated for use in pharmacy admixture programs for the preparation of three-in-one or total nutrition admixtures. Protect the admixed PN solution from light.

Table 1: Recommended Adult and Pediatric Dosage

Age	Nutritional Requirements	
	Initial Recommended Dosage	Maximum Dosage
Birth to 2 years of age (including preterm and term neonates)	0.5 to 1 g/kg/day	3 g/kg/day
Pediatric patients 2 to < 12 years of age	1 to 2 g/kg/day	3 g/kg/day
Pediatric patients 12 to 17 years of age	1 g/kg/day	2.5 g/kg/day
Adults	1 to 2 g/kg/day	2.5 g/kg/day

SMOFlipid is contraindicated in patients with known hypersensitivity to fish, egg, soybean, peanut, or any of the active or inactive ingredients, and severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglycerides > 1,000 mg/dL).

Clinical Decompensation with Rapid Infusion of Intravenous Lipid Emulsion in Neonates and Infants: Acute respiratory distress, metabolic acidosis, and death after rapid infusion of intravenous lipid emulsions have been reported.

Parenteral Nutrition-Associated Liver Disease: Increased risk in patients who received parenteral nutrition for greater than 2 weeks, especially preterm neonates. Monitor liver tests; if abnormalities occur, consider discontinuation or dosage reduction.

Hypersensitivity Reactions: Monitor for signs or symptoms. Discontinue infusion if reactions occur.

Risk of Infections, Fat Overload Syndrome, Refeeding Syndrome, Hypertriglyceridemia, and Essential Fatty Acid Deficiency: Monitor for signs and symptoms; monitor laboratory parameters.

Aluminum Toxicity: Increased risk in patients with renal impairment, including preterm neonates.

Most common adverse drug reactions (≥ 5%) from clinical trials in adults were nausea, vomiting, and hyperglycemia. Most common adverse drug reactions (≥ 5%) from clinical trials in pediatric patients were anemia, vomiting, increased gamma-glutamyltransferase, and nosocomial infection.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176, option 5, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

This Important Safety Information does not include all the information needed to use SMOFlipid safely and effectively. Please see Full Prescribing Information for SMOFlipid (lipid injectable emulsion), for intravenous use at www.FreseniusKabiNutrition.com/SMOFlipidPI.

Omegaven®
(fish oil triglycerides) injectable
emulsion, for intravenous use

Y-Site Drug Compatibility Reference Guide

Omegaven Compatibility and Stability

- Internal compatibility and stability studies were conducted in March 2023 to evaluate medication compatibility with Omegaven administered via Y-site with pediatric parenteral nutrition (PN) formulations containing Premasol® 10%, TrophAmine® 10%, and Travasol® 10%.
- A series of PN formulations were designed based on the following weight categories: 500 g, 2 kg, and 29 kg. Each medication was tested with PN formulations containing the maximum electrolyte content as per ASPEN dosing guidelines.[1] After mixing PN formulations with medications, the samples were tested as soon as possible (i.e., within 1 hour) and again after 4 hours at room temperature from 20°C to 25°C [68°F to 77°F]. Medications were mixed at a 1-to-1 ratio with the PN formulations.
- Table 1 outlines testing methods. No microbiological or chemical tests were conducted on the PN formulations or medications. The presence of lipid injectable emulsion (i.e., Omegaven) prohibits the direct assessment of potential precipitation. Therefore, sample preparation and the subsequent analyses were divided into two parts: assessment of potential precipitate (lipid-free PN) and analysis of emulsion stability (all constituents of PN present). Results are only valid for the branded products listed at the time of testing. Additions to the PN admixtures should be evaluated by a pharmacist for compatibility. If it is deemed advisable to introduce additives, use strict aseptic technique to avoid microbial contamination.

Admixing Instructions[2]

- Prepare the admixture in PN containers using strict aseptic techniques to avoid microbial contamination.
- Additions to the PN admixture should be evaluated by a pharmacist for compatibility. Questions about compatibility may be directed to Fresenius Kabi USA.
- Infuse admixtures containing Omegaven immediately. If not used immediately, admixtures can be stored for up to 6 hours at room temperature or up to 24 hours under refrigeration. Complete the infusion within 24 hours after removal from storage. Discard any remaining admixture.

References: 1. ASPEN. Appropriate Dosing for Parenteral Nutrition: ASPEN Recommendations. http://www.nutritioncare.org/PNDosing. Published 2020. Accessed March 6, 2026. **2.** Omegaven. Prescribing information. Fresenius Kabi USA, LLC; 2025.

Please see IMPORTANT SAFETY INFORMATION for Omegaven at the end of this Section.

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Table 1. Testing Methods and Criteria for Admixtures[1]

Method	Description
Visual inspection of lipid phase	No free oil droplets on the admixture surface, white emulsion with no visual signs of discoloration[a]
pH of lipid/aqueous phase	A change in pH of not more than ± 0.5 during the testing period for formulations with and without lipids
Lipid globule distribution[2]	MDD < 500 nm Percentage of fat globules > 5 micron < 0.4%
Visual inspection of aqueous phase	Observation of cloudiness, discoloration, visible particles (unaided eye), and clarity. The liquid should be clear and practically free from particles, and only colors of the components in the mix.
Subvisible particles in aqueous phase	Limits in accordance with USP Chapter <788> for LVP (≥ 100 mL) products: NMT 25 particles/mL ≥ 10 microns NMT 3 particles/mL ≥ 25 microns
Turbidity[3]	Change of 0.5 NTU or more over the baseline turbidity value

LVP = large volume parenterals; MDD = mean droplet diameter; NMT = no more than; NTU = nephelometric turbidity units
[a]Addition of vitamins causes discoloration of the admixture (light yellow-yellow/cream color depending on the concentration). If vitamins are added, the acceptance criterion "white emulsion" cannot be met, and the results of the discoloration parameter are only for information.

References: 1. Staven V, Wang S, Grønlie I, Tho I. Development and evaluation of a test program for Y-site compatibility testing of total parenteral nutrition and intravenous drugs. *Nutr J*. 2016;15:29. **2.** Driscoll DF, Bhargava HN, Li L, Zaim RH, Babayan VK, Bistrian BR. Physicochemical stability of total nutrient admixtures. *Am J Health Syst Pharm*. 1995;52(6):623-634. **3.** Trissel LA, Bready BB. Turbidimetric assessment of the compatibility of taxol with selected other drugs during simulated Y-site injection. *Am J Hosp Pharm*. 1992;49(7):1716-1719.

Omegaven®

(fish oil triglycerides) injectable emulsion, for intravenous use

Only the PN formulations listed in Table 2 below have been tested and shown to be physically stable. Tables 3-5 list the compatible and incompatible medications tested via Y-site. ***Note that only the components in the specific amounts listed below were tested and no ranges were included.***

Table 2. Admixtures Tested With Omegaven

Admixtures		1	2	3	4
Patient Weight (kg)		0.5	2	2	29
Final Concentrations (%)					
Omegaven 10%		1	0.8	0.8	1.5
TrophAmine® 10%		3	3.2	–	–
Premasol® 10%		–	–	3.2	–
Travasol® 10%		–	–	–	3.8
Dextrose 70%		8.6	16.2	16.2	22
Volume (mL)		50	250	250	1900
Micronutrients					
Sodium[a]	mEq/kg/day (mEq/L)	7 (66)	8 (61)	8 (61)	8 (117)
Potassium Acetate	mEq/kg/day (mEq/L)	4 (40)	4 (32)	4 (32)	4 (61)
Calcium Gluconate	mEq/kg/day (mEq/L)	4 (40)	4 (32)	4 (32)	1 (15)
Magnesium Sulfate	mEq/kg/day (mEq/L)	0.5 (5)	0.5 (4)	0.5 (4)	0.5 (8)
(Inorganic) Phosphate[b]	mmol/kg/day (mmol/L)	2 (20)	2 (16)	2 (16)	2 (31)
INFUVITE® PEDIATRIC Multivitamin (mL/day) (Sandoz Inc.)		1.5	3.25	3.25	5
Zinc Sulfate (mcg/kg/day) (American Regent Inc.)		400	400	400	50
Selenium (selenious acid) (mcg/kg/day) (American Regent Inc.)		2	2	2	2
Copper (cupric chloride) (mcg/kg/day) (Hospira)		20	20	20	20

[a]The total sodium content includes sodium chloride and sodium phosphates.

[b]The phosphate content is entirely provided as sodium phosphate.

Any significant change in pH from additives not listed compared to what has been evaluated in this study may affect compatibility.

Omegaven®

(fish oil triglycerides) injectable emulsion, for intravenous use

Table 3: Medication Compatibility Tested With Omegaven and TrophAmine 10% via Simulated Y-Site

Reference Table 2 for complete PN admixtures tested with each medication.

Drug Infusion Via Y-Site		
Admixture	**1**	**2**
Patient Weight (kg)	0.5	2
Drug Compounded Concentration (Manufacturer)	**Compatible/Incompatible (C/I)**	
Ampicillin 10 mg/mL (Fresenius Kabi)	C	C
Cefepime 20 mg/mL (B. Braun)	I	I
Cisatracurium Besylate 0.1 mg/mL (Fresenius Kabi)	C	C
Dexmedetomidine 4 mcg/mL (Fresenius Kabi)	C	C
Dopamine HCl 1600 mcg/mL (Hospira/Pfizer)	I	C
Famotidine 0.4 mg/mL (Baxter)	C	C
Fluconazole 2 mg/mL (Hospira/Pfizer)	C	C
Gentamicin 2 mg/mL (Baxter)	C	C
Meropenem 20 mg/mL (B. Braun)	I	I
Metronidazole 5 mg/mL (Hospira/Pfizer)	C	I
Micafungin 1 mg/mL (Fresenius Kabi)	I	I
Norepinephrine 16 mcg/mL (Baxter)	C	C
Vancomycin 5 mg/mL (Hospira/Pfizer)	I	C

Omegaven®

(fish oil triglycerides) injectable emulsion, for intravenous use

Table 4: Medication Compatibility Tested With Omegaven and Premasol 10% via Simulated Y-Site

Reference Table 2 for complete PN admixtures tested with each medication.

Drug Infusion Via Y-Site	
Admixture	**3**
Patient Weight (kg)	2
Drug Compounded Concentration (Manufacturer)	**Compatible/Incompatible (C/I)**
Ampicillin 10 mg/mL (Fresenius Kabi)	C
Cefepime 20 mg/mL (B. Braun)	C
Cisatracurium Besylate 0.1 mg/mL (Fresenius Kabi)	C
Dexmedetomidine 4 mcg/mL (Fresenius Kabi)	C
Dopamine HCl 1600 mcg/mL (Hospira/Pfizer)	C
Famotidine 0.4 mg/mL (Baxter)	C
Fluconazole 2 mg/mL (Hospira/Pfizer)	C
Gentamicin 2 mg/mL (Baxter)	C
Meropenem 20 mg/mL (B. Braun)	I
Metronidazole 5 mg/mL (Hospira/Pfizer)	I
Micafungin 1 mg/mL (Fresenius Kabi)	I
Norepinephrine 16 mcg/mL (Baxter)	C
Vancomycin 5 mg/mL (Hospira/Pfizer)	C

Omegaven®

(fish oil triglycerides) injectable emulsion, for intravenous use

Table 5: Medication Compatibility Tested With Omegaven and Travasol 10% via Simulated Y-Site

Reference Table 2 for complete PN admixtures tested with each medication.

Drug Infusion Via Y-Site	
Admixture	**4**
Patient Weight (kg)	29
Drug Compounded Concentration (Manufacturer)	**Compatible/Incompatible (C/I)**
Ampicillin 10 mg/mL (Fresenius Kabi)	C
Cefepime 20 mg/mL (B. Braun)	C
Cisatracurium besylate 0.1 mg/mL (Fresenius Kabi)	C
Dexmedetomidine 4 mcg/mL (Fresenius Kabi)	C
Dopamine HCl 1600 mcg/mL (Hospira/Pfizer)	C
Famotidine 0.4 mg/mL (Baxter)	I
Fluconazole 2 mg/mL (Hospira/Pfizer)	C
Gentamicin 2 mg/mL (Baxter)	C
Meropenem 20 mg/mL (B. Braun)	I
Metronidazole 5 mg/mL (Hospira/Pfizer)	C
Micafungin 1 mg/mL (Fresenius Kabi)	I
Norepinephrine 16 mcg/mL (Baxter)	C
Vancomycin 5 mg/mL (Hospira/Pfizer)	C

Omegaven®

(fish oil triglycerides) injectable emulsion, for intravenous use

The information presented in this document is not a substitute for clinical or professional judgment. Please review the Full Prescribing Information before administering Omegaven.

INDICATIONS AND USAGE

Omegaven is indicated as a source of calories and fatty acids in pediatric patients with parenteral nutrition-associated cholestasis (PNAC).

Limitations of Use

Omegaven is not indicated for the prevention of PNAC. It has not been demonstrated that Omegaven prevents PNAC in parenteral nutrition (PN)-dependent patients.

It has not been demonstrated that the clinical outcomes observed in patients treated with Omegaven are a result of the omega-6:omega-3 fatty acid ratio of the product.

IMPORTANT SAFETY INFORMATION

Protect the admixed PN solution from light. Prior to administration, correct severe fluid and electrolyte disorders and measure serum triglycerides to establish a baseline level. Initiate dosing in PN-dependent pediatric patients as soon as direct or conjugated bilirubin levels are 2 mg/dL or greater. The recommended nutritional requirements of fat and recommended dosages of Omegaven to meet those requirements for pediatric patients are provided in Table 1, along with recommendations for the initial and maximum infusion rates. Administer Omegaven until direct or conjugated bilirubin levels are less than 2 mg/dL or until the patient no longer requires PN.

Table 1: Recommended Pediatric Dosage and Infusion Rate

Nutritional Requirements	Direct Infusion Rate	
Recommended Initial Dosage and Maximum Dosage	Initial	Maximum
1 g/kg/day; this is also the maximum daily dose	0.2 mL/kg/hour for the first 15 to 30 minutes; gradually increase to the required rate after 30 minutes	1.5 mL/kg/hour

Omegaven is contraindicated in patients with known hypersensitivity to fish or egg protein or to any of the active ingredients or excipients, severe hemorrhagic disorders due to a potential effect on platelet aggregation, severe hyperlipidemia, or severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglyceride concentrations greater than 1,000 mg/dL).

Clinical Decompensation with Rapid Infusion of Lipid Injectable Emulsions in Neonates and Infants: Acute respiratory distress, metabolic acidosis, and death after rapid infusion of intravenous lipid emulsions have been reported. Hypertriglyceridemia was commonly reported. Strictly adhere to the recommended total daily dosage; the hourly infusion rate should not exceed 1.5 mL/kg/hour. Carefully monitor the infant's ability to eliminate the infused lipids from the circulation (e.g., measure serum triglycerides and/or plasma free fatty acid levels). If signs of poor clearance of lipids from the circulation occur, stop the infusion and initiate a medical evaluation.

Hypersensitivity Reactions: Monitor for signs or symptoms. Discontinue infusion if reaction occurs.

Infections, Fat Overload Syndrome, Refeeding Syndrome, and Hypertriglyceridemia: Monitor for signs and symptoms; monitor laboratory parameters.

Aluminum Toxicity: Increased risk in patients with renal impairment, including preterm infants.

Monitoring and Laboratory Tests: Routine laboratory monitoring is recommended, including monitoring for essential fatty acid deficiency.

The most common adverse drug reactions (> 15%) are vomiting, agitation, bradycardia, apnea, and viral infection.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176, option 5, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

This Important Safety Information does not include all the information needed to use Omegaven safely and effectively. Please see Full Prescribing Information for Omegaven (fish oil triglycerides) injectable emulsion, for intravenous use at www.FreseniusKabiNutrition.com/OmegavenPI.

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If you have any questions about the testing results, and for more insights into how to use this information for your PN patients, please contact Fresenius Kabi Medical Information at 1.800.551.7176 (option 4) or email Nutrition.MedInfo.USA@fresenius-kabi.com

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Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047
Phone: 1.888.386.1300
www.fresenius-kabi.com/us