SMOFlipid® Case Study:
Small Bowel Syndrome (SBS)

Patient

56-year-old female, underweight (BMI 16), who has been home parenteral nutrition (HPN) dependent for 10 years.

Medical/Surgical History

- Small bowel resection due to volvulus
- Liver disease (stage 1 fibrosis and steatosis) with elevated liver function tests (LFTs)
- Hypertriglyceridemia

Nutrition History

- **HPN:** 1800 mL x 5 days/week providing dextrose at 7.4 g/kg/d, protein 1 g/kg/d, 1 g/kg/d of a 100% soybean oil-based lipid injectable emulsion (ILE). LFTs continued to fluctuate over time, despite changes in PN dextrose and lipid
- **PO Diet:** 5-6 small meals (adequate in protein, high calorie, no concentrated sweets) and oral rehydration therapy
- **PRN:** injectable fluid (IVF) with normal saline (NS) 250-500 mL on non-HPN days (average 2-3 days/week)

Rationale for SMOFlipid and Updated Nutrition Management

- Patient was underweight and needed additional calories that were not able to be provided with soybean oil-based lipid emulsion due to liver disease and hypertriglyceridemia
- ILE was changed to SMOFlipid 1.2 g/kg/d for 6 days per week
- Allowed an increase in calories without increasing dextrose or protein

SMOFlipid®
Lipid Injectable Emulsion, USP 20%

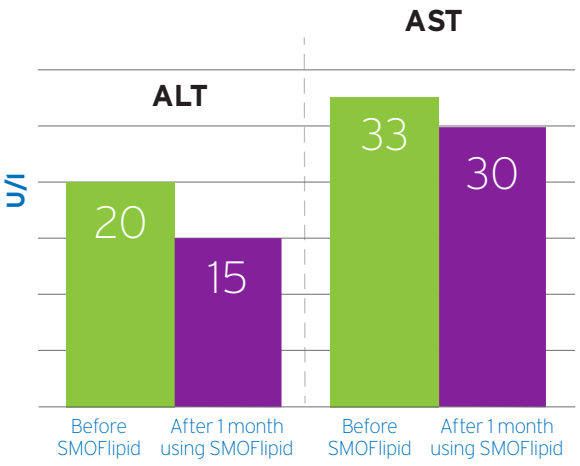
See full Prescribing Information for SMOFlipid available at **www.FreseniusKabiNutrition.com/SMOFlipidPI.**

Please seeIndications and Important Safety Information on next page.

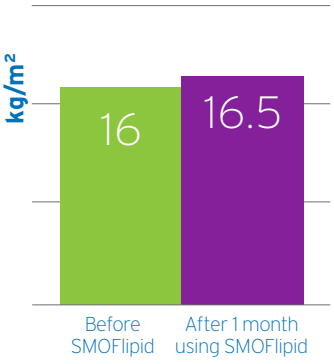
CLINICAL RESULTS

Triglyceride Change

Parameters of Liver Function



BMI



ALT: alanine aminotransferase **AST:** aspartate aminotransferase

Overall Clinical Assessment

During treatment, the patient's LFTs, triglyceride levels, and BMI remained stable.

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 https://freseniuskabinutrition.com/SMOFlipidPI.

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