

Fresenius Kabi USA **Nutrition**

As a global innovator in clinical nutrition,  
we create innovations that nourish

Explore the full portfolio of **lipid injectable emulsions (ILEs)**  
for parenteral nutrition (PN) from the U.S. market leader in ILEs.<sup>1</sup>



*We're proud to support marine conservation by ensuring  
that the fish oil in our products is sustainably sourced.*

# Omegaven®

(fish oil triglycerides) injectable emulsion

## A first in PN from the leaders in PN

Omegaven is the **FIRST** and **ONLY fish-oil ILE** for pediatric patients with parenteral nutrition-associated cholestasis (PNAC) in the U.S.<sup>2</sup>

- Omegaven is a source of calories and fatty acids for pediatric patients with PNAC<sup>2</sup>
- Patients receiving Omegaven attained and maintained age-appropriate growth<sup>2</sup>
- Omegaven-treated patients experienced improvement in liver function parameters<sup>2</sup>
  - During clinical trials, 113 out of 189 of Omegaven-treated patients reached direct bilirubin (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<sup>2</sup>



**Patients in our clinical trials conducted at Boston Children's Hospital and Texas Children's Hospital received Omegaven for a median of 2.7 months and up to 8 years.<sup>2</sup>**

**ESPGHAN/ESPEN/ESPR/CSPEN guidelines for pediatric patients<sup>3</sup>:**

"In pediatric patients, intravenous lipid emulsions (ILEs) should be an integral part of parenteral nutrition (PN) either exclusive or complementary to enteral feeding (LoE 1-, RG A, strong recommendation for)."

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 hyperlipidemia or severe disorders of lipid metabolism with serum triglycerides greater than 1,000 mg/dL.

## Omegaven has been shown to reduce liver injury and transplantation in a recent study<sup>4</sup>

**Study Objective:** To compare aminotransferase with platelet ratio index (APRI), liver transplantation, and mortality rates between children with intestinal failure-associated liver disease (IFALD) who received fish-oil lipid emulsion (FOLE [Omegaven]) or soybean-oil lipid emulsion (SOLE [Intralipid]).

- Results:**
- Among FOLE recipients, 65% experienced cholestasis resolution vs. 16% of SOLE ( $P<0.0001$ )
  - APRI scores improved in FOLE (1.235 at baseline to 0.810 at cholestasis resolution and 0.758 at end of study,  $P<0.02$ ) but worsened in SOLE recipients (0.540 at baseline to 2.564 at cholestasis resolution and 2.098 at end of study,  $P\leq0.0003$ ).
  - Liver transplantation was reduced in FOLE vs. SOLE (4% vs. 12%,  $P=0.0245$ )
  - Death rates were similar (FOLE vs. SOLE: 10% vs. 14% at direct or conjugated bilirubin [DBIL] of 2 mg/dL; 17% vs. 23% at a DB of 12.87 mg/dL,  $P=0.36$  for both)

**Conclusion:**

This demonstrates that FOLE may be the preferred parenteral lipid emulsion in children with IFALD when DBIL reaches 2 mg/dL.



ORDERING INFORMATION		
Bottle Size	50 mL single-dose glass bottle	100 mL single-dose glass bottle
NDC Code	63323-205-50	63323-205-00
Bottles/Carton	10	10



**SMOFlipid®**  
Lipid Injectable Emulsion, USP 20%

Discover the SMOF difference

Brought to you by a global innovator in parenteral nutrition,  
**SMOFlipid** is a unique blend of 4 oil sources.<sup>5</sup>



**Soybean oil 30%** (omega-6)  
Provides essential fatty acids.



**Medium-chain triglycerides (MCT) 30%**  
A source of rapidly available energy and clear faster from the bloodstream than other fatty acids.<sup>6,7</sup>



**Olive oil 25%** (omega-9)  
Supplies monounsaturated fatty acids and contains small amounts of linoleic acid and alpha-linolenic acid.



**Fish oil 15%** (omega-3)  
A source of omega-3 fatty acids, including EPA and DHA.<sup>8</sup>

SMOFlipid is indicated in adults as a source of calories and essential fatty acids for PN when oral or enteral nutrition is not possible, insufficient, or contraindicated. **Limitations of Use:** The omega-6:omega-3 fatty acid ratio and medium-chain triglycerides in SMOFlipid have not been shown to improve clinical outcomes compared to other intravenous lipid emulsions.

**Contraindications:** Known hypersensitivity to fish, egg, soybean, or peanut protein, or to any of the active ingredients or excipients. Severe hyperlipidemia or severe disorders of lipid metabolism with serum triglycerides >1,000 mg/dL.

**WARNING: DEATH IN PRETERM INFANTS**

- Deaths in preterm infants after infusion of intravenous lipid emulsions have been reported in the medical literature.
- Autopsy findings included intravascular fat accumulation in the lungs.
- Preterm infants and low-birth-weight infants have poor clearance of intravenous lipid emulsion and increased free fatty acid plasma levels following lipid emulsion infusion.



This **unique 4-oil blend** aligns with recommended ratios

Lipid Emulsion	Ratio of omega-6: omega-3 Fatty Acids
Recommendations <sup>9-12</sup>	2:1 to 4:1
Soybean-Oil Emulsion	7:1
MCT/LCT Emulsion	7:1
Olive Oil/ Soybean-Oil Emulsion	9:1
SMOFlipid <sup>5</sup>	2.5:1

MCT=medium-chain triglyceride; LCT=long-chain triglyceride

- Patients receiving soybean oil-based lipid emulsions may be exposed to high levels of omega-6 polyunsaturated fatty acids and a virtual absence of omega-3 fatty acids<sup>9</sup>
- The omega-6:omega-3 fatty acid ratio in SMOFlipid has not been shown to improve clinical outcomes compared to other ILEs<sup>5</sup>

Clinical guidelines support the use of alternative-oil ILEs

**ASPEN position paper<sup>13</sup>:**

“Alternative oil-based IVFEs are safe and effective alternatives to SO IVFEs for a source of energy and essential [fatty acids] and may have potential biochemical and/or clinical benefits.”

**Canadian Critical Care Nutrition guidelines<sup>14</sup>:**

“When parenteral nutrition with intravenous lipids is indicated, IV lipids that reduce the load of  $\omega$ -6 fatty acids/soybean oil emulsions should be considered.”

**ESPEN guidelines for critically ill patients<sup>15</sup>:**

“The administration of intravenous lipid emulsions should be generally a part of PN.”

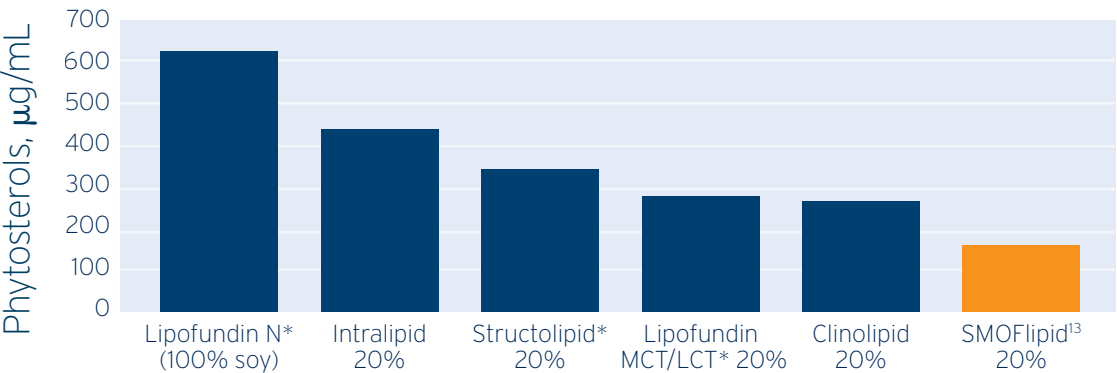
**ESPEN guidelines for surgical patients<sup>16</sup>:**

“Postoperative parenteral nutrition including  $\omega$ -3- fatty acids should be considered only in patients who cannot be adequately fed enterally and, therefore, require parenteral nutrition.”



# Phytosterols in PN

## ILEs and Phytosterol Content



Xu Z, et al. *Nutrients*. 2012;4:904-921.<sup>17</sup>  
\*Not approved in the U.S.  
†Data on file.

- The predominant phytosterol in these emulsions was beta-sitosterol, the major phytosterol in plant oils (eg, soybean oil, olive oil, sunflower oil, etc.)



Per milliliter, **SMOFlipid contains the lowest amount of phytosterols in commercially available ILEs** indicated for adults<sup>17,18</sup>

SMOFlipid is indicated in adults as a source of calories and essential fatty acids for PN when oral or enteral nutrition is not possible, insufficient, or contraindicated. **Limitations of Use:** The omega-6:omega-3 fatty acid ratio and medium-chain triglycerides in SMOFlipid have not been shown to improve clinical outcomes compared to other intravenous lipid emulsions. **Contraindications:** Known hypersensitivity to fish, egg, soybean, or peanut protein, or to any of the active ingredients or excipients. Severe hyperlipidemia or severe disorders of lipid metabolism with serum triglycerides >1,000 mg/dL.

### WARNING: DEATH IN PRETERM INFANTS

- Deaths in preterm infants after infusion of intravenous lipid emulsions have been reported in the medical literature.
- Autopsy findings included intravascular fat accumulation in the lungs.
- Preterm infants and low-birth-weight infants have poor clearance of intravenous lipid emulsion and increased free fatty acid plasma levels following lipid emulsion infusion.



# Give your patients the one and only SMOF

- Meets the essential fatty acid requirements of adults<sup>5</sup>
- Contains fish oil, which is rich in omega-3s
- Demonstrated safety and tolerability<sup>19,20</sup> in more than 6 million patients worldwide<sup>‡</sup>
- AST, ALT, and triglyceride levels increased less in patients receiving SMOFlipid compared to ILEs with a 100% soybean oil emulsion<sup>19,21,22</sup>

‡Data on file.

## ORDERING INFORMATION



Bag Size	100 mL	250 mL	500 mL	1000 mL
NDC Code	63323-820-00	63323-820-74	63323-820-50	63323-820-10
Product Number	830307310	830570310	830820310	830920310
Unit of Sale	1 x 10	1 x 10	1 x 12	1 x 6



Kabiven®

(Amino Acids, Electrolytes, Dextrose, and Lipid Injectable Emulsion), for intravenous use

Perikabiven®

(Amino Acids, Electrolytes, Dextrose, and Lipid Injectable Emulsion), for intravenous use

Drive standardization with the **FIRST** and **ONLY 3-chamber bag** for PN in the U.S.

The Kabiven and Perikabiven 3-chamber bags efficiently deliver 3 macronutrients (dextrose, protein, and lipids) plus electrolytes, in volumes and concentrations that meet the needs of PN patients.<sup>23,24</sup>

Standardization with a 3-chamber bag can:

- Limit the risk of contamination that may be introduced by traditional compounding<sup>25</sup>
- Minimize errors associated with ordering, transcription, and compounding<sup>26</sup>
- Eliminate the need to piggyback lipids
- Be dispensed by pharmacy anytime, including nights and weekends
- Be a source of electrolytes, such as magnesium sulfate and sodium glycerophosphate, during drug shortages

An all-in-one solution in a 3-chamber bag can **simplify**:



Calculations for dietitians



Compounding for pharmacists



Prescription writing for clinicians



Administration for nurses

Evaluating **time, labor, and cost savings**

In a multicenter, prospective, time and motion study evaluating PN delivery systems, Kabiven (representing 3CB delivery system) was associated with a 62% reduction in pharmacy staff time and workload as well as a 37% reduction in costs compared with hospital-compounded bags (representing PN prepared with automated compounding devices).<sup>27</sup>



Kabiven was associated with a **62% reduction** in pharmacy staff time<sup>27</sup>



Kabiven was associated with a **37% reduction** in costs<sup>27</sup>

ORDERING INFORMATION

	Kabiven (central PN)				Perikabiven (peripheral or central PN)	
Volume	1026 mL	1540 mL	2053 mL	2566 mL	1440 mL	1920 mL
NDC Code	63323-712-10	63323-712-15	63323-712-20	63323-712-25	63323-714-14	63323-714-19
Product Number	831220310	831221310	831222310	831223310	831231310	831232310
Number of Bags per Case	4	4	4	3	4	4

Kabiven and Perikabiven are each indicated as a source of calories, protein, electrolytes and essential fatty acids for adult patients requiring parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated. Kabiven and Perikabiven may be used to prevent essential fatty acid deficiency or treat negative nitrogen balance in adult patients. **Limitations of Use:** Not recommended for use in pediatric patients <2 years, including preterm infants, because the fixed content of the formulation does not meet nutritional requirements in this age group.

WARNING: DEATH IN PRETERM INFANTS

- Deaths in preterm infants after infusion of intravenous lipid emulsions have been reported in the medical literature.
- Autopsy findings included intravascular fat accumulation in the lungs.
- Preterm infants and low-birth-weight infants have poor clearance of intravenous lipid emulsion and increased free fatty acid plasma levels following lipid emulsion infusion.



**OMEGAVEN (fish oil triglycerides) injectable emulsion, for intravenous use**

**BRIEF SUMMARY OF PRESCRIBING INFORMATION**

**This brief summary 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](http://www.FreseniusKabiNutrition.com).**

**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.

**DOSAGE AND ADMINISTRATION**

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 daily dose (and the maximum dose) in pediatric patients is 1 g/kg/day. Administer Omegaven until direct or conjugated bilirubin levels are less than 2 mg/dL or until the patient no longer requires PN.

**CONTRAINDICATIONS**

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).

**WARNINGS AND PRECAUTIONS**

- Risk of Death in Preterm Infants due to Pulmonary Lipid Accumulation: Deaths in preterm infants after infusion of soybean oil-based intravenous lipid emulsions have been reported in medical literature. Autopsy findings in these preterm infants included intravascular lipid accumulation in the lungs. The risk of pulmonary lipid accumulation with Omegaven is unknown. Preterm and small-for-gestational-age infants have poor clearance of intravenous lipid emulsion and increased free fatty acid plasma levels following lipid emulsion infusion. This risk due to poor lipid clearance should be considered when administering intravenous lipid emulsions. Monitor patients receiving Omegaven for signs and symptoms of pleural or pericardial effusion.
- Hypersensitivity Reactions: Omegaven contains fish oil and egg phospholipids, which may cause hypersensitivity reactions. Signs or symptoms of a hypersensitivity reaction may include: tachypnea, dyspnea, hypoxia, bronchospasm, tachycardia, hypotension, cyanosis, vomiting, nausea, headache, sweating, dizziness, altered mentation, flushing, rash, urticaria, erythema, fever, or chills. If a hypersensitivity reaction occurs, stop infusion of Omegaven immediately and initiate appropriate treatment and supportive measures.
- Risk of Infections: The risk of infection is increased in patients with malnutrition-associated immunosuppression, long-term use and poor maintenance of intravenous catheters, or immunosuppressive effects of other conditions or concomitant drugs. To decrease the risk of infectious complications, ensure aseptic technique in catheter placement and maintenance, as well as in the preparation and administration of Omegaven. Monitor for signs and symptoms of early infections including fever and chills, laboratory test results that might indicate infection (including leukocytosis and hyperglycemia), and frequently inspect the intravenous catheter insertion site for edema, redness, and discharge.
- Fat Overload Syndrome: A reduced or limited ability to metabolize lipids accompanied by prolonged plasma clearance may result in this syndrome, which is characterized by a sudden deterioration in the patient's condition including fever, anemia, leukopenia, thrombocytopenia, coagulation disorders, hyperlipidemia, hepatomegaly, deteriorating liver function, and central nervous system manifestations (e.g., coma).
- Refeeding Syndrome: Administering PN to severely malnourished patients may result in refeeding syndrome, which is characterized by the intracellular shift of potassium, phosphorus, and magnesium as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. To prevent these complications, closely monitor severely malnourished patients and slowly increase their nutrient intake.
- Hypertriglyceridemia: Impaired lipid metabolism with hypertriglyceridemia may occur in conditions such as inherited lipid disorders, obesity, diabetes mellitus, and metabolic syndrome. Serum triglyceride levels greater than 1,000 mg/dL have been associated with an increased risk of pancreatitis. To evaluate the patient's capacity to metabolize and eliminate the infused lipid emulsion, measure serum triglycerides before the start of infusion (baseline value), and regularly throughout treatment. If hypertriglyceridemia (triglycerides greater than 250 mg/dL in neonates and infants or greater than 400 mg/dL in older children) develops, consider stopping the administration of Omegaven for 4 hours and obtain a repeat serum triglyceride level. Resume Omegaven based on new result as indicated.
- Aluminum Toxicity: Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Preterm infants are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum. Patients with impaired kidney function, including preterm infants, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

- Monitoring and Laboratory Tests: Routine Monitoring: Monitor serum triglycerides, fluid and electrolyte status, blood glucose, liver and kidney function, coagulation parameters, and complete blood count including platelets throughout treatment. Essential Fatty Acids: Monitoring patients for laboratory evidence of essential fatty acid deficiency (EFAD) is recommended. Laboratory tests are available to determine serum fatty acids levels. Reference values should be consulted to help determine adequacy of essential fatty acid status.
- Interference with Laboratory Tests: The lipids contained in Omegaven may interfere with some laboratory blood tests (e.g., hemoglobin, lactate dehydrogenase, bilirubin, and oxygen saturation) if blood is sampled before lipids have cleared from the bloodstream. Lipids are normally cleared after a period of 5 to 6 hours once the lipid infusion is stopped.

**ADVERSE REACTIONS**

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

Clinical Trials Experience

The safety database for Omegaven reflects exposure in 189 pediatric patients (19 days to 15 years of age) treated for a median of 14 weeks (3 days to 8 years) in two clinical trials.

Adverse reactions that occurred in more than 5% of patients who received Omegaven and with a higher incidence than the comparator group are: vomiting, agitation, bradycardia, apnea, viral infection, erythema, rash, abscess, neutropenia, hypertonia and incision site erythema. Patients had a complicated medical and surgical history prior to receiving Omegaven treatment and the mortality was 13%. Underlying clinical conditions prior to the initiation of Omegaven therapy included prematurity, low birth weight, necrotizing enterocolitis, short bowel syndrome, ventilator dependence, coagulopathy, intraventricular hemorrhage, and sepsis.

Twelve (6%) Omegaven-treated patients were listed for liver transplantation (1 patient was listed 18 days before treatment, and 11 patients after a median of 42 days [range: 2 days to 8 months] of treatment); 9 (5%) received a transplant after a median of 121 days (range: 25 days to 6 months) of treatment, and 3 (2%) were taken off the waiting list because cholestasis resolved.

One hundred thirteen (60%) Omegaven-treated patients reached DBil levels less than 2 mg/dL and AST or ALT levels less than 3 times the upper limit of normal, with median AST and ALT levels for Omegaven-treated patients at 89 and 65 U/L, respectively, by the end of the study.

Median hemoglobin levels and platelet counts for Omegaven-treated patients at baseline were 10.2 g/dL and 173 x 10<sup>9</sup>/L, and by the end of the study these levels were 10.5 g/dL and 217 x 10<sup>9</sup>/L, respectively. Adverse reactions associated with bleeding were experienced by 74 (39%) of Omegaven-treated patients.

Median glucose levels at baseline and the end of the study were 86 and 87 mg/dL for Omegaven-treated patients, respectively.

Hyperglycemia was experienced by 13 (7%) Omegaven-treated patients.

Median triglyceride levels at baseline and the end of the study were 121 mg/dL and 72 mg/dL for Omegaven-treated patients respectively.

Hypertriglyceridemia was experienced by 5 (3%) Omegaven-treated patients.

The triene:tetraene (Mead acid:arachidonic acid) ratio was used to monitor essential fatty acid status in Omegaven-treated patients only in Study 1 (n = 123). The median triene:tetraene ratio was 0.02 (interquartile range: 0.01 to 0.03) at both baseline and the end of the study. Blood samples for analysis may have been drawn while the lipid emulsion was being infused and patients received enteral or oral nutrition.

Postmarketing Experience

The following adverse reaction has been identified with use of Omegaven in another country. Life-threatening hemorrhage following a central venous catheter change was reported in a 9month-old infant with intestinal failure who received PN with Omegaven as the sole lipid source; he had no prior history of bleeding, coagulopathy, or portal hypertension.

**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](http://www.fda.gov/medwatch).**

**DRUG INTERACTIONS**

Prolonged bleeding time has been reported in patients taking antiplatelet agents or anticoagulants and oral omega-3 fatty acids. Periodically monitor bleeding time in patients receiving Omegaven and concomitant antiplatelet agents or anticoagulants.

**USE IN SPECIFIC POPULATIONS**

- Pregnancy: There are no available data on Omegaven use in pregnant women to establish a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Animal reproduction studies have not been conducted with fish oil triglycerides. The estimated background risk of major birth defects and miscarriage in the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.
- Lactation: No data available regarding the presence of fish oil triglycerides from Omegaven in human milk, the effects on the breastfed infant, or the effects on milk production. Lactating women receiving oral omega-3 fatty acids have been shown to have higher levels of omega-3 fatty acids in their milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Omegaven, and any potential adverse effects of Omegaven on the breastfed infant.
- Pediatric Use: The safety of Omegaven was established in 189 pediatric patients (19 days to 15 years of age). The most common adverse reactions in Omegaven-treated patients were vomiting, agitation, bradycardia, apnea and viral infection.
- Geriatric Use: Clinical trials of Omegaven did not include patients 65 years of age and older.

**OVERDOSE**

In the event of an overdose, fat overload syndrome may occur. Stop the infusion of Omegaven until triglyceride levels have normalized and any symptoms have abated. The effects are usually reversible by stopping the lipid infusion. If medically appropriate, further intervention may be indicated. Lipids are not dialyzable from serum.

**SMOFLIPID (lipid injectable emulsion), for intravenous use**

**BRIEF SUMMARY OF PRESCRIBING INFORMATION**

**This brief summary does not include all the information needed to use SMOFlipid safely and effectively. Please see full prescribing information, including Boxed Warning for SMOFlipid (lipid injectable emulsion), for intravenous use at [www.FreseniusKabiNutrition.com](http://www.FreseniusKabiNutrition.com).**

**WARNING: DEATH IN PRETERM INFANTS**

- **Deaths in preterm infants after infusion of intravenous lipid emulsions have been reported in the medical literature.**
- **Autopsy findings included intravascular fat accumulation in the lungs.**
- **Preterm infants and low-birth-weight infants have poor clearance of intravenous lipid emulsion and increased free fatty acid plasma levels following lipid emulsion infusion.**

**INDICATIONS AND USAGE**

SMOFlipid is indicated in adults as a source of calories and essential fatty acids for parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated.

Limitations of Use

The omega-6: omega-3 fatty acid ratio and Medium Chain Triglycerides in SMOFlipid have not been shown to improve clinical outcomes compared to other intravenous lipid emulsions.

**DOSAGE AND ADMINISTRATION**

The recommended daily dosage in adults is 1 to 2 grams/kg per day and should not exceed 2.5 grams/kg per day. SMOFlipid 1000 mL is supplied as a Pharmacy Bulk Package for admixing only and is not for direct infusion. Prior to administration, transfer to a separate PN container. Protect the admixed PN solution from light.

**CONTRAINDICATIONS**

Known hypersensitivity to fish, egg, soybean, or peanut protein, or to any of the active ingredients or excipients.

Severe hyperlipidemia or severe disorders of lipid metabolism with serum triglycerides > 1,000 mg/dL.

**WARNINGS AND PRECAUTIONS**

- Death in Preterm Infants: (see BLACK BOX WARNING)
- Hypersensitivity Reactions: SMOFlipid contains soybean oil, fish oil, and egg phospholipids, which may cause hypersensitivity reactions. Cross reactions have been observed between soybean and peanut oil. Signs or symptoms of a hypersensitivity reaction may include: tachypnea, dyspnea, hypoxia, bronchospasm, tachycardia, hypotension, cyanosis, vomiting, nausea, headache, sweating, dizziness, altered mentation, flushing, rash, urticaria, erythema, pyrexia, or chills. If a hypersensitivity reaction occurs, stop infusion of SMOFlipid immediately and undertake appropriate treatment and supportive measures.
- Risk of Catheter-Related Infections: Lipid emulsions, such as SMOFlipid, can support microbial growth and is an independent risk factor for the development of catheter-related bloodstream infections. The risk of infection is increased in patients with malnutrition-associated immunosuppression, long-term use and poor maintenance of intravenous catheters, or immunosuppressive effects of other concomitant conditions or drugs.
- Fat Overload Syndrome: This is a rare condition that has been reported with intravenous lipid emulsions. A reduced or limited ability to metabolize lipids accompanied by prolonged plasma clearance may result in a syndrome characterized by a sudden deterioration in the patient's condition including fever, anemia, leukopenia, thrombocytopenia, coagulation disorders, hyperlipidemia, fatty liver infiltration (hepatomegaly), deteriorating liver function, and central nervous system manifestations (e.g., coma).
- Refeeding Syndrome: Reintroducing calories and protein to severely undernourished patients with PN may result in the refeeding syndrome, characterized by the intracellular shift of potassium, phosphorus, and magnesium as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop.
- Aluminum Toxicity: SMOFlipid contains no more than 25 mcg/L of aluminum. During prolonged PN administration in patients with renal impairment, the aluminum levels in the patient may reach toxic levels. Preterm infants are at greater risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum. Patients with renal impairment, including preterm infants, who receive parenteral intakes of aluminum at greater than 4 to 5 mcg/kg/day can accumulate aluminum to levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration of PN products.
- Risk of Parenteral Nutrition-Associated Liver Disease (PNALD): PNALD has been reported in patients who receive PN for extended periods of time, especially preterm infants, and can present as cholestasis or steatohepatitis. The exact etiology is unknown and is likely multifactorial. Intravenously administered phytosterols (plant sterols) contained in plant-derived lipid formulations have been associated with development of PNALD, although a causal relationship has not been established. If SMOFlipid-treated patients develop liver test abnormalities, consider discontinuation or dose reduction.
- Hypertriglyceridemia: Impaired lipid metabolism with hypertriglyceridemia may occur in conditions such as inherited lipid disorders, obesity, diabetes mellitus, and metabolic syndrome.

- Monitoring/Laboratory Tests: Routinely monitor serum triglycerides, fluid and electrolyte status, blood glucose, liver and kidney function, blood count including platelets, and coagulation parameters throughout treatment. Monitoring patients for signs and symptoms of essential fatty acid deficiency (EFAD) is recommended.
- Interference with Laboratory Tests: Content of vitamin K may counteract anticoagulant activity. The lipids contained in this emulsion may interfere with some laboratory blood tests (e.g., hemoglobin, lactate dehydrogenase [LDH], bilirubin, and oxygen saturation) if blood is sampled before lipids have cleared from the bloodstream.

**ADVERSE REACTIONS**

Most common adverse drug reactions >1% of patients who received SMOFlipid from clinical trials were nausea, vomiting, hyperglycemia, flatulence, pyrexia, abdominal pain, increased blood triglycerides, hypertension, sepsis, dyspepsia, urinary tract infection, anemia and device-related infection.

Less common adverse reactions in ≤ 1% of patients who received SMOFlipid were dyspnea, leukocytosis, diarrhea, pneumonia, cholestasis, dysgeusia, increased blood alkaline phosphatase, increased gamma-glutamyltransferase, increased C-reactive protein, tachycardia, liver function test abnormalities, headache, pruritis, dizziness, rash, and thrombophlebitis.

The following adverse reactions have been identified during post-approval use of SMOFlipid in countries where it is registered. Infections and Infestations: infection. Respiratory, Thoracic and Mediastinal Disorders: dyspnea.

**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](http://www.fda.gov/medwatch).**

**DRUG INTERACTIONS**

Coumarin and Coumarin Derivatives, Including Warfarin: Anticoagulant activity may be counteracted; monitor laboratory parameters.

**USE IN SPECIFIC POPULATIONS**

- Pregnancy and Lactation: There are no available data on risks associated with SMOFlipid when used in pregnant or lactating women.
- Pediatric Use: The safety and effectiveness of SMOFlipid have not been established in pediatric patients.
- Hepatic Impairment: Parenteral nutrition should be used with caution in patients with hepatic impairment. Hepatobiliary disorders are known to develop in some patients without preexisting liver disease who receive PN, including cholestasis, hepatic steatosis, fibrosis and cirrhosis (PN associated liver disease), possibly leading to hepatic failure.

**OVERDOSE**

In the event of an overdose, fat overload syndrome may occur. Stop the SMOFlipid infusion until triglyceride levels have normalized. The effects are usually reversible by stopping the lipid infusion. If medically appropriate, further intervention may be indicated. Lipids are not dialyzable from serum.

**KABIVEN® (Amino Acids, Electrolytes, Dextrose, and Lipid Injectable Emulsion), for intravenous use**  
**PERIKABIVEN® (Amino Acids, Electrolytes, Dextrose, and Lipid Injectable Emulsion), for intravenous use**

**BRIEF SUMMARY OF PRESCRIBING INFORMATION**

**This brief summary does not include all the information needed to use KABIVEN and PERIKABIVEN safely and effectively. Please see full prescribing information, including Boxed Warning for KABIVEN® (Amino Acids, Electrolytes, Dextrose, and Lipid Injectable Emulsion), for intravenous use and PERIKABIVEN® (Amino Acids, Electrolytes, Dextrose, and Lipid Injectable Emulsion), for intravenous use at [www.FreseniusKabiNutrition.com](http://www.FreseniusKabiNutrition.com).**

**WARNING: DEATH IN PRETERM INFANTS**

- **Deaths in preterm infants after infusion of intravenous lipid emulsions have been reported in the medical literature.**
- **Autopsy findings included intravascular fat accumulation in the lungs.**
- **Preterm infants and low-birth-weight infants have poor clearance of intravenous lipid emulsion and increased free fatty acid plasma levels following lipid emulsion infusion.**

**INDICATIONS AND USAGE**

KABIVEN and PERIKABIVEN are each indicated as a source of calories, protein, electrolytes and essential fatty acids for adult patients requiring parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated. KABIVEN and PERIKABIVEN may be used to prevent essential fatty acid deficiency or treat negative nitrogen balance in adult patients.

Limitations of Use

Neither KABIVEN nor PERIKABIVEN is recommended for use in pediatric patients < 2 years including preterm infants because the fixed content of the formulation does not meet nutritional requirements in this age group.

**DOSAGE AND ADMINISTRATION**

KABIVEN is indicated for intravenous infusion into a **central vein**. PERIKABIVEN is indicated for intravenous infusion into a **peripheral or central vein**. It is recommended to mix the contents thoroughly by inverting the bags upside down to ensure a homogenous admixture. Ensure the vertical seals between chambers are broken and the contents of all three chambers for KABIVEN and PERIKABIVEN are mixed together prior to infusion. The dosage of KABIVEN and PERIKABIVEN should be individualized based on the patient's clinical condition (ability to adequately metabolize amino acids, dextrose and lipids), body weight and nutritional/fluid requirements, as well as additional energy given orally/enterally to the patient. Prior to administration of KABIVEN and PERIKABIVEN, correct severe fluid, electrolyte and acid-base disorders. Before starting the infusion, obtain serum triglyceride levels to establish the baseline value. The recommended dosage of KABIVEN in adults is 19 to 38 mL/kg/day. The recommended dosage of PERIKABIVEN in adults is 27 to 40 mL/kg/day. The maximum daily dosage of KABIVEN and PERIKABIVEN in adults should not exceed 40 mL/kg/day.

**CONTRAINDICATIONS**

Kabiven and Perikabiven is contraindicated in patients with known hypersensitivity to egg, soybean proteins, peanut proteins, corn or corn products or to any of the active substances or excipients. Severe hyperlipidemia or severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglyceride concentration >1,000 mg/dL). Inborn error of amino acid metabolism. Cardiopulmonary instability (including pulmonary edema, cardiac insufficiency, myocardial infarction, acidosis and hemodynamic instability requiring significant vasopressor support). Hemophagocytic syndrome.

**WARNINGS AND PRECAUTIONS (also see BOXED WARNING)**

- **Death in Preterm Infants:** Deaths in preterm infants after infusion of intravenous lipid emulsions have been reported. Autopsy findings included intravascular lipid accumulation in the lungs. Preterm and small for gestational age infants have poor clearance of intravenous lipid emulsion and increased free fatty acid plasma levels following lipid emulsion infusion. The safe and effective use of KABIVEN and PERIKABIVEN injection in pediatric patients, including preterm infants, has not been established. KABIVEN and PERIKABIVEN is not recommended for use in pediatric patients under the age of 2 years including preterm infants.
- **Hypersensitivity Reactions:** Stop infusion immediately and treat patient accordingly if signs or symptoms of a hypersensitivity or allergic reaction develop. Signs or symptoms may include: tachypnea, dyspnea, hypoxia, bronchospasm, tachycardia, hypotension, cyanosis, vomiting, nausea, headache, sweating, dizziness, altered mentation, flushing, rash, urticaria, erythema, pyrexia and chills.
- **Infections:** Patients who require parenteral nutrition are at high risk of infections due to malnutrition and their underlying disease state. Infection and sepsis may occur as a result of the use of intravenous catheters to administer parenteral nutrition, poor maintenance of catheters, or immunosuppressive effects of illness, drugs, and parenteral formulations. Decrease the risk of septic complications. Monitor for signs and symptoms (including fever and chills) of early infections, including laboratory test results (including leukocytosis and hyperglycemia) and frequent checks of the parenteral access device.
- **Fat Overload Syndrome:** Fat overload syndrome is a rare condition that has been reported with intravenous lipid emulsions. A reduced or limited ability to metabolize lipids accompanied by prolonged plasma clearance may result in a syndrome characterized by a sudden deterioration in the patient's condition accompanied by fever, anemia, leukopenia, thrombocytopenia, coagulation disorders, hyperlipidemia, liver fatty infiltration (hepatomegaly), deteriorating liver function, and central nervous system manifestations (e.g., coma).
- **Refeeding Syndrome:** Refeeding severely undernourished patients with parenteral nutrition may result in the refeeding syndrome, characterized by the intracellular shift of potassium, phosphorus, and magnesium as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop.
- **Diabetes/Hyperglycemia:** KABIVEN and PERIKABIVEN should be used with caution in patients with diabetes mellitus or hyperglycemia. With the administration of KABIVEN and PERIKABIVEN, hyperglycemia and hyperosmolar syndrome may result. Administration of dextrose at a rate exceeding the patient's utilization rate may lead to hyperglycemia, coma and death. Monitor blood glucose levels and treat hyperglycemia to maintain optimum levels while infusing KABIVEN or PERIKABIVEN.
- **Monitoring/Laboratory Tests:** Routine Monitoring: Monitor fluid status closely in patients with heart failure or pulmonary edema. Monitor serum triglycerides, fluid and electrolyte status, serum osmolality, blood glucose, liver and kidney function, and blood count, including platelet and coagulation parameters, throughout treatment. In situations of severely elevated electrolyte levels stop KABIVEN or PERIKABIVEN until levels have been corrected. Essential Fatty Acids: Monitoring patients for signs and symptoms of essential fatty acid deficiency (EFAD) is recommended. Laboratory tests are available to determine serum fatty acids levels. Reference values should be consulted to help determine adequacy of essential fatty acid status. Increasing essential fatty acid intake (enterally or parenterally) is effective in treating and preventing EFAD.
- **Vein Damage and Thrombosis:** **KABIVEN** is indicated for administration into a **central vein only**, such as the superior vena cava. The infusion of hypertonic nutrient injections into a peripheral vein may result in vein irritation, vein damage, and/or thrombosis.
- **Thrombophlebitis:** **PERIKABIVEN** is indicated for **peripheral administration or may be infused into a central vein**. Peripheral catheters should not be used for solutions with osmolality of  $\geq$  900 mOsm/L. The primary complication of peripheral access is venous thrombophlebitis, which manifests as pain, erythema, tenderness or a palpable cord. The catheter should be removed as soon as thrombophlebitis develops.
- **Precipitation with Ceftriaxone:** Precipitation of ceftriaxone-calcium can occur when ceftriaxone is mixed with calcium-containing parenteral nutrition solutions, such

as KABIVEN or PERIKABIVEN in the same intravenous administration line. Ceftriaxone **must not be** administered simultaneously with KABIVEN or PERIKABIVEN via a Y-site. However, ceftriaxone and KABIVEN or ceftriaxone and PERIKABIVEN may be administered sequentially if the infusion lines are thoroughly flushed between infusions with a compatible fluid.

- **Hepatobiliary Disorders:** Hepatobiliary disorders are known to develop in some patients without preexisting liver disease who receive parenteral nutrition, including cholecystitis, cholelithiasis, cholestasis, hepatic steatosis, fibrosis and cirrhosis, possibly leading to hepatic failure. The etiology of these disorders is thought to be multifactorial and may differ between patients. Increase of blood ammonia levels and hyperammonemia may occur in patients receiving amino acid solutions. In some patients this may indicate hepatic insufficiency or the presence of an inborn error of amino acid metabolism or hepatic insufficiency. Monitor liver function parameters and ammonia.
- **Electrolyte Imbalance and Fluid Overload in Renal Impairment:** Patients with renal impairment, such as pre-renal azotemia, renal obstruction and protein-losing nephropathy may be at increased risk of electrolyte and fluid volume imbalance. KABIVEN and PERIKABIVEN should be used with caution in patients with renal impairment. KABIVEN and PERIKABIVEN dosage may require adjustment with specific attention to fluid, protein and electrolyte content in these patients. Monitor renal function parameters.
- **Hypertriglyceridemia:** To evaluate the patient's capacity to eliminate and metabolize the infused lipid emulsion, measure serum triglycerides before the start of infusion (baseline value), with each increase in dosage, and regularly throughout treatment. Reduce dose of KABIVEN or PERIKABIVEN and monitor serum triglyceride levels in patients with serum triglyceride concentrations above 400 mg/dL to avoid the clinical consequences associated with hypertriglyceridemia. Serum triglyceride levels above 1,000 mg/dL have been associated with an increased risk of pancreatitis. Impaired lipid metabolism with hypertriglyceridemia may occur in conditions such as inherited lipid disorders, obesity, diabetes mellitus, and metabolic syndrome.
- **Aluminum Toxicity:** KABIVEN and PERIKABIVEN contains no more than 25 mcg/L of aluminum. The aluminum contained in KABIVEN and PERIKABIVEN may reach toxic levels with prolonged parenteral administration in patients with impaired kidney function. Preterm infants are at greater risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions that contain aluminum. Patients with impaired kidney function, including preterm infants, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day, accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration of total parenteral nutrition products.
- **Interference with Laboratory Tests:** High levels of lipids in plasma may interfere with some laboratory blood tests such as hemoglobin, triglycerides, bilirubin, LDH, and oxygen saturation, if blood is sampled before lipid has been cleared from the bloodstream. Lipids are normally cleared after a lipid-free interval of 5 to 6 hours in most patients. KABIVEN and PERIKABIVEN contains Vitamin K1 which may interfere with anticoagulant activity.
- **Risk of Parenteral Nutrition Associated Liver Disease:** Parenteral Nutrition Associated Liver Disease (PNALD) has been reported in patients who receive parenteral nutrition for extended periods of time, especially preterm infants, and can present as cholestasis or steatohepatitis. The exact etiology is unknown and is likely multifactorial. Intravenously administered phytosterols (plant sterols) contained in plant-derived lipid formulations have been associated with development of PNALD although a causal relationship has not been established. If KABIVEN and PERIKABIVEN treated patients develop liver test abnormalities, consider discontinuation or dose reduction.

**ADVERSE REACTIONS**

Clinical Trials Experience

Adverse reactions occurring in >1% of patients who received **KABIVEN** were nausea, pyrexia, hypertension, vomiting, decreased hemoglobin, decreased total protein, hypokalemia, decreased blood potassium, increased gamma-glutamyltransferase, hyperglycemia, increased blood alkaline phosphatase, decreased blood calcium, prolonged prothrombin time, pruritus and tachycardia.

Less common adverse reactions in  $\leq$ 1% of patients who received **KABIVEN** were hyperkalemia, hypertriglyceridemia, headache, dizziness, dysgeusia, rash, eczema, blood glucose increased, and increase in blood triglycerides.

Adverse reactions occurring in >2% of patients who received **PERIKABIVEN** were hyperglycemia, hypokalemia, pyrexia, increased blood triglycerides, phlebitis, nausea, pruritus, increased gamma-glutamyltransferase, increased blood alkaline phosphatase, increased alanine aminotransferase, increased blood glucose, increased C-reactive protein, increased blood urea and hypoalbuminemia.

Less common adverse reactions in  $\leq$ 1% of patients who received **PERIKABIVEN** were hyperkalemia, hypomagnesaemia, hyponatremia, tachycardia, hypertension, thrombophlebitis, vomiting, jaundice, rash and increased blood bilirubin.

Post-Marketing Experience

The following additional adverse reactions have been identified during post-approval use of **KABIVEN** in countries where it is registered. Hepatobiliary disorders: cholestasis. Infections and infestations: infection. Nervous system disorders: subependymal hemorrhage.

The following additional adverse reactions have been identified during post-approval use of **PERIKABIVEN** in countries where it is registered. Gastrointestinal disorders: abdominal distension, abdominal pain. General disorders and administration site conditions: chest tightness. Hepatobiliary disorders: cholestasis. Immune system disorders: allergic reaction, anaphylaxis. Infections and infestations: infection. Vascular disorders: flushed face.

**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](http://www.fda.gov/medwatch).**

**DRUG INTERACTIONS**

Coumarin and Coumarin Derivatives, Including Warfarin: Anticoagulant activity may be counteracted; monitor laboratory parameters.

**USE IN SPECIFIC POPULATIONS**

- **Pregnancy:** The limited available data on the use of KABIVEN and PERIKABIVEN in pregnant women are not sufficient to inform a drug-associated risk. There are clinical considerations if KABIVEN or PERIKABIVEN is used in pregnant women. Animal reproduction studies have not been conducted with KABIVEN and PERIKABIVEN.
- **Lactation:** There are no data available to assess the presence of KABIVEN and PERIKABIVEN and/or its active metabolite(s) in human milk, the effects on the breastfed child or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for KABIVEN or PERIKABIVEN, and any potential adverse effects of KABIVEN and PERIKABIVEN on the breastfed child or from the underlying maternal condition.
- **Pediatric Use:** The safety and effectiveness of KABIVEN and PERIKABIVEN in pediatric patients has not been established. Deaths in preterm infants after infusion of intravenous lipid emulsion have been reported. Patients, particularly preterm infants, are at risk for aluminum toxicity.
- **Geriatric Use:** Clinical studies of KABIVEN and PERIKABIVEN did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from other younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.
- **Hepatic Impairment:** In patients with impaired liver function KABIVEN and PERIKABIVEN should be administered with caution. Frequent clinical evaluation and laboratory tests to monitor liver function such as bilirubin and liver function parameters should be conducted.
- **Renal Impairment:** In patients with impaired renal function, KABIVEN and PERIKABIVEN should be administered with caution. Frequent clinical evaluation and laboratory tests to monitor renal function such as serum electrolytes (especially phosphate and potassium) and fluid balance should be conducted.

**OVERDOSE**

In the event of an overdose, fat overload syndrome may result. Stop the infusion KABIVEN or PERIKABIVEN to allow lipids to clear from serum. The effects are usually reversible after the lipid infusion is stopped. If medically appropriate, further intervention may be indicated. The lipid administered and fatty acids produced are not dialyzable.



# Fresenius Kabi Nutrition will continue to pioneer PN products and bring innovative alternative lipid emulsions to market



The **FIRST** and **ONLY** fish-oil ILE for pediatrics.



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