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.¹

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 100% fish oil ILE** for pediatric patients with parenteral nutrition-associated cholestasis (PNAC) in the U.S.²

- Omegaven is a source of calories and fatty acids for pediatric patients with PNAC²
- Patients receiving Omegaven achieved age-appropriate growth²
- Omegaven-treated patients experienced improvement in liver function parameters²
  - 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 study²

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.²

ESPGHAN/ESPC/ESPR/CSPEN guidelines for pediatric patients:³

“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 demonstrated reduced liver parameters and reduced transplantation in patients with PNAC

**Study design**⁴

In this multicenter integrated analysis, fish oil-based lipid emulsions (FOLE) recipients (1 g/kg/d) (n = 189) were compared with historical controls administered soybean oil-based lipid emulsion (SOLE) (<3 g/kg/d) (n = 73). Patients were <2 years of age with direct bilirubin ≥2 mg/dL. They were also expected to require PN for 30 days or more and had failed to respond to standard therapies for intestinal failure-associated liver disease (IFALD).

**Results**⁴

FOLE recipients experienced a higher rate of cholestasis resolution (P <0.001), lower aspartate aminotransferase to platelet ratio index (APRI; P <0.02 vs P <0.0003, respectively), and fewer liver transplants (P <0.0245) compared with SOLE. This study demonstrates that a fish oil ILE may be preferred in children with IFALD when direct or conjugated bilirubin reaches 2 mg/dL.⁴

**ORDERING INFORMATION**

<table>
<thead>
<tr>
<th>Bottle Size</th>
<th>50 mL single-dose glass bottle</th>
<th>100 mL single-dose glass bottle</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDC Code</td>
<td>63323-205-50</td>
<td>63323-205-00</td>
</tr>
<tr>
<td>Bottles/Carton</td>
<td>10 bottles/carton</td>
<td>10 bottles/carton</td>
</tr>
</tbody>
</table>

Please see Brief Summary of Prescribing Information for Omegaven on pages 12-13.
Discover the SMOF difference

**SMOFlipid** is a unique blend of 4 oil sources:

- **S**oybean oil 30% (omega-6) Provides essential fatty acids.
- **M**edium-chain triglycerides (MCT) 30% A source of rapidly available energy.
- **O**live oil 25% (omega-9) Supplies monounsaturated fatty acids.
- **F**ish oil 15% (omega-3) A source of EPA and DHA.

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

<table>
<thead>
<tr>
<th>Lipid Emulsion</th>
<th>Ratio of Omega-6:Omega-3 Fatty Acids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendations*</td>
<td>2:1 to 4:1</td>
</tr>
<tr>
<td>Soybean-Oil Emulsion</td>
<td>7:1</td>
</tr>
<tr>
<td>MCT/LCT Emulsion</td>
<td>7:1</td>
</tr>
<tr>
<td>Olive Oil/Soybean-Oil Emulsion</td>
<td>9:1</td>
</tr>
<tr>
<td>SMOFlipid®</td>
<td>2.5:1</td>
</tr>
</tbody>
</table>

*Based on composition of the product.

**The SMOF Difference**

**In adults**
- SMOFlipid has been shown to improve EPA and DHA in adult patients compared to those receiving a soybean oil-based lipid emulsion*.

**In pediatrics**
- The safety and efficacy of SMOFlipid compared to soybean oil in pediatric patients of all groups, including term and preterm neonates, was evaluated in 333 pediatric patients in four randomized, active-controlled, double-blind, parallel-group controlled clinical studies:
  - SMOFlipid is safe and well tolerated in preterm neonates, infants, and children*.
  - Preterm infants receiving SMOFlipid experienced higher EPA and DHA levels compared to those receiving a soybean oil lipid emulsion*.

**EPA and DHA**

- ESPEN states, “Addition of EPA and DHA to lipid emulsions has demonstrable effects on cell membranes and inflammatory processes (Grade B)”

**Contraindications:** Known hypersensitivity to fish, egg, soybean, or 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).

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

**ILEs and Phytosterol Content**

<table>
<thead>
<tr>
<th>Emulsion</th>
<th>Phytosterols, µg/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipofundin N*</td>
<td>700</td>
</tr>
<tr>
<td>Intralipid 20%</td>
<td>600</td>
</tr>
<tr>
<td>Structolipid* 20%</td>
<td>500</td>
</tr>
<tr>
<td>Lipofundin MCT/LCT* 20%</td>
<td>400</td>
</tr>
<tr>
<td>Clinolipid 20%</td>
<td>300</td>
</tr>
<tr>
<td>SMOFlipid† 20%</td>
<td>200</td>
</tr>
</tbody>
</table>

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

Per milliliter, **SMOFlipid contains the lowest amount of phytosterols in commercially available ILEs indicated for adults**.

**Give your patients the one and only SMOF**

- Meets the essential fatty acid requirements for PN patients of all ages
- Contains fish oil, which is rich in omega-3s
- Demonstrated safety and tolerability
- More than 7 million patients globally received SMOFlipid

**SMOFlipid resulted in a lower incidence of parenteral nutrition-associated cholestasis (PNAC)**

**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.

**Results**

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

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

**ORDERING INFORMATION**

<table>
<thead>
<tr>
<th>Bag Size</th>
<th>100 mL</th>
<th>250 mL</th>
<th>500 mL</th>
<th>1000 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDC Code</td>
<td>63323-820-00</td>
<td>63323-820-74</td>
<td>63323-820-50</td>
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<tr>
<td>Bags/Case</td>
<td>10 bags/case</td>
<td>10 bags/case</td>
<td>12 bags/case</td>
<td>6 bags/case</td>
</tr>
</tbody>
</table>

Please see Brief Summary of Prescribing Information for SMOFlipid on pages 14-15.
Drive standardization with the **FIRST** and **ONLY** three-chamber bag for PN in the U.S.

The Kabiven and Perikabiven three-chamber PN bags efficiently deliver three macronutrients (dextrose, protein, and lipids) plus electrolytes in volumes and concentrations that meet the needs of most PN patients.\(^{21,22}\)

**Standardization** with a three-chamber bag can:
- Limit the risk of contamination that may be introduced by traditional compounding\(^{23}\)
- Minimize errors associated with ordering, transcription, and compounding\(^{24}\)
- 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 three-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 systems) 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).\(^{25}\)

**ORDERING INFORMATION**

<table>
<thead>
<tr>
<th>Kabiven (central PN)</th>
<th>Perikabiven (peripheral or central PN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td></td>
</tr>
<tr>
<td>1026 mL</td>
<td>1440 mL</td>
</tr>
<tr>
<td>1540 mL</td>
<td>1920 mL</td>
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<tr>
<td>2053 mL</td>
<td></td>
</tr>
<tr>
<td>2566 mL</td>
<td></td>
</tr>
<tr>
<td>NDC Code</td>
<td></td>
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<tr>
<td>63323-712-10</td>
<td>63323-714-14</td>
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<tr>
<td>63323-712-15</td>
<td>63323-714-19</td>
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<tr>
<td>63323-712-25</td>
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<tr>
<td>Number of Bags per Case</td>
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</tr>
<tr>
<td>4 bags/case</td>
<td>4 bags/case</td>
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<tr>
<td>4 bags/case</td>
<td>3 bags/case</td>
</tr>
<tr>
<td>4 bags/case</td>
<td></td>
</tr>
</tbody>
</table>

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 are 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.

Contraindications: Concomitant treatment with ceftriaxone in neonates (28 days of age or younger), Known hypersensitivity to egg, soybean, peanut, or any of the active or inactive ingredients. Severe disorders of lipid metabolism characterized by hypertriglyceridemia (with serum triglyceride concentration >1,000 g/dL). Inborn errors of amino acid metabolism. Cardiopulmonary instability. Hemophagocytic syndrome.
Intralipid®
(lipid injectable emulsion, USP 20%)

A long-standing and trusted lipid choice worldwide

- FDA approved for over 40 years
- 100% soybean oil
- Well documented in medical literature
- Provided in more than 200 million infusions* for adult and pediatric patients
- Effective source of calories and essential fatty acids

Intralipid 20% composition

<table>
<thead>
<tr>
<th>Content per 1L</th>
<th>Intralipid 20%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soybean oil (g)</td>
<td>200</td>
</tr>
<tr>
<td>Osmolality (mOsm/kg water)</td>
<td>350</td>
</tr>
<tr>
<td>Inorganic phosphate (mmol)</td>
<td>15</td>
</tr>
<tr>
<td>Total caloric value (kcal/mL)</td>
<td>2</td>
</tr>
</tbody>
</table>

Lipids are an efficient energy source

Compared with other PN macronutrients, lipids are the most calorically dense and can be the most beneficial for volume-restricted patients

Intralipid has been used in a wide range of patient types

Critically ill patients e.g. with trauma, burns, sepsis, and SIRS

Surgical patients

Patients with gastrointestinal tract cancer

Patients with renal insufficiency

Pediatric patients

Patients on Home Parenteral Nutrition (HPN)

Energy content of nutrients*

<table>
<thead>
<tr>
<th>Energy (kcal/g)</th>
<th>Amino acids</th>
<th>Dextrose</th>
<th>Lipids</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>1</td>
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<td>9</td>
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<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>


Intralipid 20% (A 20% Intravenous Fat Emulsion), is indicated as a source of calories and essential fatty acids for patients requiring parenteral nutrition (PN) and as a source of essential fatty acids for prevention of essential fatty acid deficiency (EFAD).

Intralipid 20% Pharmacy Bulk Package and Intralipid 30% Pharmacy Bulk Package are intended for use in a pharmacy admixture program for the preparation of three-in-one or total nutrition admixtures (TNAs) to provide a source of calories and essential fatty acids for adult and pediatric patients requiring PN and a source of essential fatty acids for prevention of EFAD.

INTRALIPID 20% and 30% PHARMACY BULK PACKAGES ARE NOT INTENDED FOR DIRECT INTRAVENOUS ADMINISTRATION.

Contraindications: Known hypersensitivity to egg, soybean, or peanut, or any of the active ingredients or excipients. Severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglyceride > 1,000 mg/dL). Disturbances of normal fat metabolism such as pathologic hyperlipemia, lipid nephrosis or acute pancreatitis if accompanied by hyperlipidemia.
OMEGAVEN* (fish oil triglycerides) injectable emulsion

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, at www.FreseniusKabi.com/OmegavenPI

INDICATIONS AND USAGE

Omegaven is indicated as a source of calories and fatty acids in patients treated with Omegaven are the result of omega-6 fatty acids.

Limitations of Use

Omegaven is not indicated for the prevention of PNAC. It has not been demonstrated that Omegaven prevents PNAC in premature infants after rapid infusion of lipid injectable emulsions.

Dosage and Administration

Administer the recommended daily dose using a 1.2 micron in-line filter. Protect the admixed PN solution from light. Prior to infusion, visually inspect Omegaven for particulate matter and discoloration. If either is present, do not use.

Recommended Initial Dosage and Maximum Dosage

Route: Intravenous administration

NUTRITIONAL REQUIREMENTS

Protein

Carbohydrate

Fat

OMEGAVEN contains only medium chain triglycerides (MCT) and is not a complete enteral formula. Further enteral nutrition is required for patients requiring calories and amino acids. The energy provided by Omegaven should be calculated to avoid overfeeding patients. It is recommended that the infused calories from the Omegaven be considered as the patient's enteral feeding.

CONTRAINdications

Omegaven is contraindicated in patients with known hypersensitivity to fish or egg protein or to any of the active ingredients or excipients, severe hemolytic anemia, and potential effect on platelet aggregation. Severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglycerides concentration more than 1000 mg/dL).

WARNINGS AND PREcautions

• Clinical Decompensation with Rapid Infusion of Lipid Inj ectable Emulsions in Neonates and Infants In the postmarket setting, serious adverse reactions including acute respiratory distress, metabolic acidosis, and death have been reported in neonates and infants after rapid infusion of lipid injectable emulsions. Hypertriglyceridemia was commonly reported. It is strongly recommended that the protocol for the recommended daily dosage, the daily infusion rate, and the total volume of Omegaven administered (which includes individual doses) be closely monitored to avoid potential adverse reactions.

• Monitoring and Laboratory Tests: Routine Monitoring

Serum triglyceride levels greater than 1,000 mg/dL have been reported in neonates and infants who receive treatment with Omegaven. Lipids are removed from the bloodstream and incorporated into very low density lipoproteins (VLDLs), which are then metabolized in the liver. Hypertriglyceridemia may occur in patients with severe liver disease, malnutrition-associated immunosuppression, long-term use and supportive measures.

• Serum triglyceride levels greater than 500 mg/dL in neonates and infants after rapid infusion of lipid injectable emulsions.

• 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 infection complications, Omegaven should be given through a central catheter placement and maintenance, as well as the preparation and administration of Omegaven. Monitor for early signs and symptoms of infections including fever, tachycardia, and leukocytosis in neonates and infants after rapid infusion of lipid injectable emulsions.

• Dosage and Administration

Initial

Recommended Initial and Maximum Dosage

1 mL/kg/hour for the first 2 hours, then 0.5 mL/kg/hour for the next 30 minutes.

0.2 mL/kg/hour for the first 5 to 10 minutes, gradually increase to the maximum rate after 30 minutes.

15 mL/kg/hour

Recommended Initial and Maximum Dosage

NUTRITIONAL REQUIREMENTS

Direct Infusion Rate

Initial

Maximum

0.2 mL/kg/hour for the first 5 to 10 minutes, gradually increase to the maximum rate after 30 minutes.

0.5 mL/kg/hour for the next 30 minutes.

15 mL/kg/hour

Monit or and Laboratory Tests: Routine Monitoring

Serum triglyceride levels greater than 1,000 mg/dL have been reported in neonates and infants who receive treatment with Omegaven. Lipids are removed from the bloodstream and incorporated into very low density lipoproteins (VLDLs), which are then metabolized in the liver. Hypertriglyceridemia may occur in patients with severe liver disease, malnutrition-associated immunosuppression, long-term use and supportive measures.

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Use SMOFlipid safely and effectively. Please see full prescribing information. For more information, please visit: https://www.FreseniusKabi.com/SMOFlipid

INDICATIONS AND USAGE
SMOFlipid is indicated for the treatment of pediatric and adult patients, including preterm and term 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. (See CONTRAINDICATIONS.)

DOSE AND ADMINISTRATION
The recommended daily dosage and initial maximum infusion rates for pediatric and adult patients are provided in Table 1. Do not exceed the maximum 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 patient’s clinical condition and the site of administration. Monitor liver tests in patients treated with SMOFlipid and consider discontinuation or dosage reduction if abnormalities occur. (See Table 1: Recommended Pediatric and Adult Dosage and Infusion Rate.)

SMOFlipid use is contraindicated in patients who are hypersensitive to soybeans, peanut, tree nuts, or any of the components of SMOFlipid. (See WARNINGS AND PRECAUTIONS, HYPERSENSITIVITY REACTIONS.) SMOFlipid should not be used in patients with known deficiency states of lipids, including hypertriglyceridemia. (See WARNINGS AND PRECAUTIONS, ESSENTIAL FATTY ACID DEFICIENCY.) Infusions should be administered with an approved DEHP 1.2 micron in-line filter during administration. Protect the admixed solution from light. (See TABLE 1: Recommended Pediatric and Adult Dosage and Infusion Rate.)

Table 1: Recommended Pediatric and Adult Dosage and Infusion Rate

<table>
<thead>
<tr>
<th>Age</th>
<th>Pediatric</th>
<th>Adult</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6 months</td>
<td>100-150 mL/hour</td>
<td>150-200 mL/hour</td>
</tr>
<tr>
<td>6 months-1 year</td>
<td>150-200 mL/hour</td>
<td>200-250 mL/hour</td>
</tr>
<tr>
<td>&gt;1 year</td>
<td>200-250 mL/hour</td>
<td>300-350 mL/hour</td>
</tr>
</tbody>
</table>

*Contraindicated in patients who are hypersensitive to soybeans, peanut, tree nuts, or any of the components of SMOFlipid.

CONTRAINDICATIONS
- Severe disorders of lipid metabolism characterized by hyperlipidemia, hypercholesterolemia, and hypertriglyceridemia (1000 mg/dL).
- Contraindicated in patients with known deficiency states of lipids, including hypertriglyceridemia (See WARNINGS AND PRECAUTIONS, ESSENTIAL FATTY ACID DEFICIENCY.) Infusions should be administered with an approved DEHP 1.2 micron in-line filter during administration. Protect the admixed solution from light. (See TABLE 1: Recommended Pediatric and Adult Dosage and Infusion Rate.)

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 the rapid administration of various intravenous lipid emulsions. Hypertriglyceridemia was commonly reported. Strictly adhere to the maximum recommended maximum infusion rate, the hourly infusion rate should not exceed 0.75 mL/kg/hour. Preadm and small for gestational age infants have poor clearance of intravenous lipid emulsions and may have increased free fatty acid plasma levels following lipid infusion.

Patients with conditions such as inherited lipid disorders, obesity, diabetes mellitus, or obesity syndromes have a higher risk of developing hypertriglyceridemia with the use of SMOFlipid. In addition, patients with hypertriglyceridemia may have an increased risk of developing hypertriglyceridemia with administration of SMOFlipid. Excessive deoxystearate administration may further increase such risk. Evaluate patients and eliminate the infused lipid infusion by measuring serum triglycerides before the start of infusion (baseline value) and regularly throughout treatment. If triglyceride levels are above the recommended levels, use SMOFlipid and monitor serum triglyceride levels to avoid clinical consequences of hypertriglyceridemia such as pancreatitis, intravascular lipid deposition (i.e., lower than 400 mg/dL) may be associated with adverse reactions such as hypertriglyceridemia, headaches, and flushing. Avoid potential complications with hypertriglyceridemia such as pancreatitis, lipid pneumonitis, and neurologic changes, including keratoconjunctivitis.

The most common adverse reactions in >1% of pediatric and adult patients were anemia, vomiting, general malaise, metabolic acidosis, increased fluid load, hypertension, hypertriglyceridemia, and rash. The following adverse reactions have been identified during post-approval use of SMOFlipid. Cardiac death, development of hyperglycemia, elevated liver enzymes, hepatic steatosis, and increased bilirubin conjugated. The most common adverse reactions in >1% of pediatric and adult patients were anemia, vomiting, general malaise, hypertension, hypertriglyceridemia, headaches, and flushing. Avoid potential complications with hypertriglyceridemia such as pancreatitis, lipid pneumonitis, and neurologic changes, including keratoconjunctivitis.

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

This brief summary does not include all of the information needed to use KABIVEN and PERIKABIVEN safely and effectively. Read the full Prescribing Information before using KABIVEN and PERIKABIVEN. For more information, please see www.FreseniusKabiNutrition.com/KabivenPI and www.FreseniusKabiNutrition.com/PerikabivenPI.

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 are recommended for use in pediatric patients <2 years of age or preterm infants when the fixed content of the formulation used meets nutritional needs in this age group.

DOSE AND ADMINISTRATION

KABIVEN is indicated for intravenous infusion into a central vein. PeriKABIVEN is indicated for intravenous infusion into a peripheral vein. It is recommended to mix the contents thoroughly by inverting the bags up to 20 times. To ensure a homogenous admixture, KABIVEN and PERIKABIVEN should be individualized based on the patient’s clinical condition to adequately meet their nutritional and fluid requirements. Individual body weight and nutritional/fluid requirements, as well as additional energy given orally/enterally must be considered when administering KABIVEN and PERIKABIVEN.

KABIVEN or PERIKABIVEN should be infused at a rate of 15 to 30 mL/kg/day for KABIVEN and 25 to 45 mL/kg/day for PERIKABIVEN in adults. The maximum daily dosage of KABIVEN and PERIKABIVEN in adults should not exceed 40 mL/kg/day. Do not exceed a maximum daily rate of 3.7 mL/kg/hour for KABIVEN and 3.7 mL/kg/hour for PERIKABIVEN.

The following adverse reactions have been identified during post-approval use of KABIVEN and PERIKABIVEN in countries where it is registered. Gastrointestinal disorders: abdominal distension, abdominal pain. General disorders and administration site conditions: chest tightness. Hematopoietic disorders: thrombocytopenia, coagulation disorders, hyperlipidemia, hepatomegaly, sudden deterioration in the patient’s condition (e.g., fever, anemia, leukopenia, hyperkalemia, hypertriglyceridemia, headache, dizziness, dysgeusia, rash, eczema, hyperglycemia, hypokalemia, pyrexia, increased blood triglycerides, phlebitis, thrombosis, nausea, pruritus, increased gamma-glutamyltransferase, increased blood alkaline phosphatase, decreased coagulation parameters, mental confusion, subependymal hemorrhage.

Diabetes/Hyperglycemia: The use of KABIVEN and PERIKABIVEN are contraindicated in patients with hyperglycemia, who can only be managed by the use of insulin. Hyperglycemia may also be managed by dietary means. KABIVEN or PERIKABIVEN may be administered or adjusted to maintain optimal blood glucose levels during KABIVEN or PERIKABIVEN therapy. If blood glucose levels are above 200 mg/dL during the infusion of KABIVEN or PERIKABIVEN, the infusion rate may need to be decreased. KABIVEN or PERIKABIVEN may be administered or adjusted to maintain optimal blood glucose levels during KABIVEN or PERIKABIVEN therapy. Hyperglycemia may be managed by dietary means, insulin, or other hypoglycemic agents. KABIVEN or PERIKABIVEN may be administered or adjusted to maintain optimal blood glucose levels during KABIVEN or PERIKABIVEN therapy. Hyperglycemia may be managed by dietary means, insulin, or other hypoglycemic agents. KABIVEN or PERIKABIVEN may be administered or adjusted to maintain optimal blood glucose levels during KABIVEN or PERIKABIVEN therapy. Hyperglycemia may be managed by dietary means, insulin, or other hypoglycemic agents. KABIVEN or PERIKABIVEN may be administered or adjusted to maintain optimal blood glucose levels during KABIVEN or PERIKABIVEN therapy. Hyperglycemia may be managed by dietary means, insulin, or other hypoglycemic agents. KABIVEN or PERIKABIVEN may be administered or adjusted to maintain optimal blood glucose levels during KABIVEN or PERIKABIVEN therapy.

KABIVEN or PERIKABIVEN should be used with caution in patients with diabetes or other conditions that may be associated with hyperglycemia. KABIVEN or PERIKABIVEN should be used with caution in patients with diabetes or other conditions that may be associated with hyperglycemia. KABIVEN or PERIKABIVEN should be used with caution in patients with diabetes or other conditions that may be associated with hyperglycemia. KABIVEN or PERIKABIVEN should be used with caution in patients with diabetes or other conditions that may be associated with hyperglycemia. KABIVEN or PERIKABIVEN should be used with caution in patients with diabetes or other conditions that may be associated with hyperglycemia. KABIVEN or PERIKABIVEN should be used with caution in patients with diabetes or other conditions that may be associated with hyperglycemia. KABIVEN or PERIKABIVEN should be used with caution in patients with diabetes or other conditions that may be associated with hyperglycemia. 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**INDICATIONS AND USAGE**

Intralipid® is a 20% Intravenous Fat Emulsion. Intralipid® is indicated as a source of calories and essential fatty acids for adult and pediatric patients requiring parenteral nutrition and as a source of essential fatty acids for prevention of essential fatty acid deficiency (EFAD).

**BRIEF SUMMARY OF PRESCRIBING INFORMATION**

This brief summary does not include all the information needed to use Intralipid® safely and effectively. Please see full prescribing information for intravenous use at www.FreseniusKabiNutrition.com/intralipidPL.

**SAFETY INFORMATION**

INTRALIPID® (A 20% INTRAVENOUS FAT EMULSION) PHARMACY BULK PACK AND INTRALIPID® 30% (A 20% INTRAVENOUS FAT EMULSION) PHARMACY BULK PACK ARE NOT INTENDED FOR DIRECT INTRAVENOUS ADMINISTRATION. INTRALIPID® 20% AND 30% PHARMACY BULK PACK ARE NOT INTENDED FOR DIRECT INTRAVENOUS ADMINISTRATION.

**Dosage and Administration**

The recommended nutritional requirements of lipid and recommended dosages of intralipid 20% to be administered daily to adult and pediatric patients are provided in Table 1, along with recommendations for the initial and maximum infusion rates of intralipid depends on the patient's individual energy requirements influenced by age, body weight, metabolic needs, and other treatment factors. Maximum infusion rates should not exceed the recommended maximum infusion rate in Table 1. Use a 1.2 microne filter before administration.

**Dosage for Intralipid®**

**Adult Patients:**

The initial infusion rate of the nutrient admixture in adults should be equal to 0.125 g fat/kg/hour (1.0 mL/kg/hour) for the first 15 minutes of infusion, followed by a reduction to the required rate after 15 minutes. If the patient has not reached the required rate after 15 minutes, the hourly infusion rate should not exceed 0.25 g fat/kg/hour (2.0 mL/kg/hour) for the first 60 minutes of infusion.

**Pediatric Patients:**

The recommended dosage for premature infants starts at 0.5 g/kg body weight per day. The initial hourly infusion rate should be limited to ensure that the infant's ability to eliminate fat is not exceeded. The maximum recommended dosage is 3 g fat/kg/hour. The initial rate of infusion of the nutrient admixture in pediatric patients should be no more than 0.25 g fat/kg/hour for the first 15 minutes. If/when of the recommended lipid dose or infusion rate was exceeded, cases have also been described when the lipid formulation was administered at a rate exceeding the maximum recommended infusion rate. If signs of symptoms of fat overload syndrome occur, stop the infusion of Intralipid. The syndrome is usually reversible when the infusion of the lipid emulsion is stopped.

**Refueling Syndrome**

Ad libitum administration of Intralipid may result in refueling syndrome, which is characterized by the intracellular shift of potassium, sodium, phosphorus, and magnesium as patients become anuric. Thrombocytopenia and fluid retention may also develop. To prevent these complications, closely monitor hemodynamic changes, continuously infused patients and slowly increase the lipid infusion rate.

**Hypertriglyceridemia**

Ad libitum administration of Intralipid is contraindicated in patients with known hypertriglyceridemia. However, if the triglyceride level is below 1,000 mg/dL in patients with hypertriglyceridemia, it may be possible to administer Intralipid at the recommended infusion rate provided that the patient is monitored closely. In these patients, serum triglyceride levels should be closely monitored and dose adjustments made when indicated.

The use of Intralipid is contraindicated in patients with hypertriglyceridemia in some cases, especially if the triglyceride level is above 1,000 mg/dL. However, if the triglyceride level is below 1,000 mg/dL in patients with hypertriglyceridemia, it may be possible to administer Intralipid at the recommended infusion rate provided that the patient is monitored closely. In these patients, serum triglyceride levels should be closely monitored and dose adjustments made when indicated.

**Fat Overload Syndrome**

Fat overload syndrome is a rare condition that has been reported with intravenous lipid emulsions. In the postmarketing setting, serious adverse reactions including acute respiratory distress, metabolic acidosis, and death have been reported in patients who were treated with Intralipid®. Patients with conditions such as intestinal dysfunction, obesity, diabetes, malnutrition, and end-stage renal disease may be at higher risk for fat overload syndrome with the use of Intralipid®. In addition, patients with hypertriglyceridemia, clinical signs of dehydration, and hypovolemic shock may be at higher risk for fat overload syndrome with Intralipid®. Excessive dose administration may further increase the risk of fat overload syndrome.

Evaluate patients’ capacity to metabolize and eliminate the intralipid lipid microparticles and serum triglyceride levels before the start of dosing. Serum triglyceride levels should be closely monitored and dose adjustments made when indicated.

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

Parenteral nutrition-associated liver disease (PNALD), also referred to as hypertriglyceridemia and cholestasis, is a rare condition that has been reported with intravenous lipid emulsions. In the postmarketing setting, serious adverse reactions including acute respiratory distress, metabolic acidosis, and death have been reported in patients who were treated with Intralipid®. Intralipid® is associated with an increased risk of liver disease, including cholestasis, as a result of its high dose of triglycerides. Intralipid® is contraindicated in patients with known liver disease and a history of PNALD.

To minimize the risk of new or worsening of hypertriglyceridemia, assess serum triglyceride levels to avoid potential complications with intravenous lipid emulsions. Intralipid® is contraindicated in patients with known hypertriglyceridemia. However, if the triglyceride level is below 1,000 mg/dL in patients with hypertriglyceridemia, it may be possible to administer Intralipid® at the recommended infusion rate provided that the patient is monitored closely. In these patients, serum triglyceride levels should be closely monitored and dose adjustments made when indicated.

**Allergic Reactions**

Intralipid® contains soybean and egg phospholipids, which may cause hypersensitivity reactions. Cross reactions have been observed between soybean and egg proteins. Intralipid® contains milk and egg phospholipids, which may cause anaphylactic reactions to egg, soybean, or any of the active or inactive ingredients in Intralipid®. If a hypersensitivity reaction occurs, stop infusion immediately and initiate appropriate treatment and support measures.

**Parenteral Nutrition**

Parenteral nutrition, such as Intralipid, can support microbial growth and is an inducer of endotoxin release as a result of lipid emulsion administration. To reduce the risk of increasing infections, ensure adequate antibiotic precautions (e.g., use of central line catheter, catheter care, and preparation and administration of Intralipid). Monitor for signs and symptoms of clinical infection and observe the patient for at least 24 hours after the daily dosage is stopped, which might indicate infection (including leukocytosis and hyperglycemia). Perform frequent monitoring as required for intravenous catheter insertion site for edema, redness, and discharge.

**Phlebitis**

Phlebitis 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 at a rate exceeding the maximum recommended infusion rate. If signs of symptoms of fat overload syndrome occur, stop the infusion of Intralipid. The syndrome is usually reversible when the infusion of the lipid emulsion is stopped.

**Adverse Reactions**

The adverse reactions contained in 1% of adult patients treated with Intralipid®/sodium of emulsion include nausea, vomiting, pyrexia, hypertension, headache, abdominal pain, diarrhea, flatulence, cough, respiratory tract infection, urticaria, wheezing, anaphylaxis, fever, bleeding, hyperkalemia, hyperbilirubinemia, pyrexia, cholestasis, sepsis, diabetes mellitus, hyperglycemia, liver function test abnormalities, diziness, rash, and thrombocytopenia.

The most common adverse reactions in 1% of patients treated with Intralipid® include anemia, vomiting, increased gamma-glutamyltransferase, cholestasis, pyrexia, increased C-reactive protein, hyperglycemia, increased conglobated bilirubin, some increase in total blood alkaline phosphatase, thrombocytopenia, jaundice, diarrhea, tachycardia, thrombocytopenia, increased alanine amminotransferase, increased aspartate amminotransferase, and PNLAD.

The following adverse reactions from voluntary reports have been reported with Intralipid®: Cardiac disorders: palpitations, Gastrintestinal disorders: vomiting, nausea. General disorders and administration site conditions: chills, discomfort, pyrexia. Nervous system disorders: diziness, Respiratory, thoracic and mediastinal disorders: dyspnea, immune system disorders: hypersensitivity, Vascular disorders: phlebitis, Blood and lymphatic system disorders: anemia.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7776, option 5, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

**Drug Interactions**

Sodium in Intralipid contains vitamin K, which may mask the anticoagulant activity of vitamin K antagonists such as warfarin. In patients who concomitantly receive warfarin, increase monitor laboratory parameters for anticoagulant activity.

**Use in Specific Populations**

Pediatric Patients: The safety and effectiveness of Intralipid have been established in a single study involving 12 pediatric patients aged between 1 and 24 months of age. These patients were anemia, vomiting, gamma-glutamyltransferase increased and cholestasis. In a pediatric study, developed more frequently in intravenously treated patients than in patients treated with a 20% lipid mixed emulsion lipoprotein.

Parenteral nutrition-associated liver disease (PNALD) also referred to as hypertriglyceridemia and cholestasis, is a rare condition that has been reported with intravenous lipid emulsions. In the postmarketing setting, serious adverse reactions including acute respiratory distress, metabolic acidosis, and death have been reported in patients who were treated with Intralipid®. Intralipid® is associated with an increased risk of liver disease, including cholestasis, as a result of its high dose of triglycerides. Intralipid® is contraindicated in patients with known liver disease and a history of PNALD.

To minimize the risk of new or worsening of hypertriglyceridemia, assess serum triglyceride levels to avoid potential complications with intravenous lipid emulsions. Intralipid® is contraindicated in patients with known hypertriglyceridemia. However, if the triglyceride level is below 1,000 mg/dL in patients with hypertriglyceridemia, it may be possible to administer Intralipid® at the recommended infusion rate provided that the patient is monitored closely. In these patients, serum triglyceride levels should be closely monitored and dose adjustments made when indicated.

**Geriatric Use:**

Reported clinical experience has not identified differences in effects between the elderly and other populations. In general, selection for an elderly patient should be cautious, usually starting at the low end of the dose range, reflecting the greater frequency of decreased hepatic, renal, and cardiac function, of concomitant disease or drug therapy.

**Overdosage**

In the event of an overdose, serious adverse reactions may result. Stop the infusion of Intralipid until triglyceride levels have normalized and symptoms have resolved. If symptoms are unresolved by stopping the lipid infusion, if medically appropriate, further intervention may be indicated. Lipids are not dialyzable from plasma.
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

The **FIRST** and **ONLY** 4-oil ILE for all ages and stages

The **FIRST** and **ONLY** three-chamber bag for PN

**References:**
1. Data on file; 06/1/23; calculation includes all ILEs approved in the U.S.
2. Omegaven Prescribing Information, Fresenius Kabi USA, LLC. 2023.
5. SMOFlipid Prescribing Information, Fresenius Kabi USA, LLC. 2023.

Visit [www.FreseniusKabiNutrition.com](http://www.FreseniusKabiNutrition.com) to learn more