

Nourish and nurture with **SMOFlipid**[®] and **Omegaven**[®]

Lipid injectable emulsions (ILEs) in
pediatric parenteral nutrition (PN)



From the first feed to long-term nutrition, pediatric patients depend on the right lipid at the right time.

SMOFlipid is indicated in pediatric patients, including term and preterm neonates, as a source of calories and essential fatty acids for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.¹

Omegaven is indicated as a source of calories and fatty acids in pediatric patients with PN-associated cholestasis (PNAC).²

Omegaven 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.

Omegaven and SMOFlipid are contraindicated in patients with known hypersensitivity to any of the active ingredients or excipients, severe hemorrhagic disorders (Omegaven), severe hyperlipidemia or severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglyceride concentrations greater than 1,000 mg/dL).

SMOFlipid[®]
(lipid injectable emulsion),
for intravenous use

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

Please see Full Important Safety Information for SMOFlipid and Omegaven on pages 6-7.

pn4

SMOFlipid®
(lipid injectable emulsion),
for intravenous use



Nourish from the start with **more** oil sources

SMOFlipid is chosen by healthcare providers in 93 countries worldwide* and provides a proprietary blend of 4 oils: **S**oybean oil (SO), 30%; **M**edium-chain triglycerides (MCTs), 30%; **O**live oil, 25%; **F**ish oil, 15%

*Data on file 12/1/25.

PNAC may develop less frequently in pediatric patients fed a 4-oil ILE vs 100% SO ILE[†]

Study design

The hepatic safety of SMOFlipid was evaluated in a randomized, active-controlled, double-blind, parallel group, multi-center study that included 152 neonates and 9 patients ranging in age from 29 to 153 days who were expected to require PN for at least 28 days.¹

Results

PNAC mostly occurred in patients who received treatment for more than 28 days.¹

- **2.4%** (2/83) of SMOFlipid-treated patients developed PNAC.
- **11.5%** (9/78) of SO lipid emulsion-treated patients developed PNAC.

[†]There is increasing uncertainty in the estimate of the cumulative incidence as fewer patients are at risk over the course of 84 days.¹

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.¹

Do not exceed the maximum infusion rate of 0.75 mL/kg/hour in pediatric patients.¹

SAFETY CONSIDERATIONS

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.



2 Please see Full Important Safety Information for SMOFlipid on page 6.

pn³

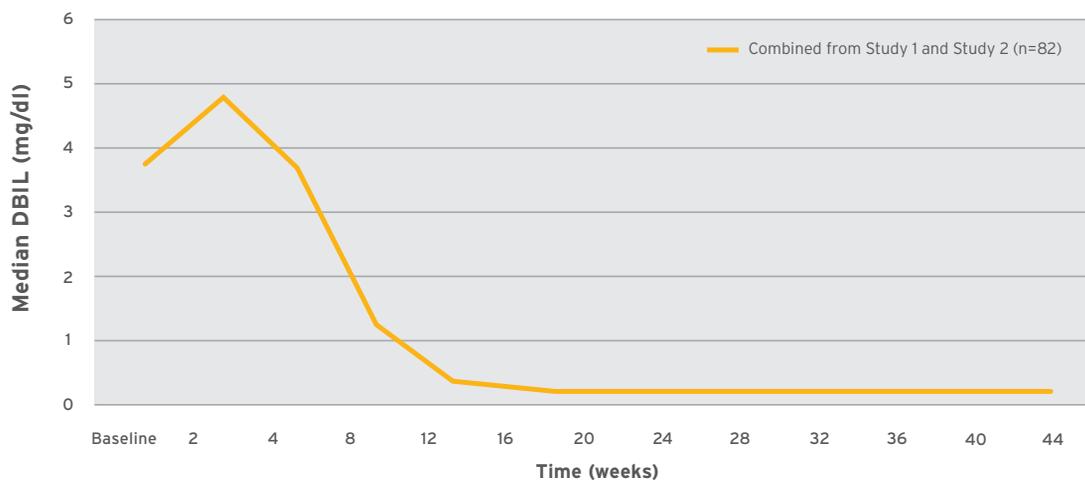
Omegaven[®]
(fish oil triglycerides) injectable emulsion, for intravenous use



Nurture PNAC patients with Omegaven, providing **more** omega-3s than any other ILE on the market³

The only 100% fish oil ILE on the market, Omegaven is indicated as a source of calories and fatty acids in pediatric patients with PNAC. In clinical studies²:

- 60% of Omegaven-treated patients achieved direct bilirubin (DBil) levels <2 mg/dL, with reductions in aspartate aminotransferase (AST) and alanine aminotransferase (ALT) levels <3 times the upper limit of normal.
- The studies were not adequately designed to demonstrate noninferiority or superiority of Omegaven to the SO-based lipid emulsion comparator.



DBil levels may fluctuate during therapy. Continue Omegaven until DBil is <2 mg/dL or PN is discontinued, as recommended in the Prescribing Information. The Kaplan Meier estimate of the median time for DBil values to return to <2.0 mg/dL was approximately 5.7 weeks.²

SAFETY CONSIDERATIONS

Omegaven 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.

Please see Full Important Safety Information for Omegaven on page 7.

Clinical nutrition for the moments that matter

The following profiles are hypothetical and provided for illustrative purposes only.

Moment 1: initial nourishment

Lucy, preterm infant, 32 weeks gestational age (GA), 1.6 kg, requires PN

PN course: Postsurgical recovery, started on SMOFlipid to provide essential fatty acids (EFAs) and calories.

Decision point: Continue daily SMOFlipid; monitor bilirubin and liver function weekly.



SMOFlipid dosing recommendations¹

Do not exceed the maximum infusion rate listed in table below.

Age	Nutritional Requirements	Direct Infusion Rate	
	Recommended Initial Dosage and Maximum Dosage	Initial	Maximum
Birth to 2 years of age (including preterm and term neonates)	Initial 0.5 to 1 g/kg/day not to exceed 3 g/kg/day	0.1 to 0.2 mL/kg/hour for the first 15 to 30 minutes; gradually increase to the required rate after 30 minutes	0.75 mL/kg/hour
Pediatric patients 2 to <12 years of age	Initial 1 to 2 g/kg/day not to exceed 3 g/kg/day	0.2 to 0.4 mL/kg/hour for the first 15 to 30 minutes; gradually increase to the required rate after 30 minutes	
Pediatric patients 12 to 17 years of age	Initial 1 g/kg/day not to exceed 2.5 g/kg/day		

Moment 2: nurture during PNAC

Ethan, 5-month-old with intestinal failure and PNAC

PN course: Rising bilirubin >2 mg/dL; switched from SO ILE to Omegaven.

Decision point: Continue Omegaven until bilirubin normalizes or until PN is no longer indicated.



Omegaven dosing recommendations²

Do not exceed the maximum infusion rate listed in table below.

Nutritional Requirements	Direct Infusion Rate	
	Initial	Maximum
Recommended Initial Dosage and Maximum Dosage		
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

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.

4 Please see Full Important Safety Information for SMOFlipid and Omegaven on pages 6-7.

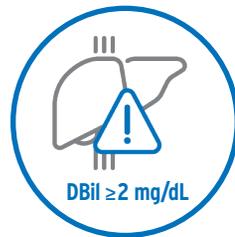
Moment 3: continued nourishment

Nora, 2-year-old, recently had liver surgery and requires PN for EFAs and calories

PN course:



Daily SMOFlipid initiated post-op as part of PN



Switch to daily Omegaven



Switch back to daily SMOFlipid until she no longer requires PN

or

Continue on daily Omegaven until she no longer requires PN

Monitor throughout treatment^{1,2}:

- Serum triglycerides
- Fluid and electrolyte status
- Blood glucose
- Liver and kidney function
- Coagulation parameters
- Complete blood count (including platelets)

Monitor for essential fatty acid deficiency (EFAD)

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 $>1,000 \text{ mg/dL}$).

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 $1,000 \text{ mg/dL}$).

Please see Full Important Safety Information for SMOFlipid and Omegaven on pages 6-7.

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

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	
	Initial	Maximum
Recommended Initial Dosage and Maximum Dosage		
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.

Clinical nutrition designed to support the moments that matter



SMOFlipid®
(lipid injectable emulsion), for intravenous use

ORDERING INFORMATION				
NDC	63323-820-00	63323-820-74	63323-820-50	63323-820-10*
Bag Size	100 mL	250 mL	500 mL	1000 mL
Bags/Case	10	10	12	6

*Pharmacy Bulk Package.



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

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



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. SMOFlipid Prescribing Information, Fresenius Kabi USA, LLC. 2025. 2. Omegaven Prescribing Information, Fresenius Kabi USA, LLC. 2025. 3. Data on file.

Please see Full Important Safety Information for SMOFlipid and Omegaven on pages 6-7.



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