INDICATIONS AND USAGE

2.2 Dosage Instructions

Use the following instructions to prepare and infuse SMOFlipid, if used, to minimize pH-related problems by ensuring that typically tolerated pH levels are maintained.

4.1 Opening the Container

• If used, pierce the overpouch with a sterile, single-use fenestrated needles and the infusion port. Ensure the correct needle is used.

To minimize pH-related problems by ensuring that typically tolerated pH levels are maintained.

4.7 Incompatibilities

• SMOFlipid is not compatible with chlorhexidine, thiamine, vitamin E, and amphotericin B.

5 WARNINGS AND PRECAUTIONS

5.1 Hypertrophic Heart Disease

• Hypertrophic heart disease (HHD) is a cardiac disease that can be associated with SMOFlipid use. Appropriate monitoring of cardiac function is recommended in patients with known or suspected HHD.

5.2 Parenteral Nutrition-Associated Liver Disease and Other Hepatobiliary Disorders

• Parenteral nutrition-associated liver disease (PNALD) is a common complication of parenteral nutrition (PN) therapy. It can be associated with SMOFlipid use, particularly when the PN formula contains high levels of triglycerides. Appropriate monitoring of liver function and intervention in case of PNALD is recommended.

5.3 Hypersensitivity Reactions

• Hypersensitivity reactions to SMOFlipid may occur. Appropriate monitoring and intervention in case of adverse reactions is recommended.

5.4 Infections

• Infections may occur in patients treated with SMOFlipid. Appropriate monitoring and intervention in case of adverse reactions is recommended.

5.5 Phosphorus Sensitivity

• Phosphorus sensitivity may occur in patients treated with SMOFlipid. Appropriate monitoring and intervention in case of adverse reactions is recommended.

5.6 Refeeding Syndrome

• Refeeding syndrome may occur in patients treated with SMOFlipid. Appropriate monitoring and intervention in case of adverse reactions is recommended.

5.7 Hypertriglyceridemia

• Hypertriglyceridemia may occur in patients treated with SMOFlipid. Appropriate monitoring and intervention in case of adverse reactions is recommended.

5.8 Aluminum Toxicity

• Aluminum toxicity may occur in patients treated with SMOFlipid. Appropriate monitoring and intervention in case of adverse reactions is recommended.

5.9 Hypothalamic-Pituitary-Adrenal (HPA) Axis Suppression

• HPA axis suppression may occur in patients treated with SMOFlipid. Appropriate monitoring and intervention in case of adverse reactions is recommended.

6 DRUG INTERACTIONS

6.1 General Considerations

• General considerations for drug interactions with SMOFlipid are documented when administering other medications. Appropriate monitoring and intervention in case of adverse reactions is recommended.

6.2 Specific Considerations

• Specific considerations for drug interactions with SMOFlipid are documented when administering other medications. Appropriate monitoring and intervention in case of adverse reactions is recommended.

7 DRUG INTERACTIONS

7.1 General Considerations

• General considerations for drug interactions with SMOFlipid are documented when administering other medications. Appropriate monitoring and intervention in case of adverse reactions is recommended.

7.2 Specific Considerations

• Specific considerations for drug interactions with SMOFlipid are documented when administering other medications. Appropriate monitoring and intervention in case of adverse reactions is recommended.

8.5 Geriatric Use

• Geriatric use of SMOFlipid is recommended. Appropriate monitoring and intervention in case of adverse reactions is recommended.

8.6 Pregnancy

• Pregnancy use of SMOFlipid is recommended. Appropriate monitoring and intervention in case of adverse reactions is recommended.

8.7 Nursing Mothers

• Nursing mothers use of SMOFlipid is recommended. Appropriate monitoring and intervention in case of adverse reactions is recommended.

8.8 Pediatric Use

• Pediatric use of SMOFlipid is recommended. Appropriate monitoring and intervention in case of adverse reactions is recommended.

9 ADVERSE REACTIONS

9.1 General Considerations

• General considerations for adverse reactions with SMOFlipid are documented when administering other medications. Appropriate monitoring and intervention in case of adverse reactions is recommended.

9.2 Specific Considerations

• Specific considerations for adverse reactions with SMOFlipid are documented when administering other medications. Appropriate monitoring and intervention in case of adverse reactions is recommended.

10 OVERDOSAGE

10.1 General Considerations

• General considerations for overdose with SMOFlipid are documented when administering other medications. Appropriate monitoring and intervention in case of adverse reactions is recommended.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 Packaged Container

• SMOFlipid is packed in a single-dose flexible container. Appropriate handling and storage are recommended to minimize pH-related problems by ensuring that typically tolerated pH levels are maintained.

16.2 Storage

• SMOFlipid must be stored at room temperature. Appropriate storage and handling are recommended to minimize pH-related problems by ensuring that typically tolerated pH levels are maintained.

16.3 Handling

• Handling of SMOFlipid should be performed with care to minimize pH-related problems by ensuring that typically tolerated pH levels are maintained.

17 PATIENT COUNSELING INFORMATION

17.1 General Considerations

• General considerations for patient counseling with SMOFlipid are documented when administering other medications. Appropriate monitoring and intervention in case of adverse reactions is recommended.

17.2 Specific Considerations

• Specific considerations for patient counseling with SMOFlipid are documented when administering other medications. Appropriate monitoring and intervention in case of adverse reactions is recommended.

18 REPRODUCIBILITY OF PRESCRIBED INFORMATION

18.1 General Considerations

• General considerations for reproducibility of prescribed information with SMOFlipid are documented when administering other medications. Appropriate monitoring and intervention in case of adverse reactions is recommended.

18.2 Specific Considerations

• Specific considerations for reproducibility of prescribed information with SMOFlipid are documented when administering other medications. Appropriate monitoring and intervention in case of adverse reactions is recommended.
SMOFlipid for the maximum study duration of 78-84 days. Adult Study 3 was a double-blind randomized, active-controlled, parallel-group study that compared SMOFlipid to a time-matched soybean oil lipid emulsion comparator. The results were similar in both the SMOFlipid and comparator group. Mean changes in body weight (kg) and BMI (kg/m²) were similar in both groups. Mean changes in body weight and BMI were not significantly different between the two groups.

**6 ADVERSE REACTIONS**

Adverse reactions described elsewhere in this prescribing information are:

- **Transaminase elevations** in infants and neonates,; and
- **Transaminase elevations** in children and young patients.

**7 DRUG INTERACTIONS**

The safety and effectiveness of SMOFlipid have been established in adults, children, and neonates with PNAC (a component of PN delivered in a 3-chamber bag). The safety database for SMOFlipid includes exposure in 399 patients ranging in age from 29 to 153 days who were expected to receive parenteral nutrition for more than 2 weeks. SMOFlipid was administered to 9 patients ranging in age from 29 to 153 days who were expected to receive parenteral nutrition for more than 2 weeks. SMOFlipid was administered to 9 patients ranging in age from 1 to 7 years.

**8 USE IN SPECIFIC POPULATIONS**

**8.1 Pregnancy**

The safety and effectiveness of SMOFlipid were assessed in 169 pregnant women who received SMOFlipid in combination with a time-matched soybean oil lipid emulsion comparator. Although the clinical significance of the following adverse effects was not evaluated, they were seen in pregnant women who received SMOFlipid.

**14 CLINICAL PHARMACOLOGY**

**14.1 Mechanism of Action**

The effects in vitro of SMOFlipid are based on the PK and PD profiles of the lipid components of SMOFlipid. The PK and PD profiles of the lipid components of SMOFlipid are based on the PK and PD profiles of the individual lipid components. The PK and PD profiles of the lipid components of SMOFlipid are based on the PK and PD profiles of the individual lipid components. The PK and PD profiles of the lipid components of SMOFlipid are based on the PK and PD profiles of the individual lipid components.

**15 CLINICAL PHARMACOLOGY**

**15.1 Mechanism of Action**

The effects of SMOFlipid in vivo are based on the PK and PD profiles of the lipid components of SMOFlipid. The PK and PD profiles of the lipid components of SMOFlipid are based on the PK and PD profiles of the individual lipid components. The PK and PD profiles of the lipid components of SMOFlipid are based on the PK and PD profiles of the individual lipid components. The PK and PD profiles of the lipid components of SMOFlipid are based on the PK and PD profiles of the individual lipid components.

**16 CLINICAL PHARMACOLOGY**

**16.1 Mechanism of Action**

The effects of SMOFlipid in vivo are based on the PK and PD profiles of the lipid components of SMOFlipid. The PK and PD profiles of the lipid components of SMOFlipid are based on the PK and PD profiles of the individual lipid components. The PK and PD profiles of the lipid components of SMOFlipid are based on the PK and PD profiles of the individual lipid components. The PK and PD profiles of the lipid components of SMOFlipid are based on the PK and PD profiles of the individual lipid components.