

SMOFlipid®

Lipid Injectable Emulsion, USP 20%

SMOFlipid® (lipid injectable emulsion, USP), for intravenous use IMPORTANT SAFETY INFORMATION

What is SMOFlipid?

- Indicated in adult and pediatric patients as a source of calories and essential fatty acids for parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated.
- The hourly infusion rate in pediatrics should not exceed 0.75 mL/kg/hour and 0.5 mL/kg/hour in adults.

SMOFlipid should not be received by patients who have:

- A known allergy to fish, egg, soybean, or peanut, or to any of the active or inactive ingredients in SMOFlipid.
- Abnormally high levels of lipid (triglycerides) in the blood.

SMOFlipid may cause serious side effects including:

- **Serious Adverse Reactions with Rapid Infusion of Intravenous Lipid Emulsion in Neonates and Infants:** Strictly follow the recommended total daily dosage and do not exceed the maximum infusion rate. If poor clearance of fats occurs, the infusion should be stopped, and a medical evaluation started.
- **Risk of Parenteral Nutrition-Associated Liver Disease:** Parenteral nutrition-associated liver disease (PNALD) may progress to liver inflammation and damage caused by a buildup of fat in the liver with scarring and cirrhosis.
- **Allergic Reactions:** Contact your healthcare provider immediately if you are experiencing an allergic reaction.
- **Fat Overload Syndrome, Refeeding Syndrome, Elevated Triglycerides (Hypertriglyceridemia):** Your healthcare provider will monitor you for signs and symptoms of early infection and blood levels.

Monitoring/Laboratory Tests: The content of vitamin K may interfere with blood clotting activity of medications.

The most common side effects (>1%) in adult patients include nausea, vomiting, and high levels of glucose in the blood and **in pediatric patients include** low levels of red blood cells, vomiting, increased levels of liver enzymes (i.e., gamma-glutamyltransferase) and hospital-acquired infections.

These are not all the possible side effects associated with SMOFlipid. Call your healthcare provider for medical advice regarding SMOFlipid side effects. You are encouraged to report negative side effects of SMOFlipid. Contact Fresenius Kabi USA, LLC at: 1-800-551-7176 or FDA at: 1-800-FDA-1088 or www.fda.gov/medwatch. The FDA-approved product labeling can be found at www.FreseniusKabiNutrition.com/SMOFlipidPI.



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Advancing nutrition with **you** in mind



Is **SMOFlipid** right for you?

- SMOFlipid is a prescription for adults and children given intravenously (in the vein)¹
- SMOFlipid is a source of calories and essential fats¹

Talk to your healthcare provider to discuss if SMOFlipid is right for you

SMOFlipid[®] Lipid Injectable Emulsion, USP 20%

Discover the SMOF difference

- Before SMOFlipid, parenteral nutrition in the US included 100% soybean oil as the lipid source
- SMOFlipid is the first lipid advancement in over 40 years, providing a unique blend of soybean, medium-chain triglycerides, olive, and fish oils¹
- Well established safety and tolerability profile¹
- Provides a source of omega-3 fats, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)¹



What should you keep in mind?

- SMOFlipid should not be received by patients who have¹:
 - An allergy to fish, egg, soybean, or peanut, or to any of the active or inactive ingredients in SMOFlipid
 - Abnormally high levels of lipid (triglycerides) in the blood
- The content of vitamin K may interfere with blood clotting activity of medications¹
- Follow the recommended rate of infusion provided by your healthcare provider; if the maximum infusion rate is exceeded, your infusion should be stopped, and you should contact your medical team for an evaluation

Please see Important Safety Information for SMOFlipid on the back cover.



SMOFlipid is a globally recognized lipid for patients of all ages requiring parenteral nutrition*

*Data on file.

What is parenteral nutrition?

- Intravenous (IV) administration of nutrition for patients who cannot eat or absorb enough food through tube feeding formula or by mouth to maintain good nutrition status
- May include protein, carbohydrate, fat, minerals and electrolytes, vitamins, and other trace elements

Who can use **SMOFlipid**?

- SMOFlipid may be used in adults and children who need parenteral nutrition.¹ It is a source of calories and essential fats.¹
- Types of patients on parenteral nutrition:
 - Short bowel syndrome
 - Crohn's disease
 - Malabsorption
 - Intestinal failure or dysfunction
 - Chronic bowel obstruction

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SMOFlipid has been used in more than 7 million patients worldwide*

*Data on file.

What are lipids and why are they important?

- Lipids (also called “fats”) are part of the key nutrients given in parenteral nutrition because they:
 - Are a source of energy the body uses for fuel
 - Provide essential fats that are needed but not produced by the body
 - Provide structure to our cells
 - Carry certain vitamins through the body
- SMOFlipid is an intravenous lipid emulsion which contains 4 oil sources¹:
 - Soybean oil: source of essential fats
 - Medium-chain triglycerides found in coconut and palm kernel oil: clears faster from the bloodstream than other fats²
 - Olive oil: supply of monounsaturated fats
 - Fish oil: source of omega-3 fats, EPA and DHA³

Parenteral nutrition resources

- **ASPEN**
https://www.nutritioncare.org/About_Clinical_Nutrition/What_Is_Parenteral_Nutrition/
- **National Institutes of Health**
<https://medlineplus.gov/nutritionalsupport.html>
- www.FreseniusKabiNutrition.com/products/smoflipid/
- **The Oley Foundation**
https://oley.org/page/HPN_LandingPage

References: 1. SMOFlipid Prescribing Information, Fresenius Kabi USA, LLC. 2023. 2. Bach AC, et al. *Am J Clin Nutr*. 1982;36(5):950-962. 3. Kalish BT, et al. *JPEN J Parenter Enteral Nutr*. 2012;36(4):380-388.

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