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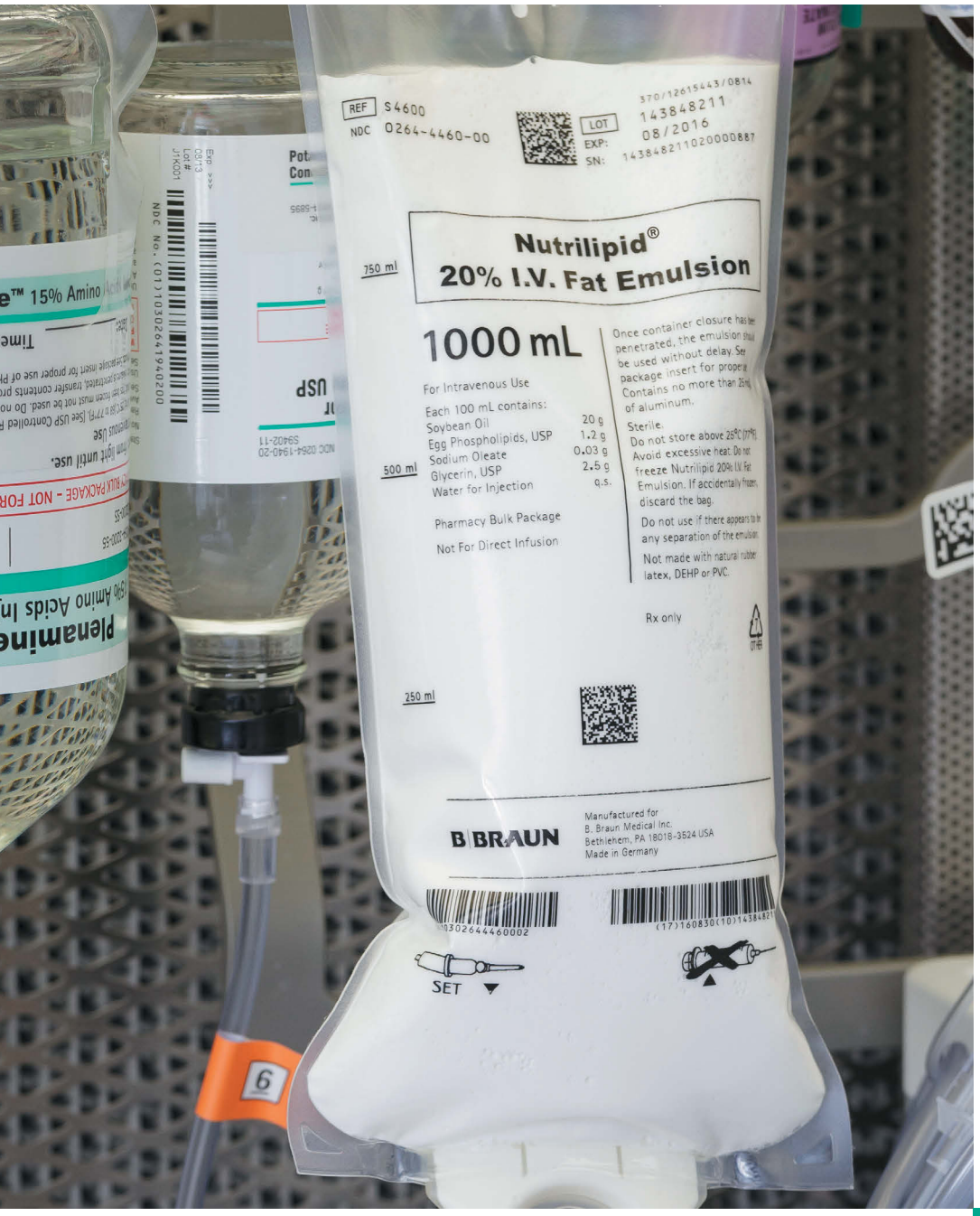

- Flexible container not made with natural rubber latex, DEHP or PVC
- Oxygen sensor to detect product integrity
- Linear and 2D-barcoding
- 20% Soybean Oil

NDC	Catalog No.	Fill Size
0264-4460-00	S4600	1000 mL
0264-4460-10	S4601	500 mL
0264-4460-30	S4603	250 mL

Nutrilipid® IV Fat Emulsion

PN 360

Part of B. Braun's Parenteral Nutrition 360 Program:
Collaboration That Goes Beyond Products

B. Braun Medical Inc. | Bethlehem PA
1-800-227-2862 | BBraunLipids.com

Refer to back page for complete product package insert.

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Brief Summary (for full Prescribing Information and Patient Information, refer to Package Insert)

Nutrilipid® I.V. Fat Emulsion - soybean oil injection, solution

WARNING: DEATH IN PRETERM INFANTS

- Deaths in preterm infants after infusion of intravenous lipid emulsions have been reported in the medical literature.
- Autopsy findings included intravascular fat accumulation in the lungs.
- Preterm infants and low birth weight infants have poor clearance of intravenous lipid emulsion and increased free fatty acid plasma levels following lipid emulsion infusion.

INDICATIONS AND USAGE

Nutrilipid® 20% is indicated as a source of calories and essential fatty acids for parenteral nutrition and as a source of essential fatty acids when a deficiency occurs when oral or enteral nutrition is not possible, insufficient, or contraindicated.

CONTRAINDICATIONS

Nutrilipid® 20% is contraindicated in patients who have:

- Known hypersensitivity to egg or soybean proteins or to any of the ingredients, including excipients, or
- Severe hyperlipidemia (serum triglyceride concentrations above 1000 mg/dL) or severe disorders of lipid metabolism characterized by hypertriglyceridemia.

WARNINGS AND PRECAUTIONS

Death in Preterm Infants

Deaths in preterm infants after infusion of intravenous lipid emulsions have been reported. Autopsy findings included intravascular lipid accumulation in the lungs.

Base the decision to treat preterm and small for gestational age infants with intravenous lipid emulsion upon careful benefit-risk assessment. Strictly adhere to the recommended total daily dose; hourly infusion rate should be as slow as possible and should not exceed 0.75 mL/kg/hour.

Preterm and small for gestational age infants have poor clearance of intravenous lipid emulsion and increased free fatty acid plasma levels following lipid emulsion infusion; therefore, seriously consider administration of less than the maximum recommended doses in these patients in order to decrease the likelihood of intravenous fat overload.

Carefully monitor the infant's ability to eliminate the infused lipids from the circulation (such as serum triglycerides and/or plasma free fatty acid levels).

Because of the risk of thrombocytopenia, monitor platelet counts frequently in neonatal patients receiving parenteral nutrition with Nutrilipid® 20%.

Hypersensitivity Reactions

Stop infusion immediately and treat patient accordingly if signs or symptoms of a hypersensitivity or allergic reaction develop. Signs or symptoms may include: tachypnea, dyspnea, hypoxia, bronchospasm, tachycardia, hypotension, cyanosis, vomiting, nausea, headache, sweating, dizziness, altered mentation, flushing, rash, urticaria, erythema, pyrexia, and chills.

Infections

Patients who require parenteral nutrition are at high risk of infections due to malnutrition and their underlying disease state.

Infection and sepsis may occur as a result of the use of intravenous catheters to administer parenteral nutrition, poor maintenance of catheters, or immunosuppressive effects of illness, drugs, and parenteral formulations.

Decrease the risk of septic complications with heightened emphasis on aseptic technique in catheter placement and maintenance, as well as aseptic technique in the preparation of the nutritional formula.

Carefully monitor for signs and symptoms (including fever and chills) of early infections, including laboratory test results (including leukocytosis and hyperglycemia) and frequent checks of the parenteral access device.

Fat Overload Syndrome

Fat overload syndrome is a rare condition that has been reported with intravenous lipid formulations. A reduced or limited ability to metabolize the lipids contained in Nutrilipid® 20% accompanied by prolonged plasma clearance may result in a syndrome characterized by a sudden deterioration in the patient's condition accompanied by fever, anemia, leukopenia, thrombocytopenia, coagulation disorders, hyperlipidemia, liver fatty infiltration (hepatomegaly), deteriorating liver function, and central nervous system manifestations (e.g., coma). The cause of the fat overload syndrome is unclear. The syndrome is usually reversible when the infusion of the lipid emulsion is stopped. Although it has been most frequently observed when the recommended lipid dose was exceeded, cases have also been described where the lipid formulation was administered according to instructions.

Refeeding Syndrome

Refeeding severely undernourished patients with parenteral nutrition may result in the refeeding syndrome, characterized by the intracellular shift of potassium, phosphorus, and magnesium as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. Carefully monitor severely undernourished patients and slowly increase their nutrient intakes, while avoiding overfeeding, to prevent these complications.

Monitoring / Laboratory Tests

Monitor fluid status closely in patients with pulmonary edema or heart failure.

Monitor serum triglycerides, fluid and electrolyte status, serum osmolarity, blood glucose, liver and kidney function, blood count (including platelets), and coagulation parameters throughout treatment.

Interference with Laboratory Tests

Content of Vitamin K may counteract anticoagulant activity.

The lipids contained in this emulsion may interfere with the results of certain laboratory tests if the blood sample is taken before the lipids are eliminated from the serum (these are generally eliminated after a period of 5 to 6 hours without receiving lipids).

Aluminum Toxicity

Nutrilipid® 20% contains no more than 25 mcg/L of aluminum.

The aluminum contained in Nutrilipid® 20% may reach toxic levels with prolonged administration in patients with impaired kidney function. Preterm infants are at greater risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions that contain aluminum.

Patients with impaired kidney function, including preterm infants, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day, accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration of total parenteral nutrition products.

Risk of Parenteral Nutrition Associated Liver Disease

Parenteral Nutrition Associated Liver Disease (PNALD) has been reported in patients who receive parenteral nutrition for extended periods of time, especially preterm infants, and can present as cholestasis or steatohepatitis. The exact etiology is unknown and is likely multifactorial. Intravenously administered phytosterols (plant sterols) contained in plant-derived lipid formulations have been associated with development of PNALD although a causal relationship has not been clearly established.

If Nutrilipid® 20% treated patients develop liver test abnormalities consider discontinuation or dose reduction.

Hypertriglyceridemia

To evaluate the patient's capacity to eliminate and metabolize the infused lipid emulsion, measure serum triglycerides before the start of infusion (baseline value), with each increase in dosage, and regularly throughout treatment.

Reduce dose of Nutrilipid® 20% and monitor serum triglyceride levels in patients with serum triglyceride concentrations above 400 mg/dL to avoid the clinical consequences associated with hypertriglyceridemia. Serum triglyceride levels above 1000 mg/dL have been associated with an increased risk of pancreatitis.

Impaired lipid metabolism with hypertriglyceridemia may occur in conditions such as inherited lipid disorders, obesity, diabetes mellitus, and metabolic syndrome. In these cases, increased triglycerides can also be increased by glucose and/or overfeeding. Monitor overall energy intake and other sources of fat and glucose, as well as drugs that may interfere with lipid and glucose metabolism.

ADVERSE REACTIONS

- Death in Preterm Infants
- Hypersensitivity Reactions
- Infections
- Fat Overload Syndrome
- Refeeding Syndrome
- Aluminum Toxicity
- Risk of Parenteral Nutrition Associated Liver Disease
- Hypertriglyceridemia

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Adverse reactions reported with other intravenous lipid emulsions include hyperlipidemia, hypercoagulability, thrombophlebitis, and thrombocytopenia.

Adverse reactions reported in long-term use with other intravenous lipid emulsions include hepatomegaly, jaundice due to central lobular cholestasis, splenomegaly, thrombocytopenia, leukopenia, abnormalities in liver function tests, brown pigmentation of the liver and overloading syndrome (focal seizures, fever, leukocytosis, hepatomegaly, splenomegaly and shock).

DRUG INTERACTIONS

Coumarin and Coumarin Derivatives

The soybean oil present in Nutrilipid® 20% has vitamin K1. Vitamin K can reverse the anticoagulant activity of coumarin and coumarin derivatives, including warfarin, which work by blocking recycling of vitamin K. Monitor laboratory parameters for anticoagulant activity in patients who are on both Nutrilipid® 20% and coumarin or coumarin derivatives.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C

Risk Summary

There are no adequate or well controlled studies with Nutrilipid® 20% in pregnant women. Additionally, animal reproduction studies have not been conducted with Nutrilipid® 20%. It is not known whether Nutrilipid® 20% can cause fetal harm when administered to a pregnant woman. Nutrilipid® 20% should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether Nutrilipid® 20% is present in human milk. Because many drugs are present in human milk, caution should be exercised when Nutrilipid® 20% is administered to a nursing woman.

Pediatric Use

The evidence for safety and efficacy in pediatric patients of Nutrilipid® 20% as a source of calories and essential fatty acids for parenteral nutrition and as a source of essential fatty acids when a deficiency occurs when oral or enteral nutrition is not possible, insufficient, or contraindicated is derived from the published literature and clinical experience with similar soybean oil based intravenous lipid emulsions.

Deaths in preterm infants after infusion of intravenous lipid emulsion have been reported. Patients, particularly preterm infants, are at risk for aluminum toxicity. Patients, including pediatric patients, may be at risk for PNALD. In clinical trials of a pure soybean oil based intravenous lipid emulsion product, thrombocytopenia in neonates occurred (less than 1%).

Geriatric Use

Clinical studies of Nutrilipid® 20% did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Hepatic Impairment

Parenteral nutrition should be used with caution in patients with hepatic impairment. Hepatobiliary disorders are known to develop in some patients without preexisting liver disease who receive parenteral nutrition, including cholestasis, hepatic steatosis, fibrosis and cirrhosis (parenteral nutrition associated liver disease), possibly leading to hepatic failure. Cholecystitis and cholelithiasis have also been observed. The etiology of these disorders is thought to be multifactorial and may differ between patients.

Monitor liver function parameters closely. Patients developing signs of hepatobiliary disorders should be assessed early by a clinician knowledgeable in liver diseases in order to identify causative and contributory factors, and possible therapeutic and prophylactic interventions.

OVERDOSAGE

In the event of overdose, fat overload syndrome may result. Stop the infusion to allow lipids to clear from serum. The effects are usually reversible after the lipid infusion is stopped. If medically appropriate, further intervention may be indicated. The lipid administered and fatty acids produced are not dialyzable.

DESCRIPTION

Nutrilipid® 20% is a sterile, nonpyrogenic fat emulsion prepared for intravenous administration.

Each 100 mL of Nutrilipid® 20% contains: Soybean Oil 20 g; Egg Yolk Phospholipid 1.2 g; Glycerin USP (glycerol) 2.5 g; Sodium Oleate 0.03 g; Water for Injection USP qs.