FRESENIUS KABI

pn3

Omegaven®

(fish oil triglycerides) injectable emulsion, for intravenous use

Designed with **fish oil** for the tiniest patients[1]

INDICATION

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.

Contraindications

Known hypersensitivity to fish or egg protein or to any of the active ingredients or excipients. Severe hemorrhagic disorders. Severe disorders of lipid metabolism characterized by hypertriglyceridemia (with serum triglycerides greater than 1,000 mg/dL).

Please see Important Safety Information on page 7.

More fish oil. More omega-3s

than any other lipid injectable emulsion (ILE) on the market.[2]

Eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) rich: The mean content of the two major fatty acid components in 10 g/100 mL of Omegaven are 2.0 g EPA and 1.9 g DHA[1]

Essential fatty acid (EFA) provision: In an open-label single-center clinical trial (n = 123), Omegaven-treated patients had a median triene:tetraene ratio of 0.02 (interquartile range: 0.01-0.03) at baseline and at the end of the study. Omegaven contains a mean content of 0.31 g linoleic acid, 0.13 g alpha-linolenic acid, and 0.25 g arachidonic acid per 100 mL[1]

The only one of its kind

Omegaven is the first and only fish oil lipid emulsion (FOLE) approved as a source of calories and fatty acids in pediatric patients with parenteral nutrition-associated cholestasis (PNAC)[1]

Improvement in liver function parameters was observed in Omegaven-treated patients[1,2]

- **Associated with cost savings** vs 100% soybean oil lipid emulsion (SOLE) from a published simulation model of historical control data[3]
- Patients achieved **age-appropriate growth** during treatment[1,2]

PNAC (commonly defined as direct or conjugated bilirubin [DBIL] >2 mg/dL after >2 weeks on parenteral nutrition [PN]) is an early sign of PN-related liver injury and a known risk for progressive liver disease.[4-9]

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Liver parameters improved over time[10]

Pair-matched study compares FOLEs and SOLEs in pediatric PN patients

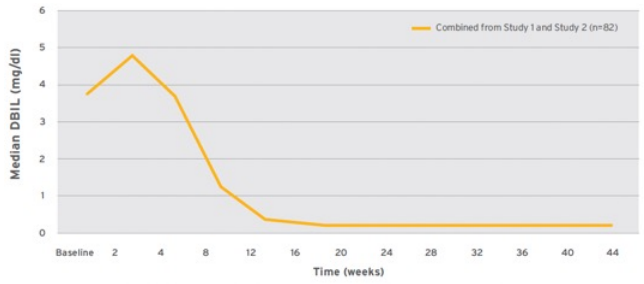
Original study[1,10]

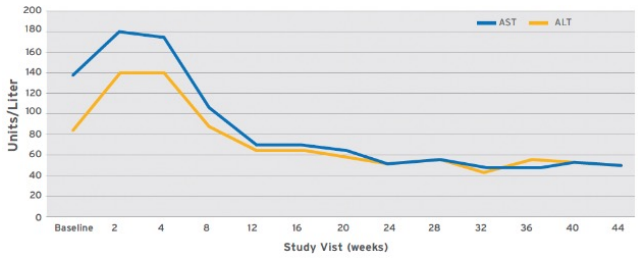
- 2 non-randomized, open-label, single-center clinical trials
- Both studies were conducted at large intestinal rehabilitation centers — Boston Children's Hospital (BCH) and Texas Children's Hospital (TCH) — and included historical control patients who received SO intravenous lipid emulsion (ILE) between 1999 and 2012 at BCH, TCH, or University of California Los Angeles
  - BCH and UCLA: patients <2 years of age; PN ≥30 days; DBIL ≥2 mg/dL
  - TCH: patients <5 years of age; PN ≥14 days; DBIL ≥2 mg/dL
- Study was not adequately designed to demonstrate noninferiority or superiority of Omegaven to the soybean oil-based lipid emulsion comparator[1]

Addition of historical control data[10]

- Analysis of pair-matched recipients of a fish oil lipid emulsion (FOLE) (n = 82) to soybean oil lipid emulsion (SOLE) recipients (n = 41) using baseline serum direct bilirubin levels and postmenstrual age
  - Growth measures (changes in body weight, height/length, and head circumference), prealbumin, triglycerides, and glucose were compared between groups over time using the Wilcoxon rank-sum test

DBIL levels were lowered in Omegaven-treated patients[1,2]





- Median DBIL first increased, then declined from week 4; over time, median DBIL levels reached values close to the normal range of <0.3 mg/dL; at the end of the studies, the median DBIL level for Omegaven-treated patients was 0.60 mg/dL
- The Kaplan Meier estimate of the median time for DBIL values to return to <2.0 mg/dL was approximately 5.7 weeks
- 113/189 Omegaven-treated patients reached DBIL levels <2 mg/dL and aspartate aminotransferase (AST) or alanine aminotransferase (ALT) levels <3 times the upper limit of normal at end of study

12/189 (6%) Omegaven-treated patients were listed for liver transplantation[1]

- **3** (2%) were taken off the waiting list after cholestasis resolved; **9** (5%) received a transplant after a median (range: 25 days-6 months) of 121 days of treatment; **1** patient was listed 18 days before treatment, and **11** patients after a median (range: 2 days-8 months) of 42 days of treatment

Liver transplants in the pair-matched population (P<0.0001)[2]: **FOLE**[10] 0 out of 82 (0%) vs **SOLE** 9 out of 41 (22%)

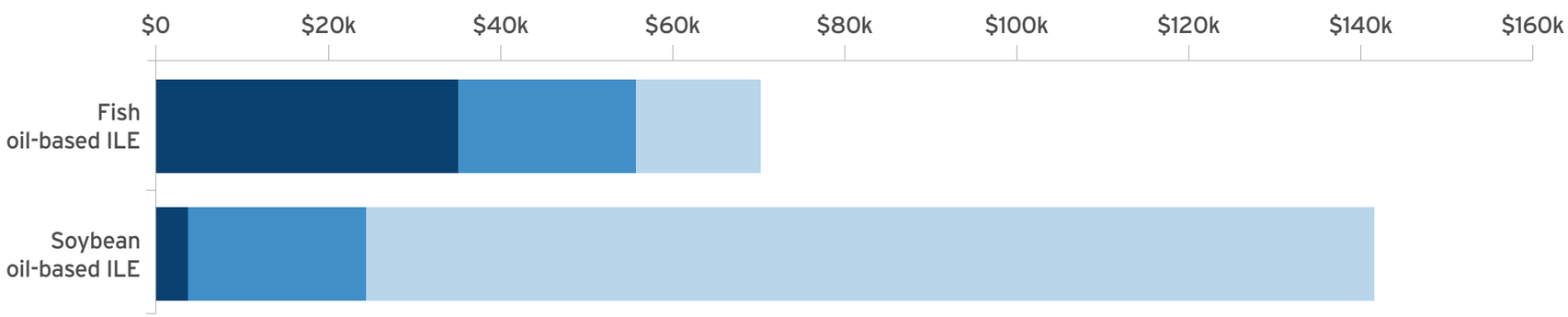
Risk of Infections, Fat Overload Syndrome, Refeeding Syndrome, and Hypertriglyceridemia: Monitor for signs and symptoms; monitor laboratory parameters.[1]

Please see Important Safety Information on page 7.

Cost-effectiveness modeling study estimated >$70K cost savings with Omegaven per patient simulation[3]

A recent cost-effectiveness study published in the *Journal of Parenteral and Enteral Nutrition* compared 2 lipid emulsions in pediatric patients with PNAC

Breakdown of total cost



	Fish oil-based ILE	Soybean oil-based ILE
Nutrition	$34,995	$3,572
Adverse events	$20,596	$20,594
Transplantation	$14,257	$117,440

Adapted from Povero M, et al. *JPEN J Parenter Enteral Nutr*. 2025;49(2):180-188.[3]

Study purpose and design

- A discrete simulation model was developed to evaluate cost effectiveness by simulating outcomes and estimating healthcare costs in pediatric patients with PNAC receiving either Omegaven (1 g/kg/day) or Intralipid® 20% (lipid injectable emulsion), for intravenous use (1.9 g/kg/day) over a time horizon of 6 years
- Model inputs were derived from the integrated analysis of the per-protocol population from 2 US Phase 3 trials

Per-protocol cost-effectiveness analysis

- Discrete event model simulated outcomes for 10,000 patients extrapolated over a time horizon of 6 years
- The costs considered in the model were related to treatment period events including cost of PN, liver transplantation, and adverse events (central line infection, sepsis, thrombocytopenia, and coagulopathy)

Results

- The total cost associated* with Omegaven was $69,847 USD per patient simulation compared with $141,605 USD for Intralipid, for an overall cost savings of $71,757 (15.7% avoidance of liver transplantation, 4.8% reduction in adverse events; product cost of Omegaven is higher)
- Costs of adverse events similar between the two groups
- Results confirmed with probabilistic sensitivity analysis (95% CI)
- Cost of Omegaven was offset by the reduction in costs by avoidance of liver transplant

Study limitations

- Data were estimated using a historical cohort that received Intralipid, resulting in a difference of treatment eras
- Only the mortality rate was reported in the combined database, with no overall survival curves available
- Lack of longitudinal data for children with PNAC and precise data to estimate the cost of treatment for specific adverse events

The findings from the study support the use of Omegaven in pediatric patients with PNAC who require PN and may lead to cost savings compared to Intralipid.

*Based on US economic data.

This research was funded by Fresenius Kabi GmbH.

Data are from non-randomized, historical comparisons and no conclusions of superiority should be drawn.

Studies were not adequately designed to demonstrate noninferiority or superiority of Omegaven to Intralipid.[1]

Risk of Infections: Monitor for signs and symptoms; monitor laboratory parameters.[1]

Most common adverse drug reactions (>15%) are: vomiting, agitation, bradycardia, apnea and viral infection.[1]

Growth maintained during treatment[10]

Pediatric patients treated with Omegaven attained and maintained age-appropriate growth.[10] **Median body weight** and **head circumference** z-scores remained within -1.0 to 1.0 from week 28 onward in Omegaven-treated patients, with no significant differences vs SOLE at any time point.[10] 84% of Omegaven-treated patients received concurrent lipids from enteral nutrition.[1]

Additional outcomes[1]: In a study with 123 patients, 6 patients treated with Omegaven for up to 2 years, there were no biochemical signs of essential fatty acid deficiency reported.

Monitoring and Laboratory Tests: Routine laboratory monitoring is recommended, including monitoring for essential fatty acid deficiency.[1]

Appropriate initiation of Omegaven is key

Dosing – Initiate in PN-dependent pediatric patients as soon as direct or conjugated DBIL levels are **≥2 mg/dL[1]**

Duration – Administer Omegaven until DBIL levels are less than 2 mg/dL or until the patient no longer requires PN[1]

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

Recommended dosage depends on age, energy expenditure, clinical status, body weight, tolerance, ability to metabolize, and consideration of additional energy sources given to the patient.[1]

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.[1]

 Please see Important Safety Information on page 7.

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

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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.

INDICATIONS AND USAGE

Intralipid is indicated as a source of calories and essential fatty acids for patients requiring parenteral nutrition (PN) and as a source of essential fatty acids for prevention of essential fatty acid deficiency (EFAD).

IMPORTANT SAFETY INFORMATION

Intralipid 20% Pharmacy Bulk Package (lipid injectable emulsion), for intravenous use and Intralipid 30% Pharmacy Bulk Package (lipid injectable emulsion), for intravenous use are for admixing use only and are not intended for direct intravenous administration.

Intralipid 30% (lipid injectable emulsion) Pharmacy Bulk Package must be combined with other PN fluids. Diluting Intralipid 30% with an intravenous fluid such as normal saline or other diluent does not produce a dilution that is equivalent in composition to Intralipid 10% or 20% intravenous lipid emulsions. Therefore, diluents other than dextrose and amino acids should not be used to prepare admixtures for direct intravenous administration. When Intralipid 30% is diluted, strictly adhere to the recommended total daily dosage; the hourly infusion rate should **not** exceed 0.125 g/kg/hour for neonates and infants.

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. Protect the admixed PN solution from light. Use a 1.2 micron in-line filter during administration.

Dosage for Intralipid 20%

Age	Direct Infusion Rate	
	Initial Recommended Dosage	Maximum Dosage
Birth to 2 years of age (including preterm and term neonates)	0.5 g/kg/day	3 g/kg/day
Pediatric patients 2 to <12 years of age	1 to 2 g/kg/day	2.5 g/kg/day
Pediatric patients 12 to 17 years of age	1 g/kg/day	2 g/kg/day
Adults	1 g/kg/day (stable) ≤1 g/kg/day (critically ill)	2.5 g/kg/day

Intralipid is contraindicated in patients with:

- Known hypersensitivity to egg, soybean, or peanut, or any of the active ingredients or excipients
- Severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglyceride > 1,000 mg/dL)

Risk of Clinical Decompensation with Rapid Infusion of Lipid Injectable Emulsion in Neonates and Infants: Acute respiratory distress, metabolic acidosis, and death after rapid infusion of lipid injectable emulsions have been reported. When Intralipid 30% is diluted, strictly adhere to the recommended total daily dosage; the hourly infusion rate should not exceed 0.125 g/kg/hour for neonates and infants.

Risk of Parenteral Nutrition-Associated Liver Disease (PNALD): Increased risk in patients who receive PN for extended periods of time, especially preterm neonates. Monitor liver function 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, and Hypertriglyceridemia: 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 pyrexia. Most common adverse drug reactions (≥5%) from clinical trials in pediatric patients were anemia, vomiting, increased gamma-glutamyltransferase, and cholestasis.

Vitamin K Antagonists (e.g., warfarin): Anticoagulant activity may be counteracted; increase monitoring of coagulation parameters.

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This Important Safety Information does not include all the information needed to use Intralipid safely and effectively. Please see full prescribing information, for intravenous use at www.FreseniusKabiNutrition.com/Intralipid20PI and www.FreseniusKabiNutrition.com/Intralipid30PI.

Omegaven®

(fish oil triglycerides) injectable emulsion, for intravenous use

ORDERING INFORMATION		HCPCS Code: B4187
NDC	63323-205-50	63323-205-00
Bottle Size	50 mL	100 mL
Bottles/Case	10	10

Learn more at **Omegaven3.com**

To Order: 1-888-386-1300

Med Info phone: 1-800-551-7176 (option 4)

Med Info email: nutrition.medinfo.USA@fresenius-kabi.com

For information on coding and billing, visit www.freseniuskabinutrition.com/billing-coding/

Sources: 1. Omegaven Prescribing Information, Fresenius Kabi USA, LLC. 2025. **2.** Data on file. **3.** Povero M, Gura KM, Premkumar MH, Pradelli L, Puder M, Calkins KL. Fish oil lipid emulsion compared with soybean oil lipid emulsion in pediatric patients with parenteral nutrition-associated cholestasis: A cost-effectiveness study. *JPEN J Parenter Enteral Nutr.* 2025;49(2):180-188. **4.** Cahova M, Bratova M, Wohl P. Parenteral Nutrition-Associated Liver Disease: The Role of the Gut Microbiota. *Nutrients*. 2017;9(9):987. Published 2017 Sep 7. **5.** Hojsak I, Colomb V, Braegger C, et al. ESPGHAN Committee on Nutrition Position Paper. Intravenous Lipid Emulsions and Risk of Hepatotoxicity in Infants and Children: a Systematic Review and Meta-analysis. *J Pediatr Gastroenterol Nutr.* 2016;62(5):776-792. **6.** Lauriti G, Zani A, Aufieri R, et al. Incidence, prevention, and treatment of parenteral nutrition-associated cholestasis and intestinal failure-associated liver disease in infants and children: a systematic review. *JPEN J Parenter Enteral Nutr.* 2014;38(1):70-85. **7.** Lapillonne A, Fidler Mis N, Goulet O, et al. ESPGHAN/ESPEN/ESPR/CSPEN guidelines on pediatric parenteral nutrition: Lipids. *Clin Nutr.* 2018;37(6 Pt B):2324-2336. **8.** Gupta K, Wang H, Amin SB. Parenteral Nutrition-Associated Cholestasis in Premature Infants: Role of Macronutrients. *JPEN J Parenter Enteral Nutr.* 2016;40(3):335-341. **9.** Tillman EM, Helms RA. Omega-3 long chain polyunsaturated Fatty acids for treatment of parenteral nutrition-associated liver disease: a review of the literature. *J Pediatr Pharmacol Ther.* 2011;16(1):31-38. **10.** Gura K, Premkumar MH, Calkins KL, Puder M. Intravenous Fish Oil Monotherapy as a Source of Calories and Fatty Acids Promotes Age-Appropriate Growth in Pediatric Patients with Intestinal Failure-Associated Liver Disease. *J Pediatr*. 2020;219:98-105.e4.

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