Between the overwrap and the inner Smoflipid® Lipid Injectable Emulsion container is an oxygen absorber and the OXALERT Integrity Indicator.

OXALERT Indicator color indicates **USABLE**.

OXALERT Indicator is black, product has had too much exposure to oxygen and should **NOT be used**.

Please see Important Safety Information, including Boxed Warning, for Smoflipid on page 4.
INSTRUCTIONS FOR USE

Smoflipid® Lipid Injectable Emulsion, USP 20%

1. Inspect the integrity indicator (Oxalert®) (A) before removing the overpouch. Discard the product if the indicator is black.

2. Place the bag on a clean, flat surface. Remove the overpouch by tearing at the notch and pulling down along the container. The Oxalert sachet (A) and the oxygen absorber (B) should be discarded.

Inspect the bag and contents prior to administration. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Inspect Smoflipid to ensure that the emulsion has not separated. The lipid emulsion should be a homogenous liquid with a milky appearance. Discard the bag if there appears to be a phase separation of the emulsion, or if any signs of discoloration, particulates, and/or leakage are observed.

Please see Important Safety Information, including Boxed Warning, for Smoflipid on page 4.
3. Break off the BLUE infusion port cap with the arrow pointing away from the bag.

**NOTE:** Choose a nonvented infusion set or close the air vent on a vented set. Follow the instructions for use for the infusion set. Use infusion sets (according to ISO Number 8536-4) with an external spike diameter of 5.5 to 5.7 mm. Use a 1.2 micron in-line filter during administration.

4. Hold the base of the infusion port. Insert the spike through the infusion port by rotating your wrist slightly until the spike is inserted.

5. Hang the bag using the hanger cut and start infusion.

**For Single Use Only.**

**Discard unused portion.**

After removing the overpouch, Smoflipid should be used immediately. If not used immediately, the product should not be stored longer than 24 hours at 2° to 8°C (36° to 46°F). After removal from storage, the emulsion should be infused within 24 hours.

See full prescribing information for admixing instructions.
INDICATIONS AND USAGE
Smoflipid is indicated in adults as a source of calories and essential fatty acids for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

Limitations of Use
The omega-6:omega-3 fatty acid ratio and Medium Chain Triglycerides in Smoflipid have not been shown to improve clinical outcomes compared to other intravenous lipid emulsions.

WARNING: DEATH IN PRETERM INFANTS
See full prescribing information for complete boxed warning
- Deaths in preterm infants have been reported in literature.
- Autopsy findings included intravascular fat accumulation in the lungs.
- Preterm and lowbirth weight infants have poor clearance of intravenous lipid emulsion and increased free fatty acid plasma levels following lipid emulsion infusion.

DOSAGE AND ADMINISTRATION
- For intravenous infusion only into a peripheral or central vein.
- Recommended dosage depends on age, energy expenditure, clinical status, body weight, tolerance, ability to metabolize, and consideration of additional energy given to the patient.
- The usual daily dosage in adults is 1 to 2 grams/kg per day and should not exceed 2.5 grams/kg per day.

DOSAGE FORMS AND STRENGTHS
Smoflipid is a lipid injectable emulsion with a lipid content of 0.2 grams/mL in 100 mL, 250 mL, and 500 mL.

CONTRAINDICATIONS
- Known hypersensitivity to fish, egg, soybean, or peanut protein, or to any of the active ingredients or excipients.
- Severe hyperlipidemia or severe disorders of lipid metabolism with serum triglycerides > 1,000 mg/dL.

WARNINGS AND PRECAUTIONS
- Hypersensitivity Reactions: Monitor for signs or symptoms. Discontinue infusion if reactions occur.
- Infection, Fat Overload, Hypertriglyceridemia, and Refeeding Complications: Monitor for signs and symptoms; monitor laboratory parameters.
- Aluminum Toxicity: Increased risk in patients with renal impairment, including preterm infants.
- Parenteral Nutrition-Associated Liver Disease: Increased risk in patients who receive parenteral nutrition for extended periods of time, especially preterm infants. Monitor liver function tests, if abnormalities occur consider discontinuation or dosage reduction.

ADVERSE REACTIONS
Most common adverse drug reactions (>1%) from clinical trials were nausea, vomiting, hyperglycemia, flatulence, pyrexia, abdominal pain, increased blood triglycerides, hypertension, sepsis, dyspepsia, urinary tract infection, anemia and device related infection.

To report suspected adverse reactions, contact Fresenius Kabi Vigilance & Medical Affairs at 1-800-551-7176 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS
Coumarin and Coumarin Derivatives, Including Warfarin: Anticoagulant activity may be counteracted; monitor laboratory parameters.

FOR MORE INFORMATION ABOUT SMOFLIPID®:
Website: www.smoflipid.com
To Order: 1.888.386.1300
Med Info phone: 1.800.551.7176 (option 4)
Med Info email: nutrition.medinfo.USA@fresenius-kabi.com

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