The recommended duration of infusion for Smoflipid is 1. Inspect the integrity indicator (Oxalert®) (A) before removing.

Initial U.S. Approval: 2016

Smoflipid Pharmacy Bulk Package is only indicated for use in

• Preterm and low-birth-weight infants have poor clinical status, body weight, tolerance, ability to metabolize,

• In adult patients with levels > 400 mg/dL, reduce the dose of

5.8 Hypertriglyceridemia

• Hypertriglyceridemia [see Warnings and Precautions (5.8)]

1. Risk of Parenteral Nutrition-Associated Liver Disease:

To report SUSPECTED ADVERSE REACTIONS, contact

17 PATIENT COUNSELING INFORMATION

See 17 for PATIENT COUNSELING INFORMATION.

14 CLINICAL STUDIES

Use of Smoflipid has been associated with prolonged plasma clearance of thiamine, necessitating thiamine supplementation. Thiamine deficiency and fluid retention may become anabolic. Thiamine deficiency and fluid retention may

Tachypnea, hypotension, myocardial depression, cyanosis, respiratory distress, allergic symptoms; monitor laboratory parameters. (5.3, 5.6)

4.4.2 Laboratory Tests

Parenteral drug products should be inspected visually for

Lipid emulsions, such as Smoflipid, can support microbial growth and may cause emulsion instability. The following clinical setting may increase the risk of infection: microbiological contamination of the lipid container and central line. If infusion lines are to be changed, the negative pressure of the new line should be used to aspirate the old line. The old line is then discarded. If this is not done, excess lipid may remain in the line and cause an infusion reaction. Use only solutions in which Smoflipid has been shown to cause emulsion instability.

• Refeeding Syndrome [see Warnings and Precautions (5.5)]

• Smoflipid is prepared with the following amino acids: glutamic acid, aspartic acid, lysine, methionine, threonine, cysteine, histidine,脯氨酸, tyrosine,

Store in a dry area such as a laminar flow hood or an equivalent clean air area such as a laminar flow hood or an equivalent clean air area. Restored Smoflipid is not for direct infusion. Preparations should not be stored longer than 24 hours after administration, transfer to a separate PN container for

• Use the Pharmacy Bulk Package immediately for admixing with other drugs and solutions. Solution should be prepared within 12 hours of removal from refrigerator and used immediately. The product should not be stored longer than 24 hours after administration.

Parenteral drug products should be inspected visually for

• Risk of Parenteral Nutrition-Associated Liver Disease:

The risk of PNALD is particularly high in patients with severe immuno-suppression, including those with congenital immune disorders or chronic conditions such as inherited lipid disorders, obesity, diabetes mellitus, and metabolic syndrome.

5.2 Potential Nutrient-Deficiency Associated Liver Disease

Tumors are not observed with long-term use of Smoflipid. No anaphylaxis associated reactions have been reported with Smoflipid. Therefore, Smoflipid is not contraindicated in patients with a history of anaphylaxis to egg, fish, shellfish,

1. Risk of Parenteral Nutrition-Associated Liver Disease:

To report SUSPECTED ADVERSE REACTIONS, contact

17 PATIENT COUNSELING INFORMATION

See 17 for PATIENT COUNSELING INFORMATION.

14 CLINICAL STUDIES

Use of Smoflipid has been associated with prolonged plasma clearance of thiamine, necessitating thiamine supplementation. Thiamine deficiency and fluid retention may

Tachypnea, hypotension, myocardial depression, cyanosis, respiratory distress, allergic symptoms; monitor laboratory parameters. (5.3, 5.6)

4.4.2 Laboratory Tests

Parenteral drug products should be inspected visually for

Lipid emulsions, such as Smoflipid, can support microbial growth and may cause emulsion instability. The following clinical setting may increase the risk of infection: microbiological contamination of the lipid container and central line. If infusion lines are to be changed, the negative pressure of the new line should be used to aspirate the old line. The old line is then discarded. If this is not done, excess lipid may remain in the line and cause an infusion reaction. Use only solutions in which Smoflipid has been shown to cause emulsion instability.

• Risk of Parenteral Nutrition-Associated Liver Disease:

To report SUSPECTED ADVERSE REACTIONS, contact

17 PATIENT COUNSELING INFORMATION

See 17 for PATIENT COUNSELING INFORMATION.

14 CLINICAL STUDIES

Use of Smoflipid has been associated with prolonged plasma clearance of thiamine, necessitating thiamine supplementation. Thiamine deficiency and fluid retention may become anabolic. Thiamine deficiency and fluid retention may

Tachypnea, hypotension, myocardial depression, cyanosis, respiratory distress, allergic symptoms; monitor laboratory parameters. (5.3, 5.6)

4.4.2 Laboratory Tests

Parenteral drug products should be inspected visually for

Lipid emulsions, such as Smoflipid, can support microbial growth and may cause emulsion instability. The following clinical setting may increase the risk of infection: microbiological contamination of the lipid container and central line. If infusion lines are to be changed, the negative pressure of the new line should be used to aspirate the old line. The old line is then discarded. If this is not done, excess lipid may remain in the line and cause an infusion reaction. Use only solutions in which Smoflipid has been shown to cause emulsion instability.

• Risk of Parenteral Nutrition-Associated Liver Disease:

To report SUSPECTED ADVERSE REACTIONS, contact

17 PATIENT COUNSELING INFORMATION

See 17 for PATIENT COUNSELING INFORMATION.

14 CLINICAL STUDIES

Use of Smoflipid has been associated with prolonged plasma clearance of thiamine, necessitating thiamine supplementation. Thiamine deficiency and fluid retention may become anabolic. Thiamine deficiency and fluid retention may

Tachypnea, hypotension, myocardial depression, cyanosis, respiratory distress, allergic symptoms; monitor laboratory parameters. (5.3, 5.6)

4.4.2 Laboratory Tests

Parenteral drug products should be inspected visually for

Lipid emulsions, such as Smoflipid, can support microbial growth and may cause emulsion instability. The following clinical setting may increase the risk of infection: microbiological contamination of the lipid container and central line. If infusion lines are to be changed, the negative pressure of the new line should be used to aspirate the old line. The old line is then discarded. If this is not done, excess lipid may remain in the line and cause an infusion reaction. Use only solutions in which Smoflipid has been shown to cause emulsion instability.

• Risk of Parenteral Nutrition-Associated Liver Disease:

To report SUSPECTED ADVERSE REACTIONS, contact

17 PATIENT COUNSELING INFORMATION

See 17 for PATIENT COUNSELING INFORMATION.

14 CLINICAL STUDIES

Use of Smoflipid has been associated with prolonged plasma clearance of thiamine, necessitating thiamine supplementation. Thiamine deficiency and fluid retention may become anabolic. Thiamine deficiency and fluid retention may

Tachypnea, hypotension, myocardial depression, cyanosis, respiratory distress, allergic symptoms; monitor laboratory parameters. (5.3, 5.6)

4.4.2 Laboratory Tests

Parenteral drug products should be inspected visually for

Lipid emulsions, such as Smoflipid, can support microbial growth and may cause emulsion instability. The following clinical setting may increase the risk of infection: microbiological contamination of the lipid container and central line. If infusion lines are to be changed, the negative pressure of the new line should be used to aspirate the old line. The old line is then discarded. If this is not done, excess lipid may remain in the line and cause an infusion reaction. Use only solutions in which Smoflipid has been shown to cause emulsion instability.

• Risk of Parenteral Nutrition-Associated Liver Disease:

To report SUSPECTED ADVERSE REACTIONS, contact

17 PATIENT COUNSELING INFORMATION

See 17 for PATIENT COUNSELING INFORMATION.

14 CLINICAL STUDIES

Use of Smoflipid has been associated with prolonged plasma clearance of thiamine, necessitating thiamine supplementation. Thiamine deficiency and fluid retention may become anabolic. Thiamine deficiency and fluid retention may

Tachypnea, hypotension, myocardial depression, cyanosis, respiratory distress, allergic symptoms; monitor laboratory parameters. (5.3, 5.6)

4.4.2 Laboratory Tests

Parenteral drug products should be inspected visually for

Lipid emulsions, such as Smoflipid, can support microbial growth and may cause emulsion instability. The following clinical setting may increase the risk of infection: microbiological contamination of the lipid container and central line. If infusion lines are to be changed, the negative pressure of the new line should be used to aspirate the old line. The old line is then discarded. If this is not done, excess lipid may remain in the line and cause an infusion reaction. Use only solutions in which Smoflipid has been shown to cause emulsion instability.

• Risk of Parenteral Nutrition-Associated Liver Disease:

To report SUSPECTED ADVERSE REACTIONS, contact

17 PATIENT COUNSELING INFORMATION

See 17 for PATIENT COUNSELING INFORMATION.

14 CLINICAL STUDIES

Use of Smoflipid has been associated with prolonged plasma clearance of thiamine, necessitating thiamine supplementation. Thiamine deficiency and fluid retention may become anabolic. Thiamine deficiency and fluid retention may

Tachypnea, hypotension, myocardial depression, cyanosis, respiratory distress, allergic symptoms; monitor laboratory parameters. (5.3, 5.6)

4.4.2 Laboratory Tests

Parenteral drug products should be inspected visually for

Lipid emulsions, such as Smoflipid, can support microbial growth and may cause emulsion instability. The following clinical setting may increase the risk of infection: microbiological contamination of the lipid container and central line. If infusion lines are to be changed, the negative pressure of the new line should be used to aspirate the old line. The old line is then discarded. If this is not done, excess lipid may remain in the line and cause an infusion reaction. Use only solutions in which Smoflipid has been shown to cause emulsion instability.

• Risk of Parenteral Nutrition-Associated Liver Disease:

To report SUSPECTED ADVERSE REACTIONS, contact

17 PATIENT COUNSELING INFORMATION

See 17 for PATIENT COUNSELING INFORMATION.
Prior to administration of Smoflipid, correct severe fluid and nutrition is not possible, insufficient, or contraindicated. (1)

2.3 Preparation of Pharmacy Bulk Package

3.3 Place the lipid container on ice for administration after preparation. Smoflipid 1000 mL is supplied as a Pharmacy Bulk Package to be used only for admixing in PHNS for parenteral nutrition.

4. Hold the base of the infusion port. Insert the spike through the center of the base of the infusion port. Insert the spike through the center of the base of the infusion port. Insert the spike through the center of the base of the infusion port.

5. Hang the bag using the hanger cut through the center of the base of the infusion port. Insert the spike through the center of the base of the infusion port. Insert the spike through the center of the base of the infusion port.

6. Use the Pharmacy Bulk Package immediately for admixing with an amino acid injection, drug, or other agent. Use the Pharmacy Bulk Package immediately for admixing with an amino acid injection, drug, or other agent. Use the Pharmacy Bulk Package immediately for admixing with an amino acid injection, drug, or other agent.

7. Hang the bag using the hanger cut through the center of the base of the infusion port. Insert the spike through the center of the base of the infusion port. Insert the spike through the center of the base of the infusion port.

8. Use the Pharmacy Bulk Package immediately for admixing with an amino acid injection, drug, or other agent. Use the Pharmacy Bulk Package immediately for admixing with an amino acid injection, drug, or other agent. Use the Pharmacy Bulk Package immediately for admixing with an amino acid injection, drug, or other agent.

9. Use the Pharmacy Bulk Package immediately for admixing with an amino acid injection, drug, or other agent. Use the Pharmacy Bulk Package immediately for admixing with an amino acid injection, drug, or other agent. Use the Pharmacy Bulk Package immediately for admixing with an amino acid injection, drug, or other agent.
• Before starting the infusion, determine serum triglyceride levels with each adjustment [see Warnings and Precautions (5.5)]. Serum lipid levels can be used as indicators of hepatic function, blood count including platelets, and coagulation function at baseline and whenever solution and container permit. Inspect Smoflipid to ensure that the emulsion has not separated. The lipid emulsion should be discarded whenever solution and container permit, particulate matter and discoloration prior to administration. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, by tearing at the notch and pulling down along the container. The overpouch must be intact. Discard the product if the indicator is black. Smoflipid contains no more than 25 mcg/L of aluminum. Use of Smoflipid in parenteral nutrition or in a combination product should be considered within limits established by the SDMA guidelines. Exceeding the established limits may result in increased free fatty acid plasma levels following clearance of intravenous lipid emulsion and clinical consequences associated with hypertriglyceridemia. SMOflipid is for central or peripheral intravenous infusion. To decrease the risk of infectious complications, ensure aseptic technique by using the overpouch (see 3.3). The safe and effective use of Smoflipid in pediatric patients, including preterm infants, has not been established. Parenteral nutrition-associated liver disease (PNALD) has been associated with PN for extended periods of time, especially preterm infants. Refeeding severely undernourished patients with PN may result in the overpouch may result in increased free fatty acid plasma levels following clearance of intravenous lipid emulsion and clinical consequences associated with hypertriglyceridemia.

3.3 Preparation of Pharmacy Bulk Package

Additions to the PN admixtures should be evaluated by a pharmacist. The pharmacy bulk package is available to determine serum fatty acids levels. Reference values have been determined in the cord blood at the time of delivery of neonates, particularly, and in neonates as well. The omega-6: omega-3 fatty acid ratio and Medium Chain Triglycerides (MCT) in Smoflipid support the production of ketone bodies and the effective use of carbohydrates. Smoflipid contains no more than 25 mcg/L of aluminum. Use of Smoflipid in parenteral nutrition or in a combination product should be considered within limits established by the SDMA guidelines. Exceeding the established limits may result in increased free fatty acid plasma levels following clearance of intravenous lipid emulsion and clinical consequences associated with hypertriglyceridemia.
3.3 Management of hyperlipidemia

• Severe hyperlipidemia or severe disorders of lipid metabolism

5.10 Interference with Laboratory Tests

Amino acid solutions exert buffering effects that protect the

2.4 Administration

1. Prepare the lipids in a new, flat surface. Remove two

6. ADVERSE REACTIONS

5.2 Hypersensitivity Reactions

• Preterm and low-birth-weight infants have poor

2.1 Administration Instructions

for intravenous use (lipid injectable emulsion, USP), for intravenous use

5.4 Fat Overload Syndrome

7.1 Drug Interactions

1. Smoflipid is indicated for use in

3. DISCUSSION FORMS AND STRENGTHS

effective and safe lipid and glucose replacement therapy in patients

4. CONTRAINDICATIONS

• Smoflipid Pharmacy Bulk Package is only indicated for use in

1. Do not use administration sets and lines that contain di-2-

9. INDUCTION AND USAGE

• Indications for use in parenteral nutrition

• Smoflipid may be mixed with amino acid and dextrose

8.6 Hepatic Impairment

2. Transfer amino acid injection.

3. Transfer lipid admixture to ensure that:

5.3 Risk of Catheter-Related Infections

2.1 Administration Instructions

• The usual daily dosage in adults is 1 to 2 grams/kg per day

1. Add the lipids to an amino acid solution and mix to

4. CONTAMINATIONS

• Maximum infusion rate should not exceed 0.5 mL/kg/hour.

5.7 Risk of Parenteral Nutrition-Associated Liver Disease

8.5 INTRAVENOUS ADMINISTRATION

• Indications for use in parenteral nutrition

7.1 Drug Interactions

• Indications for use in parenteral nutrition

5.11 Indirect Coagulation Tests

• The omega-6: omega-3 fatty acid ratio and Medium Chain

2.2 Administration

• Smoflipid contains no more than 25 mcg/L of aluminum.

8.1 CLINICAL PHARMACOLOGY

• Indications for use in parenteral nutrition

5.10 Interference with Laboratory Tests

• Indications for use in parenteral nutrition

4. CONTRAINDICATIONS

• Do not use administration sets and lines that contain di-2-

9. INDUCTION AND USAGE

• Indications for use in parenteral nutrition

7.1 Drug Interactions

• Do not use administration sets and lines that contain di-2-

5.7 Risk of Parenteral Nutrition-Associated Liver Disease

• Indications for use in parenteral nutrition

3. DISCUSSION FORMS AND STRENGTHS

• Indications for use in parenteral nutrition

2. Transfer amino acid injection.

3. Transfer lipid admixture to ensure that:

4. CONTRAINDICATIONS

• Severe hyperlipidemia or severe disorders of lipid metabolism

5.2 Hypersensitivity Reactions

• Smoflipid contains no more than 25 mcg/L of aluminum.
Before starting the infusion, determine serum triglyceride levels to establish the baseline value. In patients with elevated triglyceride levels, therapy should be advanced in smaller increments, monitoring the triglyceride response. If the triglyceride levels rise above 1000 mg/dL, therapy should be stopped and other measures taken to control lipidemia.

Discard the bag if there appears to be a phase separation of the solution or any other signs of contamination, such as discoloration, particulate matter, or discoloration. If the solution is cloudy or contains precipitate, do not infuse.

Smoflipid contains no more than 25 mcg/L of aluminum. Repeating the use of aluminum in multiple doses may result in cumulative systemic aluminum burdens that could be toxic. For patients at risk for aluminum toxicity, consider the use of lipid emulsions containing no aluminum.

Fat overload syndrome is a rare condition that has been reported with lipid emulsions, such as Smoflipid. Fat overload syndrome is usually reversible when the infusion of the lipid emulsion is discontinued, although it may be severe and result in significant morbidity or mortality. Fat overload syndrome is characterized by hypokalemia, hypertriglyceridemia, and decreased cardiac output. The exact concentration of triglycerides at which fat overload syndrome occurs is not known. Signs and symptoms of fat overload syndrome may include hypotension, tachycardia, hypokalemia, and increased free fatty acid plasma levels following lipid emulsion infusion.

The syndrome is usually reversible when the infusion of the lipid emulsion is discontinued. However, fat overload syndrome may be fatal if not recognized and treated promptly.

Smoflipid is intended for use in the preparation and administration of Smoflipid. Monitor for signs and symptoms of fat overload syndrome, including hypotension, tachycardia, hypokalemia, and increased free fatty acid plasma levels following lipid emulsion infusion. If signs and symptoms of fat overload syndrome develop, discontinue the infusion and institute appropriate treatment. If signs and symptoms of fat overload syndrome persist, discontinue the infusion and institute appropriate treatment. If signs and symptoms of fat overload syndrome persist, discontinue the infusion and institute appropriate treatment.

Smoflipid is intended for use in the preparation and administration of Smoflipid. Monitor for signs and symptoms of fat overload syndrome, including hypotension, tachycardia, hypokalemia, and increased free fatty acid plasma levels following lipid emulsion infusion. If signs and symptoms of fat overload syndrome develop, discontinue the infusion and institute appropriate treatment. If signs and symptoms of fat overload syndrome persist, discontinue the infusion and institute appropriate treatment.

Smoflipid is intended for use in the preparation and administration of Smoflipid. Monitor for signs and symptoms of fat overload syndrome, including hypotension, tachycardia, hypokalemia, and increased free fatty acid plasma levels following lipid emulsion infusion. If signs and symptoms of fat overload syndrome develop, discontinue the infusion and institute appropriate treatment. If signs and symptoms of fat overload syndrome persist, discontinue the infusion and institute appropriate treatment.

Smoflipid is intended for use in the preparation and administration of Smoflipid. Monitor for signs and symptoms of fat overload syndrome, including hypotension, tachycardia, hypokalemia, and increased free fatty acid plasma levels following lipid emulsion infusion. If signs and symptoms of fat overload syndrome develop, discontinue the infusion and institute appropriate treatment. If signs and symptoms of fat overload syndrome persist, discontinue the infusion and institute appropriate treatment.

Smoflipid is intended for use in the preparation and administration of Smoflipid. Monitor for signs and symptoms of fat overload syndrome, including hypotension, tachycardia, hypokalemia, and increased free fatty acid plasma levels following lipid emulsion infusion. If signs and symptoms of fat overload syndrome develop, discontinue the infusion and institute appropriate treatment. If signs and symptoms of fat overload syndrome persist, discontinue the infusion and institute appropriate treatment.

Smoflipid is intended for use in the preparation and administration of Smoflipid. Monitor for signs and symptoms of fat overload syndrome, including hypotension, tachycardia, hypokalemia, and increased free fatty acid plasma levels following lipid emulsion infusion. If signs and symptoms of fat overload syndrome develop, discontinue the infusion and institute appropriate treatment. If signs and symptoms of fat overload syndrome persist, discontinue the infusion and institute appropriate treatment.

Smoflipid is intended for use in the preparation and administration of Smoflipid. Monitor for signs and symptoms of fat overload syndrome, including hypotension, tachycardia, hypokalemia, and increased free fatty acid plasma levels following lipid emulsion infusion. If signs and symptoms of fat overload syndrome develop, discontinue the infusion and institute appropriate treatment. If signs and symptoms of fat overload syndrome persist, discontinue the infusion and institute appropriate treatment.

Smoflipid is intended for use in the preparation and administration of Smoflipid. Monitor for signs and symptoms of fat overload syndrome, including hypotension, tachycardia, hypokalemia, and increased free fatty acid plasma levels following lipid emulsion infusion. If signs and symptoms of fat overload syndrome develop, discontinue the infusion and institute appropriate treatment. If signs and symptoms of fat overload syndrome persist, discontinue the infusion and institute appropriate treatment.

Smoflipid is intended for use in the preparation and administration of Smoflipid. Monitor for signs and symptoms of fat overload syndrome, including hypotension, tachycardia, hypokalemia, and increased free fatty acid plasma levels following lipid emulsion infusion. If signs and symptoms of fat overload syndrome develop, discontinue the infusion and institute appropriate treatment. If signs and symptoms of fat overload syndrome persist, discontinue the infusion and institute appropriate treatment.
INDICATIONS AND USAGE

Smoflipid is indicated as a source of calories and essential fatty acids. Smoflipid is contraindicated in patients who have had an adverse reaction to Smoflipid.

The use of Smoflipid for the treatment or prevention of essential fatty acid deficiency (EFAD) is supported by scientific evidence. EFAD is defined as a deficiency of essential fatty acids (EFAs) resulting in a lack of the long chain omega-6 and omega-3 fatty acids, linoleic acid, and alpha-linolenic acid, respectively. EFAs are synthesized from their dietary precursors, linoleic acid and alpha-linolenic acid, respectively. EFAs are required for normal metabolism, production of prostaglandins, thromboxanes, and leukotrienes, and are necessary for the development of the central nervous system.

8.2 Lactation

The safety and efficacy of Smoflipid in nursing mothers have not been established. Due to the potential for adverse reactions in nursing infants, the decision to attribute the use of Smoflipid in women who are or may become pregnant should be based on the importance of the drug to the mother.

10.1 Mechanism of Action

Smoflipid contains the following EFA:
- Linoleic acid (an omega-6 fatty acid) is 35 mg/mL (range 28 to 50 mg/mL).
- Alpha-linolenic acid (an omega-3 fatty acid) is 35 mg/mL (range 30 to 40 mg/mL).


doi: 10.1097/01.brs.0000189046.56947.e9

The lipids contained in this emulsion may contain soy phosphatidylcholine and soy lecithin. Patients with a history of allergy (i.e., anaphylaxis) to soy should be observed for signs of allergy.

For parenteral nutrition admixtures, see Section 17. Use Smoflipid in addition to other parenteral nutrition admixtures as needed to achieve the desired balance of nutrients. Smoflipid is not intended for use as an exclusive source of nutrition.

The lipids contained in this emulsion may contain soy phosphatidylcholine and soy lecithin. Patients with a history of allergy (i.e., anaphylaxis) to soy should be observed for signs of allergy.

For parenteral nutrition admixtures, see Section 17. Use Smoflipid in addition to other parenteral nutrition admixtures as needed to achieve the desired balance of nutrients. Smoflipid is not intended for use as an exclusive source of nutrition.
null
parallel-group, multicenter study in patients who required PN.

Study 1 was a double-blind, randomized, active-controlled, clinical trial conducted to evaluate the nutritional efficacy of Smoflipid, a long-chain triglyceride (LCT) lipid emulsion containing 40% of total caloric intake as omega-3 fatty acids, compared to a soybean oil lipid emulsion in adult, oncology patients requiring PN. The primary outcome measure was mean change in weight, height, body mass index (BMI), and/or biomarkers of nutritional requirements. Nutritional efficacy was assessed by monitoring changes in weight, height, BMI, albumin levels, and triglyceride levels from baseline to the final assessment. The change in mean weight, height, and BMI was variable in these studies and adjusted to the patient’s needs. The study population was adequately designed to demonstrate noninferiority of Smoflipid to the soybean oil comparator, they support Smoflipid as a feasible alternative to soybean oil lipid emulsions in PN.

The study population consisted of 354 adult patients, of which 99% were Caucasian. The most frequently reported medical histories in the study population were hypertension, infections and infestations, and malignant neoplasms. Of the 354 patients in clinical studies, 35% were > 65 years of age and 10% were pediatric patients, whereas only 7% of the soybean oil comparator group. Energy expenditure and requirements may be lower for older adults than younger patients. Of the 354 patients in clinical studies, 35% were > 65 years of age and 10% were pediatric patients, whereas only 7% of the soybean oil comparator group. Energy expenditure and requirements may be lower for older adults than younger patients. Of the 354 patients in clinical studies, 35% were > 65 years of age and 10% were pediatric patients, whereas only 7% of the soybean oil comparator group.

Onset of nutritional parameters for inactive/active populations in patients are not different from those in control populations. Nutritional efficacy was assessed by monitoring changes in weight, height, BMI, albumin levels, and triglyceride levels from baseline to the final assessment. The change in mean weight, height, and BMI was variable in these studies and adjusted to the patient’s needs. The study population was adequately designed to demonstrate noninferiority of Smoflipid to the soybean oil comparator, they support Smoflipid as a feasible alternative to soybean oil lipid emulsions in PN.

The efficacy of Smoflipid compared to a control lipid emulsion was evaluated in a double-blind, randomized, active-controlled, clinical trial conducted to evaluate the nutritional efficacy of Smoflipid, a long-chain triglyceride (LCT) lipid emulsion containing 40% of total caloric intake as omega-3 fatty acids, compared to a soybean oil lipid emulsion in adult, oncology patients requiring PN. The primary outcome measure was mean change in weight, height, body mass index (BMI), and/or biomarkers of nutritional requirements. Nutritional efficacy was assessed by monitoring changes in weight, height, BMI, albumin levels, and triglyceride levels from baseline to the final assessment. The change in mean weight, height, and BMI was variable in these studies and adjusted to the patient’s needs. The study population was adequately designed to demonstrate noninferiority of Smoflipid to the soybean oil comparator, they support Smoflipid as a feasible alternative to soybean oil lipid emulsions in PN.

The clinical trial was conducted in patients who required PN, and the study population was adequately designed to demonstrate noninferiority of Smoflipid to the soybean oil comparator, they support Smoflipid as a feasible alternative to soybean oil lipid emulsions in PN.

The studies with Smoflipid have not been performed to evaluate the safety of Smoflipid when used in pregnant women. Animal reproduction studies have not been performed to evaluate the potential for Smoflipid to cause fetal harm when administered to pregnant animals. There are no available data on risks associated with Smoflipid when administered to pregnant women. The effects of maternal exposure to Smoflipid when used in pregnant women are unknown. The risk summary for Smoflipid includes information on the potential for drug interactions, and the use of Smoflipid in pregnant women is not recommended. The effects of maternal exposure to Smoflipid when used in pregnant women are unknown. The risk summary for Smoflipid includes information on the potential for drug interactions, and the use of Smoflipid in pregnant women is not recommended.

The safety and effectiveness of Smoflipid in pregnant women have not been established.

In Table 2, the efficacy of Smoflipid compared to the soybean oil lipid emulsion for intravenous infusion. The lipid content of Smoflipid is a sterile, nonpyrogenic, white, homogenous lipid emulsion for intravenous infusion. The phosphate content is established in pediatric patients. Deaths in preterm infants after treatment with Smoflipid have been reported. The safety and effectiveness of Smoflipid in pregnant women have not been established.

In conclusion, the safety and effectiveness of Smoflipid compared to the soybean oil lipid emulsion for intravenous infusion. The lipid content of Smoflipid is a sterile, nonpyrogenic, white, homogenous lipid emulsion for intravenous infusion. The phosphate content is established in pediatric patients. Deaths in preterm infants after treatment with Smoflipid have been reported.
for at least 28 days. Seventy-five patients were enrolled, and protein metabolism (albumin) and mean changes in fatty acid nutritional requirements. Nutritional efficacy was assessed by adequately designed to demonstrate noninferiority of Smoflipid effect was observed.

No drug interaction studies have been performed with in Salmonella typhimurium, chromosomal aberration assay. Respiratory, Thoracic and Mediastinal Disorders: dyspnea of uncertain size, it is not always possible to reliably estimate their because these reactions are reported voluntarily from a population increased gamma-glutamyltransferase, increased C-reactive number of patients.

<table>
<thead>
<tr>
<th>AEs Reported</th>
<th>Smoflipid Group</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>120 (11%)</td>
<td>100 (11%)</td>
<td></td>
</tr>
</tbody>
</table>


12.1 Mechanism of Action
Smoflipid causes an increase in heat production, decrease in composition, phospholipids, and provide nutrients. The content of Smoflipid is compatible with these reactions is thought to be multifactorial and may differ between patients. Because these reactions are reported voluntarily from a population increased gamma-glutamyltransferase, increased C-reactive number of patients.

<table>
<thead>
<tr>
<th>AEs Reported</th>
<th>Smoflipid Group</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>120 (11%)</td>
<td>100 (11%)</td>
<td></td>
</tr>
</tbody>
</table>


12.1 Mechanism of Action
Smoflipid causes an increase in heat production, decrease in composition, phospholipids, and provide nutrients. The content of Smoflipid is compatible with these reactions is thought to be multifactorial and may differ between patients. Because these reactions are reported voluntarily from a population increased gamma-glutamyltransferase, increased C-reactive number of patients.

<table>
<thead>
<tr>
<th>AEs Reported</th>
<th>Smoflipid Group</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>120 (11%)</td>
<td>100 (11%)</td>
<td></td>
</tr>
</tbody>
</table>


12.1 Mechanism of Action
Smoflipid causes an increase in heat production, decrease in composition, phospholipids, and provide nutrients. The content of Smoflipid is compatible with these reactions is thought to be multifactorial and may differ between patients. Because these reactions are reported voluntarily from a population increased gamma-glutamyltransferase, increased C-reactive number of patients.

<table>
<thead>
<tr>
<th>AEs Reported</th>
<th>Smoflipid Group</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>120 (11%)</td>
<td>100 (11%)</td>
<td></td>
</tr>
</tbody>
</table>


12.1 Mechanism of Action
Smoflipid causes an increase in heat production, decrease in composition, phospholipids, and provide nutrients. The content of Smoflipid is compatible with these reactions is thought to be multifactorial and may differ between patients. Because these reactions are reported voluntarily from a population increased gamma-glutamyltransferase, increased C-reactive number of patients.

<table>
<thead>
<tr>
<th>AEs Reported</th>
<th>Smoflipid Group</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>120 (11%)</td>
<td>100 (11%)</td>
<td></td>
</tr>
</tbody>
</table>


12.1 Mechanism of Action
Smoflipid causes an increase in heat production, decrease in composition, phospholipids, and provide nutrients. The content of Smoflipid is compatible with these reactions is thought to be multifactorial and may differ between patients. Because these reactions are reported voluntarily from a population increased gamma-glutamyltransferase, increased C-reactive number of patients.
parallel-group, multicenter study in patients who required PN
Study 1 was a double-blind, randomized, active-controlled, nutritional requirements. Nutritional efficacy was assessed by
All patients received Smoflipid or the comparator as part of a
14 CLINICAL STUDIES
effect was observed.

vitro studies with Smoflipid: bacterial gene mutation assay
Smoflipid. No drug interaction studies have been performed with
7.1  Coumarin and Coumarin Derivatives
15.3 Precautions (5.6)
smallest, it is not always possible to reliably estimate their
6.2 Postmarketing Experience
The following adverse reactions have been identified during
5.1 Glucose 6-Phosphate Dehydrogenase Deficiency

1. Mirtallo J, Canada T, Johnson D, Kumpf V, Petersen C, and others. "The Effects of Smoflipid on
lipase activity is beta oxidation. Fatty acids are also important for membrane structure and function,

The most common mechanism of action for energy production
10 OVERDOSAGE
Monitor liver function parameters closely. Patients developing

8.5 Geriatric Use

6.2 Postmarketing Experience
There are insufficient data from pediatric studies to establish

6.2 Postmarketing Experience
There are no available data on risks associated with Smoflipid

4.1 Pregnancy
Parenteral nutrition should be considered if the pregnant

6.3.3 Adverse Drug Reactions

5.1 Glucose 6-Phosphate Dehydrogenase Deficiency
15.3 Precautions (5.6)

The container is not made with natural rubber latex, PVC, or

5.2 Interactions

5.2 Interactions

5.1 Glucose 6-Phosphate Dehydrogenase Deficiency

5.3.7 Contraindications

5.3.7 Contraindications

5.2 Interactions

5.2 Interactions

5.1 Glucose 6-Phosphate Dehydrogenase Deficiency

5.2 Interactions

5.1 Glucose 6-Phosphate Dehydrogenase Deficiency

5.2 Interactions

5.1 Glucose 6-Phosphate Dehydrogenase Deficiency

5.1 Glucose 6-Phosphate Dehydrogenase Deficiency

5.1 Glucose 6-Phosphate Dehydrogenase Deficiency