SMOFlipid® Case Study:
Home Parenteral Nutrition (HPN) Due to Motility Disorder

Patient

32-year-old female who has been on home parenteral nutrition (HPN) since birth, with elevated liver function tests (LFTs).

Medical/Surgical History

- Presented at birth with chronic intestinal pseudo-obstruction (CIPO)
- Unable to consume adequate calories or fluids orally

Nutrition History

- Ht: 157.5 cm, Wt: 54.5 kg
- HPN: fluid 2000 ml/d, 4 days per week; 300 g/d dextrose, 85 g/d protein
- Soybean oil-based lipid injectable emulsion (ILE) dose 68 g/day
- Oral diet: Low FODMAP

Rationale for SMOFlipid and Updated Nutrition Management

- Soybean oil-based ILE dose removed and replaced with alternate ILE (SMOFlipid) isocalorically
- Goal to evaluate for potential change in liver enzymes with SMOFlipid

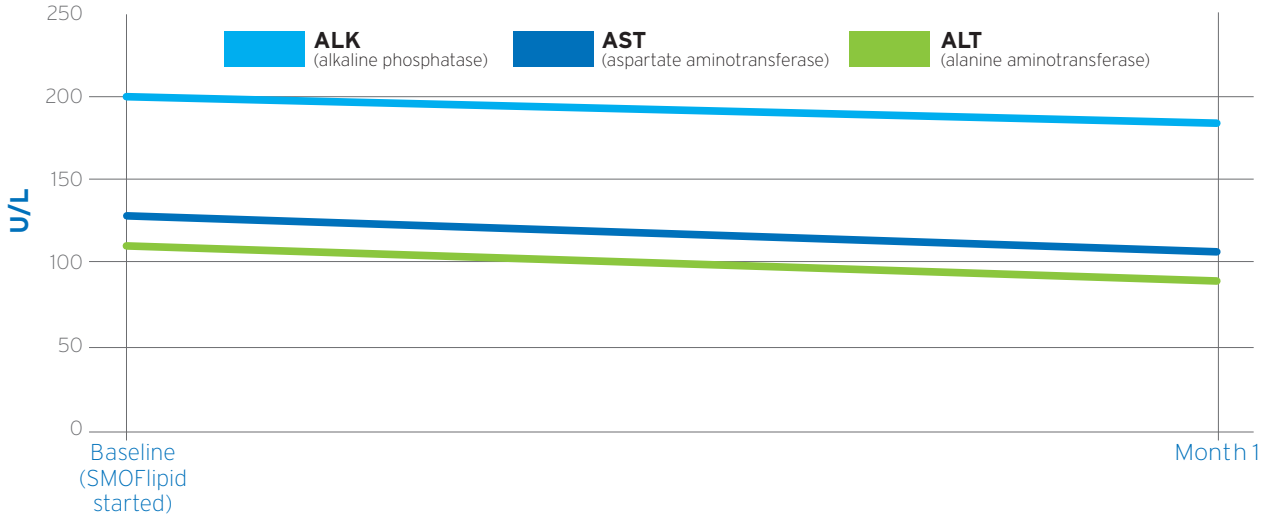
SMOFlipid®
Lipid Injectable Emulsion, USP 20%

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

Please see Indications and Important Safety Information on next page.

CLINICAL RESULTS

Parameters of Liver Function



Overall Clinical Assessment

During the first month of treatment, ALT and AST decreased.
There was no difference in ALK. SMOFlipid was well tolerated.

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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