Smoflipid

(lipid injectable emulsion)

New Product Slideshow

MPR

Introduction

- **Brand name:** Smoflipid
- **Generic name:** Lipid content (mixture of soybean oil, medium-chain triglycerides, olive- and fish-oil)
- **Pharmacological class:** Fatty acids
- **Strength and Formulation:** 0.2g/mL; emulsion for IV infusion; contains aluminum
- **Manufacturer:** Fresenius Kabi USA
- **How supplied:** Emulsion (100mL, 250mL)—10; (500mL)—12
- **Legal Classification:** Rx

SMOFLIPID


500
400
300
200
100
Smoflipid®
NDC 63323-820-50
(lipid injectable emulsion, USP), 20%
100 grams/500 mL (0.2 grams/mL)
For intravenous use.
Rx only
500 mL
Energy: 1000 kcal per 500 mL
Each 100 mL contains:
Soybean Oil, USP 6 g
Medium Chain Triglycerides, NF 6 g
Olive Oil, NF 5 g
Fish Oil, USP 3 g
Also contains: Glycerol, USP 2.5 g, Purified Egg Phospholipids, NF 1.2 g, All-rac-α-Tocopherol, USP 0.016 to 0.023 g, Sodium Oleate 0.03 g, Water for Injection, USP q.s. pH (6 to 9) adjusted with sodium hydroxide, NF.
Osmolarity: 270 mOsm/L
Contains no more than 25 mcg/L of aluminum.
Use only if bag is undamaged and emulsion is homogenous.
See prescribing information.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from freezing.
Once opened, use within 24 hours. Discard any unused portion.
Sterile single use container
Manufactured by:
FRESENIUS KABI
Uppsala, Sweden
freeflex
DEHP
05
PP
LATEX
LOT:
EXP:
DO NOT MAKE ADDITIONS
INFUSION PORT
403006
335 925

Indications

- To provide a source of calories and essential fatty acids in adults requiring **parenteral nutrition** when oral or enteral nutrition is not possible, insufficient, or contraindicated

Dosage & Administration

- Individualize
- Dose based on patient's energy requirements, age, clinical status, body weight, tolerance, ability to eliminate and metabolize lipids, and additional energy given orally/enterally
- Administer by IV infusion via a peripheral or central vein
- **Usual dose:** 1–2g/kg/day; max 2.5g/kg/day

Dosage & Administration

- Initiate rate at 0.5mL/min for the first 15–30mins; increase gradually to required rate after 30mins; max 0.5mL/kg/hr
- **Max daily dose:** 60% of total energy requirements
- Usual infusion duration: 12–24 hours based on patient's clinical status
- If serum triglycerides (>400mg/dL): initiate at a lower dose and increase in smaller increments; check levels before each adjustment

Considerations for Special Populations

- **Pregnancy:** Consider benefits and risks
- **Nursing mothers:** Consider benefits and potential adverse effects
- **Pediatric:** Not established
- **Geriatric:** No overall differences in safety and efficacy
- **Hepatic impairment:** Use with caution; monitor liver function closely

Contraindications

- Fish, egg, soybean, or peanut allergy
- Severe hyperlipidemia or severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglyceride >1000mg/dL)

Warnings/Precautions

- Risk of deaths in preterm and low birth weight infants: see full labeling
- Correct severe fluid and electrolyte disorders prior to initiating
- Measure serum triglycerides at baseline, with each dose increase, and regularly during therapy
- Discontinue and treat if hypersensitivity reactions occur

Warnings/Precautions

- Monitor for signs/symptoms of infection and essential fatty acid deficiency (EFAD)
- Severely undernourished: avoid overfeeding
- Risk of Parenteral Nutrition Associated Liver Disease (PNALD); consider discontinuation or dose reduction if abnormal LFTs occur
- Monitor fluids, electrolytes, blood glucose, liver and kidney function, CBCs, platelets, coagulation parameters throughout treatment

Interactions

- **Vitamin K content** may antagonize anticoagulants (eg, coumarin, warfarin); monitor

- High lipid levels in plasma may interfere with blood tests (eg, hemoglobin, triglycerides, bilirubin, LDH, oxygen saturation)

Adverse Reactions

- Nausea
- Vomiting
- Hyperglycemia
- Flatulence
- Pyrexia
- Abdominal pain
- Hypertriglyceridemia
- Hypertension
- Sepsis
- Dyspepsia
- UTI
- Anemia
- Device-related infections
- Refeeding syndrome
- PNALD
- Aluminum toxicity
- Fat overload syndrome

Mechanism of Action

- Smoflipid administered **intravenously** provides a biologically utilizable source of calories and essential fatty acids

- It causes an increase in heat production, decrease in respiratory quotient, and increase in oxygen consumption

Clinical Trials

- The efficacy of Smoflipid was compared to soybean oil lipid emulsions in 3 randomized, double-blind, controlled studies **(Studies 1, 2 and 3)**

- Nutritional efficacy was assessed by biomarkers of lipid metabolism, anthropometric indices (body weight, height, BMI), and/or biomarkers of protein metabolism (albumin) and mean changes in fatty acid parameters

Clinical Trials

- **Study 1** (n=73) was a double-blind, randomized, active-controlled, parallel-group, multicenter study in patients who required at least 28 days of PN
- Changes in mean triglyceride levels from Baseline to Week 4 were similar in both the Smoflipid and comparator groups
- Decrease in mean albumin levels in both groups were comparable
- Mean changes in body weight and BMI were similar in both groups

Clinical Trials

- **Study 2** (n=249) was a randomized, double-blind, active-controlled, multicenter study in postoperative patients who received either Smoflipid or a soybean oil IV lipid emulsion for at least 5 days

- From Baseline to Day 6, changes in mean triglyceride levels increased similarly in both the Smoflipid and comparator groups

Clinical Trials

- **Study 3** (n=32) was a double-blind, randomized, active-controlled, parallel-group, multicenter study in patients who required TPN for 10 to 14 days

- The increase in mean triglyceride levels from Baseline to the final assessment was similar in both the Smoflipid and comparator groups

Clinical Trials

- Although the 3 studies were not adequately designed to demonstrate noninferiority of Smoflipid to the soybean oil comparator, they support Smoflipid as a source of calories and essential fatty acids in adults

- For more clinical data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/smoflipid/drug/34596