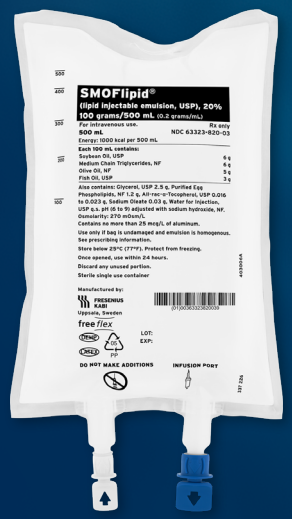
FRESENIUS KABI



PN4

SMOFlipid®

(lipid injectable emulsion),
for intravenous use

Explore the difference:
4 oils in 1 lipid emulsion

Please see Brief Summary of Prescribing Information on pages 9-11.

Bringing alternative lipid emulsions to market

SMOFlipid is an innovation in ILEs

- FDA approved for adults since 2016[1]
- Sustainably sourced fish oil is a part of the mix*
  *Data on file 11/1/24.
- Comprehensive compatibility and stability testing has been performed to help ensure the safety, quality, and integrity of admixtures
- Studied in more than 175 adult patients in 3 clinical studies[1]
- Proven to have a well-established safety and tolerability profile[1]
- Administered to more than 7 million patients worldwide*
  *Data on file 11/1/24.

Abbreviations: FDA, Food and Drug Administration; ILEs, lipid injectable emulsions.

4 oils in 1 lipid emulsion

Omega-6
(30% soybean oil)
Provides EFAs

Omega-3
(15% fish oil)
A source of EPA and DHA[2]

MCT
(30%)
A source of rapidly available energy[3]

Omega-9
(25% olive oil)
Supplies monounsaturated fatty acids

A mix of 3 fatty acids + MCTs[1]

SMOFlipid is our proprietary mixed-oil ILE from Fresenius Kabi, the US market leader in ILEs.[4] Designed to provide a source of calories and EFAs for PN, it nourishes patients—from stable to critically and chronically ill—with a one-of-a-kind blend of 4 oil sources.[1]

With **SMOFlipid**, Fresenius Kabi supported PN and critical care medical societies' need for an alternative to soybean oil ILEs, offering a diverse blend to nourish patients at any age.[1]

CONTRAINDICATIONS

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

Abbreviations: DHA, docosahexaenoic acid; EFAs, essential fatty acids; EPA, eicosapentaenoic acid; ILE, lipid injectable emulsion; MCTs, medium-chain triglycerides; PN, parenteral nutrition.

Dosing and EFA requirements for adults

SMOFlipid helps adults meet LA and ALA requirements when dosed according to the label

Recommended adult daily dose[1]

- 1-2 g/kg/d and no more than 2.5 g/kg/d

EFA requirements[5]

- 1-4% of total energy (kcals) from LA
- 0.25-0.5% of total energy (kcals) from ALA

SMOFlipid at Recommended Dose Meets EFA Requirements[1,5]

Patient weight (kg)	Calories*	Amount of SMOFlipid (g)†	Volume of SMOFlipid (mL)‡	LA % total energy provided by SMOFlipid	ALA % total energy provided by SMOFlipid	Meets EFA recommendations
50	1500	50	250	5.8	0.8	✓
60	1800	60	300	5.8	0.8	✓
70	2100	70	350	5.8	0.8	✓
80	2400	80	400	5.8	0.8	✓
90	2700	90	450	5.8	0.8	✓
100	3000	100	500	5.8	0.8	✓

*Based on 30 kcal/kg/d.
†Based on SMOFlipid recommended dose 1 g/kg/d.
‡SMOFlipid contains (mean): 35 mg/mL LA, 4.5 mg/mL ALA

Actual dose requires a clinical decision.
Recommended dosage depends on age, energy expenditure, clinical status, body weight, tolerance, ability to metabolize, and consideration of additional energy given to the patient.

DISCLAIMER: By using this resource, you agree to the following: this SMOFlipid EFA chart is being provided "AS IS" and is intended for use only by qualified healthcare providers. The information being provided is not a substitute for clinical judgment. Neither Fresenius Kabi USA nor any other party involved in the preparation or publication of this chart shall be liable to you or others for any decisions made or actions taken by you or others in reliance on this information.

Abbreviations: ALA, alpha-linolenic acid; EFA, essential fatty acid; EFAD, essential fatty acid deficiency; LA, linoleic acid.

WARNINGS AND PRECAUTIONS

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

Cases of EFAD have been reported in adult and pediatric patients in the postmarketing period with the use of SMOFlipid.[1]

Importance of lipids in PN for adults

Adult patients on PN should receive **15-30%** of nonprotein calories as fat[6]

ASPEN Recommendations*[7]	ESPEN Guideline for Critically Ill Patients[8]	ESPEN Guideline for Long-Term HPN Patients (>6 months)[9]
1 g/kg/d for stable patients <1 g/kg/d for critically ill patients	1 g/kg body weight/d with a tolerance up to 1.5 g/kg/d	The provision of intravenous soybean oil-based lipid should not exceed 1 g/kg/d. EFAs should be supplied.

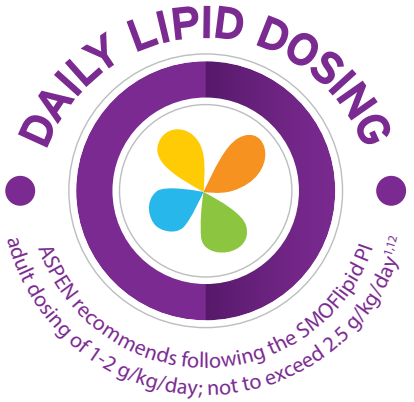
***ASPEN-recommended ILE dosing is based on a soybean oil-based emulsion.**
For indications and dosing of other ILEs, see manufacturer's product literature.

SMOFlipid is indicated for **daily lipid dosing**[1]

Daily lipids can be a part of a PN regimen because they provide EFAs and are an alternative to dextrose as a sole energy source, which can help minimize the complications of excessive dextrose administration, including hepatic steatosis, respiratory insufficiency, hyperglycemia-induced compromised immune function, metabolic stress, and fever.[10,11]

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 0.5 mL/kg/hour in adults.[1]



Abbreviations: ASPEN, American Society for Parenteral and Enteral Nutrition; EFAs, essential fatty acids; ESPEN, The European Society for Clinical Nutrition and Metabolism; HPN, home parenteral nutrition; ILE, lipid injectable emulsion; PN, parenteral nutrition.

SMOFlipid's effect on triglyceride levels

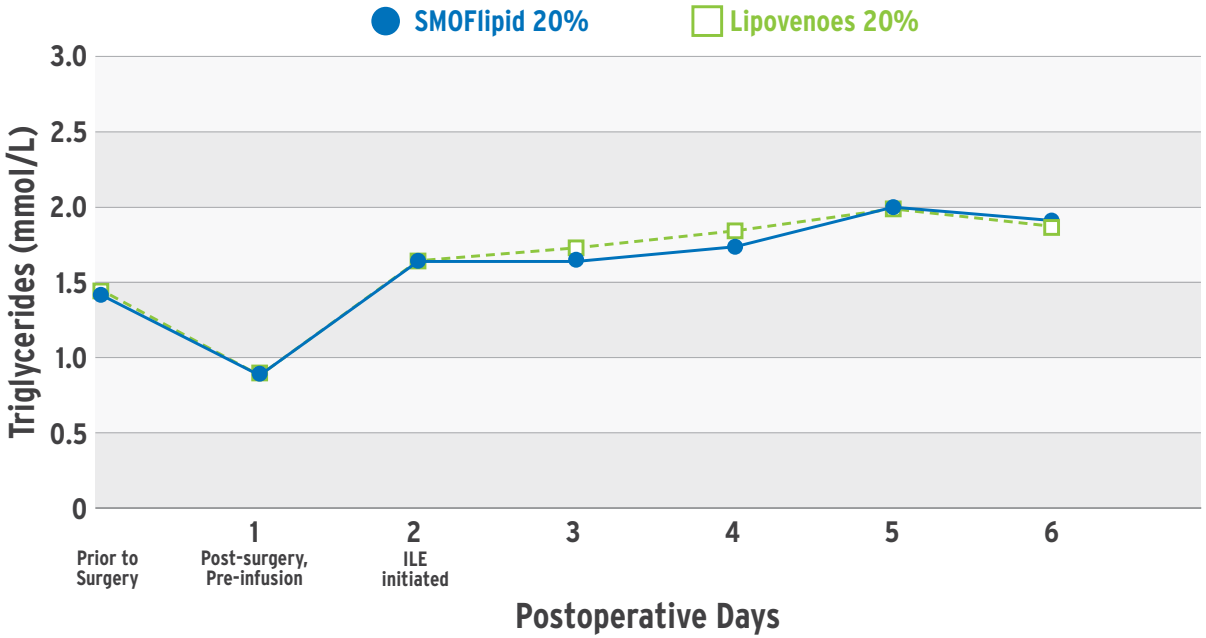


Chart adapted from Mertes, et al.[13]

This prospective, double-blind European multicenter study compared serum triglyceride concentrations over 5 days of PN supplemented with SMOFlipid 20% (n=99) or with Lipovenoes 20% (100% soybean oil) (n=100) in surgical patients.[13]

- ILE provided at 1.5 g/kg/d for both groups[13]
- Mean AUC was 0.73 and 0.72 mmol/L (SMOFlipid and Lipovenoes groups, respectively), demonstrating statistical equivalence and adequate clearance of lipid from plasma[13]

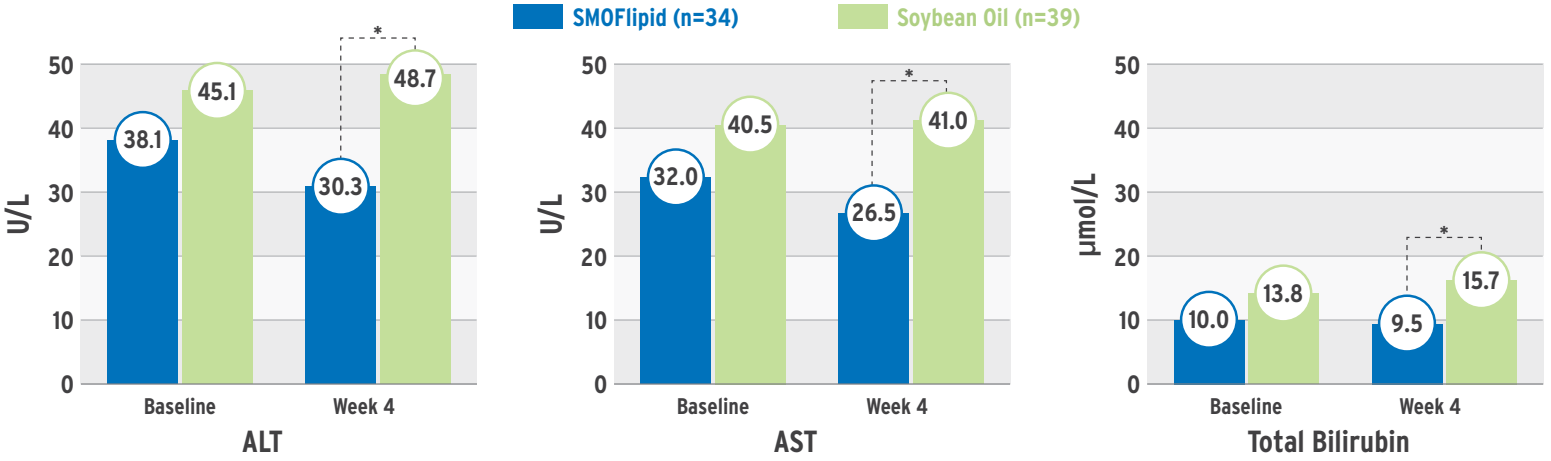
Monitor for signs and symptoms; monitor laboratory parameters.[1]

The use of SMOFlipid is contraindicated in patients with hypertriglyceridemia with serum triglyceride concentrations >1,000 mg/dL.[1]

Abbreviations: AUC, area under the curve; ILE, lipid injectable emulsion; PN, parenteral nutrition.

Effect on liver function parameters[14]

Parameters of Liver Function at Baseline and at Week 4



*Statistically significant difference between groups at week 4 (P<0.05).
Chart adapted from Klek S, et al.[14]

This randomized, controlled, double-blind, multicenter study compared PN containing SMOFlipid or a soybean oil emulsion in intestinal failure patients requiring long-term PN. Seventy-three patients (n=34 in SMOFlipid group and n=39 in the soybean oil group) received PN with either lipid emulsion and were monitored for 4 weeks.[14]

- PN intake was similar in both groups: 1.3 g/kg/d ILE, 3 g/kg/d dextrose, 1.2 g/kg/d amino acids; infusion occurred 10-24 hr/d, 5-7 days per week[14]
- After 4 weeks, the mean concentrations of ALT, AST, and total bilirubin were significantly lower in the SMOFlipid group than the comparator group (statistical significance was set at P<0.05) ; there was no significance for change within treatment groups[14]

Two on-label adult clinical trials did not show a difference in liver parameters.*
*Data on file.

Monitor liver tests; if abnormalities occur, consider discontinuation or dosage reduction.[1]

Abbreviations: ALT, alanine transaminase; AST, aspartate transaminase; ILE, lipid injectable emulsion; PN, parenteral nutrition.

Discover the ONE and ONLY **4-oil** ILE[1]

An alternative lipid for your adult patients requiring PN[1]

Designed to provide a source of calories and EFAs[1]

Nourishes your adult patients with a one-of-a-kind blend of 4 oil sources[1]

Globally recognized with approval in more than 75 countries

Learn more at **SMOFlipid4-Oil.com**

Abbreviations: EFAs, essential fatty acids; ILE, lipid injectable emulsion; PN, parenteral nutrition.

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 for SMOFlipid (lipid injectable emulsion), for intravenous use at www.FreseniusKabiNutrition.com/SMOFlipidPI.

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.

DOSAGE AND ADMINISTRATION

The recommended daily dosage and initial and maximum infusion rates for pediatric and adult patients are provided in Table 1. Do not exceed the recommended maximum infusion rate in Table 1. The recommended duration of infusion for SMOFlipid will vary depending on the clinical situation. Adjust the administration flow rate by taking into account the dose being administered, the daily volume/intake, and the duration of the infusion.

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 for individual patient use. Use a non-vented, non-DEHP 1.2 micron in-line filter during administration. Protect the admixed PN solution from light.

Table 1: Recommended Pediatric and Adult Dosage and Infusion Rate

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	0.75 mL/kg/hour
Pediatric patients 12 to 17 years of age	Initial 1 g/kg/day not to exceed 2.5 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	0.75 mL/kg/hour
Adults	1 to 2 g/kg/day not to exceed 2.5 g/kg/day**	0.2 mL/kg/hour for the first 15 to 30 minutes; gradually increase to the required rate after 30 minutes	0.5 mL/kg/hour

*The neonatal period is defined as including term, post-term, and preterm newborn infants. The neonatal period for term and post-term infants is the day of birth plus 27 days. For preterm infants, the neonatal period is defined as the day of birth through the expected age of delivery plus 27 days (i.e., 44 weeks post-menstrual age).

** Daily dosage should not exceed a maximum of 60% of total energy requirements

CONTRAINDICATIONS

- Known hypersensitivity to fish, egg, soybean, peanut or to any of the active or inactive ingredients in SMOFlipid.
- Severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglycerides >1,000 mg/dL).

WARNINGS AND PRECAUTIONS

- Clinical Decompensation with Rapid Infusion of Intravenous Lipid Emulsion in Neonates and Infants.

  In the postmarketing setting, serious adverse reactions including acute respiratory distress, metabolic acidosis, and death have been reported in neonates and infants after rapid infusion of intravenous lipid emulsions. Hypertriglyceridemia was commonly reported.

  Strictly adhere to the recommended total daily dosage; the hourly infusion rate should not exceed 0.75 mL/kg/hour.

  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.

  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.

- Parenteral Nutrition-Associated Liver Disease and Other Hepatobiliary Disorders.

  Risk of Parenteral Nutrition-Associated Liver Disease (PNALD): PNALD, or Intestinal failure-associated liver disease (IFALD), can present as cholestasis or hepatic stenosis and may progress to steatohepatitis with fibrosis and cirrhosis (possibly leading to chronic hepatic failure). The etiology of PNALD is multifactorial; however, intravenously administered phytosterols (plant sterols) contained in plant-derived lipid emulsions, including SMOFlipid, have been associated with development of PNALD.

  In a randomized study of neonates and infants expected to be treated with PN for at least 28 days, parenteral nutrition-associated cholestasis (PNAC), a precursor to PNALD, developed less frequently in SMOFlipid-treated patients than in 100% soybean oil lipid emulsion-treated patients.

  Monitor liver tests in patients treated with SMOFlipid and consider discontinuation or dosage reduction if abnormalities occur.

  Other Hepatobiliary Disorders

  Hepatobiliary disorders including cholecystitis and cholelithiasis have developed in some parenteral nutrition-treated patients without preexisting liver disease. Monitor liver tests when administering SMOFlipid. Patients developing signs of hepatobiliary disorders should be assessed early to determine whether these conditions are related to SMOFlipid use.

- 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. SMOFlipid is contraindicated in patients with known hypersensitivity to fish, egg, soybean, peanut, or any of the active or inactive ingredients in SMOFlipid. If a

hypersensitivity reaction occurs, stop infusion of SMOFlipid immediately and initiate appropriate treatment and supportive measures.

- Infections: Lipid emulsions, such as SMOFlipid, can support microbial growth and are an independent risk factor for the development of catheter-related bloodstream infections. To decrease the risk of infectious complications, ensure aseptic techniques are used for catheter placement, catheter maintenance, and preparation and administration of SMOFlipid. Monitor for signs and symptoms of infection including fever and chills, as well as laboratory test results that might indicate infection (including leukocytosis and hyperglycemia). Perform frequent checks of the intravenous catheter insertion site for edema, redness, and discharge.
- Fat Overload Syndrome: This is a rare condition that has been reported with intravenous lipid emulsions and is characterized by a sudden deterioration in the patient's condition (e.g., fever, anemia, leukopenia, thrombocytopenia, coagulation disorders, hyperlipidemia, hepatomegaly, deteriorating liver function, and central nervous system manifestations such as coma). A reduced or limited ability to metabolize lipids, accompanied by prolonged plasma clearance (resulting in higher lipid levels), may result in this syndrome. Although fat overload syndrome has been most frequently observed when the recommended lipid dose or infusion rate was exceeded, cases have also been described when the lipid formulation was administered according to instructions.

  If signs or symptoms of fat overload syndrome occur, stop SMOFlipid. The syndrome is usually reversible when the infusion of the lipid emulsion is stopped.
- 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 patients become 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: The use of SMOFlipid is contraindicated in patients with hypertriglyceridemia with serum triglyceride concentrations >1,000 mg/dL.

  Patients with conditions such as inherited lipid disorders, obesity, diabetes mellitus, or metabolic syndromes have a higher risk of developing hypertriglyceridemia with the use of SMOFlipid. In addition, patients with hypertriglyceridemia may have worsening of their hypertriglyceridemia with administration of SMOFlipid. Excessive dextrose administration may further increase such risk.

  Evaluate patients' capacity to metabolize and eliminate the infused lipid emulsion by measuring serum triglycerides before the start of infusion (baseline value) and regularly throughout treatment. If triglyceride levels are above 400 mg/dL in adults, stop the SMOFlipid infusion and monitor serum triglyceride levels to avoid clinical consequences of hypertriglyceridemia such as pancreatitis. In pediatric patients with hypertriglyceridemia, lower triglyceride levels (i.e., below 400 mg/dL) may be associated with adverse reactions. Monitor serum triglyceride levels to avoid potential complications with hypertriglyceridemia such as pancreatitis, lipid pneumonitis, and neurologic changes, including kernicterus.

  To minimize the risk of new or worsening of hypertriglyceridemia, assess high-risk patients for their overall energy intake including other sources of lipids and dextrose, as well as concomitant drugs that may affect lipid and dextrose metabolism.
- Aluminum Toxicity: SMOFlipid contains no more than 25 mcg/L of aluminum. Prolonged PN administration in patients with renal impairment may result in aluminum reaching 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 impaired kidney function, including preterm infants, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day can accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.
- Essential Fatty Acid Deficiency: Treatment-emergent cases of moderate or severe essential fatty acid deficiency (EFAD) (defined as the triene [Mead acid] to tetraene [arachidonic acid] ratio >0.2 and >0.4, respectively) were not observed in pediatric clinical trials of SMOFlipid up to 28 days. However, cases of EFAD have been reported in adults and pediatric patients in the postmarketing period with the use of SMOFlipid. The median time to onset was greater than 28 days among cases that reported time to onset. Monitor patients for laboratory evidence (e.g., abnormal fatty acid levels) and clinical symptoms of EFAD (e.g., skin manifestations and poor growth) because these signs may emerge before laboratory evidence of EFAD is confirmed. Laboratory testing using the triene to tetraene ratio may not be adequate to diagnose EFAD, and assessment of individual fatty acid levels may be needed. Ensure patients are receiving recommended dosages of SMOFlipid to prevent EFAD.
- Monitoring/Laboratory Tests: Throughout treatment monitor serum triglycerides, fluid and electrolyte status, blood glucose, liver and kidney function, coagulation parameters, and complete blood count including platelets.

  The lipids contained in SMOFlipid 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. Conduct these blood tests at least 6 hours after stopping the infusion. SMOFlipid contains vitamin K that may counteract anticoagulant activity.

ADVERSE REACTIONS

Most common adverse drug reactions >1% of adult 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 adult 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 most common adverse drug reactions in >1% of pediatric patients who received SMOFlipid were anemia, vomiting, gamma-glutamyltransferase increased, nosocomial infection, cholestasis, pyrexia, C-reactive protein increased, hyperbilirubinemia, abdominal pain, bilirubin conjugated increased, diarrhea, tachycardia, thrombocytopenia, hyperglycemia, and sepsis.

Less common adverse reactions in ≤1% of pediatric patients who received SMOFlipid were decreased hematocrit, metabolic acidosis, increased blood triglycerides, infection, increased blood alkaline phosphatase, increased alanine aminotransferase, fluid overload, hypertension, hypertriglyceridemia, and rash.

The following adverse reactions have been identified during post-approval use of SMOFlipid in countries where it is registered. Cardiac disorders: palpitations; General disorders and administration site conditions: chills, chest pain, malaise; Hepatobiliary disorders: cholestasis; Infections and infestations: infection; Metabolism and nutrition disorders: fatty acid deficiency; Respiratory, thoracic and mediastinal disorders: dyspnea; Skin and subcutaneous tissue disorders: hyperhidrosis; Vascular disorders: phlebitis.

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.

DRUG INTERACTIONS

Soybean and olive oils in SMOFlipid contain vitamin K_1 which may counteract the anticoagulant activity of vitamin K antagonists such as warfarin. In patients who receive concomitant SMOFlipid and warfarin, increase monitoring of laboratory parameters for anticoagulant activity.

USE IN SPECIFIC POPULATIONS

- Pregnancy and Lactation: Administration of the recommended dose of SMOFlipid is not expected to cause major birth defects, miscarriage, or other adverse maternal or fetal outcomes. No animal reproduction studies have been conducted with SMOFlipid. Administration of the recommended dose of SMOFlipid is not expected to cause harm to a breastfed infant. There are no data on the presence of SMOFlipid in human or animal milk or its effects on milk production.
- Pediatric Use: The safety and effectiveness of SMOFlipid have been established as a source of calories and essential fatty acids for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated in pediatric patients, including term and preterm neonates. Use of SMOFlipid in neonates is supported by evidence from short-term (i.e., 1- to 4-week) studies, and one study following neonates beyond 4 weeks. Use of SMOFlipid in older pediatric patients is supported by evidence from a short-term (i.e., <28 days) study in pediatric patients 28 days to 12 years of age and additional evidence from studies in adults. The most common adverse reactions in SMOFlipid-treated pediatric patients were anemia, vomiting, gamma-glutamyltransferase increased, and nosocomial infection. PNALD, also referred to as IFALD, has been reported in pediatric patients who received SMOFlipid for more than 2 weeks. PNAC (a precursor to PNALD) was reported less frequently in SMOFlipid-treated patients compared to soybean oil lipid emulsion-treated patients in Pediatric Study 1. Although clinically significant cases of EFAD were not observed during short-term use in pediatric clinical studies, cases of EFAD have been reported with the use of SMOFlipid in the postmarketing setting. Monitor pediatric patients for laboratory evidence of EFAD because they may be particularly vulnerable to neurologic complications if adequate amounts of essential fatty acids are not provided. In the post marketing setting, clinical decompensation with rapid infusion of intravenous lipid emulsion in neonates and infants, sometimes fatal has been reported. Because of immature renal function, preterm infants receiving prolonged treatment with SMOFlipid may be at risk for aluminum toxicity.
- Geriatric Use: Energy expenditure and requirements may be lower for older adults than younger patients. Of the 354 adult patients in clinical studies of SMOFlipid, 35% were >65 years of age and 10% were >75 years of age. No overall differences in the safety and efficacy of SMOFlipid were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity in some older patients cannot be ruled out.

OVERDOSAGE

In the event of an overdose, serious adverse reactions may result. Stop the SMOFlipid infusion until triglyceride levels have normalized and 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 plasma.

Sources: 1. SMOFlipid Prescribing Information, Fresenius Kabi USA, LLC. 2023. **2.** Kalish BT, Fallon EM, Puder M. A tutorial on fatty acid biology. *JPEN J Parenter Enteral Nutr.* 2012;36(4):380-388. **3.** Deckelbaum RJ, Hamilton JA, Moser A, et al. Medium-chain versus long-chain triacylglycerol emulsion hydrolysis by lipoprotein lipase and hepatic lipase: implications for the mechanisms of lipase action. *Biochemistry*. 1990;29(5):1136-1142. **4.** Data on File; 11/1/24; calculation includes: all ILEs approved in the US. **5.** Hise M, Brown JC. Lipids. In: *The ASPEN Adult Nutrition Support Core Curriculum*. 3rd Edition. Silver Spring, MD: American Society for Parenteral and Enteral Nutrition. 2017; pg. 79. **6.** Mirtallo JM, Ayers P, Boullata J, et al. ASPEN Lipid Injectable Emulsion Safety Recommendations, Part 1: Background and Adult Considerations [published correction appears in *Nutr Clin Pract*. 2022 Apr;37(2):482. doi: 10.1002/ncp.10843]. *Nutr Clin Pract*. 2020;35(5):769-782. **7.** Appropriate Dosing for Parenteral Nutrition: ASPEN Recommendations. ASPEN Website. November 17, 2020. Accessed December 6, 2024. https://www.nutritioncare.org/uploadedFiles/Documents/Guidelines_and_Clinical_Resources/PN%20Dosing%201-Sheet-Nov%202020-FINAL.pdf **8.** Singer P, Blaser AR, Berger MM, et al. ESPEN practical and partially revised guideline: Clinical nutrition in the intensive care unit. *Clin Nutr*. 2023;42(9):1671-1689. **9.** Staun M, Pironi L, Bozzetti F, et al. ESPEN Guidelines on Parenteral Nutrition: home parenteral nutrition (HPN) in adult patients. *Clin Nutr*. 2009;28(4):467-479. **10.** Vanek VW, Seidner DL, Allen P, et al. A.S.P.E.N. position paper: Clinical role for alternative intravenous fat emulsions. *Nutr Clin Pract*. 2012;27(2):150-192. **11.** Calder PC, Jensen GL, Koletzko BV, Singer P, Wanten GJ. Lipid emulsions in parenteral nutrition of intensive care patients: current thinking and future directions. *Intensive Care Med*. 2010;36(5):735-749. **12.** ASPEN Lipid Injectable Emulsion Safety Recommendations for Adult Patients. ASPEN website. 2021. Accessed January 27, 2025. https://www.nutritioncare.org/uploadedFiles/Documents/Guidelines_and_Clinical_Resources/ILE-Safety-Recommendations-Adult_10.18.21.pdf **13.** Mertes N, Grimm H, Fürst P, Stehle P. Safety and efficacy of a new parenteral lipid emulsion (SMOFlipid) in surgical patients: a randomized, double-blind, multicenter study. *Ann Nutr Metab*. 2006;50(3):253-259. **14.** Klek S, Chambrier C, Singer P, et al. Four-week parenteral nutrition using a third generation lipid emulsion (SMOFlipid)--a double-blind, randomised, multicentre study in adults. *Clin Nutr*. 2013;32(2):224-231.

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