

YOUR COMPLETE SOURCE FOR PARENTERAL NUTRITION





A COLLABORATION THAT GOES BEYOND THE PRODUCTS.

With the establishment of the Hospital Readmissions Reduction Program*, parenteral nutrition has never been more critical to improving patient outcomes. B. Braun and Central Admixture Pharmacy Services, Inc. (CAPS®) are focused on improving patient outcomes with PN360.

PN360 is more than solutions and technology. Backed by decades of expertise in clinical nutrition, it's your single-source provider for parenteral nutrition education, training, products, and services paired with an ongoing collaboration with your facility's nutritional support team.

*Section 3025 of the Affordable Care Act added section 1886(q) to the Social Security Act establishing the Hospital Readmissions Reduction Program, which requires CMS to reduce payments to IPPS hospitals with excess readmissions, effective for discharges beginning on October 1, 2012.

LET'S WORK TOGETHER.

We can provide the knowledge and support needed for the safe and effective use of parenteral nutrition, including:

- Order entry software
- Compounding
- Nutrition solutions and products
- Services and support

FOR THE BETTER.

For you, your patients, and the entire health care system.

Parenteral nutrition helps ensure that your most critical patients aren't negatively affected by malnutrition, both in the hospital and at home.

Malnutrition has been associated with an increased length of hospital stay, increased morbidity and mortality, impaired respiratory and cardiac function, decreased immune function, and poor growth in infants and children.¹

PN360 is designed to:

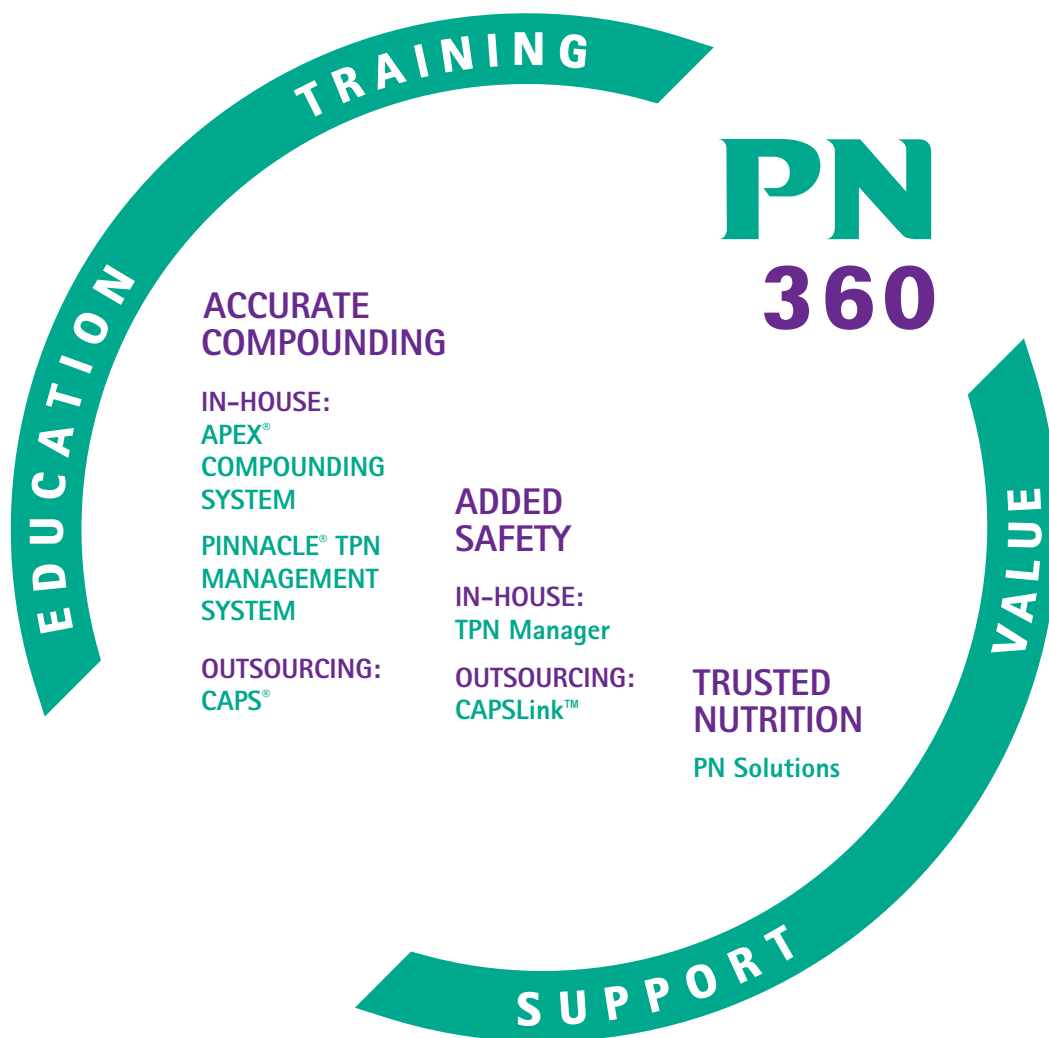
- Minimize patient health complications
- Decrease readmission rates
- Lower infection rates
- Reduce resource utilization

¹ Soliah, LuAnn, PhD, RD. Today's Dietitian, Vol.10 No7, 2008



THE MOST COMPREHENSIVE SOLUTION FOR PARENTERAL NUTRITION.

Our support starts with an assessment of your facility's needs and continues through education, training, and expert parenteral nutrition consulting. Whether your facility prefers to compound in-house, outsource, or a combination of both, you'll be covered by our line of products and services, working together with a focus on preventing malnutrition and prescribing the right dose at the right time for the best patient outcomes.





To learn more, contact your B. Braun Sales Representative,
or call Customer Service at 1-800-227-2862.

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1-800-227-2862 | BBraunUSA.com

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IN-HOUSE COMPOUNDING

AN INTEGRATED, AUTOMATED SYSTEM FOR
SAFE AND EFFICIENT PARENTERAL NUTRITION

NOW WITH
TPN COMPLETE™ THERAPY



INNOVATION FROM SETUP TO DELIVERY

AN IN-HOUSE COMPOUNDING SYSTEM FOR YOUR MOST CRITICAL NEEDS

PN360 offers fully integrated systems of software and technology to streamline the ordering, compounding, and delivery of parenteral nutrition within your facility. Our APEX® and PINNACLE® compounding devices deliver accuracy and efficiency while our TPN Manager Software brings the entire system online with automation across the board.

APEX® COMPOUNDING SYSTEM

APEX offers the latest in compounding technology, building onto the benefits of PINNACLE while delivering both macro and micro compounding with one machine. It's a comprehensive solution designed with your most critical patients and your most critical needs in mind:

- Large user interface designed to increase legibility and enable easy activation of touch screen buttons
- Dual-drive filling technology for precise automated delivery of macro and micro ingredients, as low as 0.2mL
- 26-lead, preassembled, numbered, and barcoded transfer set is designed to eliminate the possibility of transposing solution lines and reduce the risk of touch contamination

PINNACLE® TPN MANAGEMENT SYSTEM

PINNACLE offers advanced automation designed for fast, smart, and user-friendly macro compounding:

- Designed to reduce setup and TPN preparation time
- Helps promote safety and compliance with automatic, real-time checks
- Simplifies compounding process with a Windows®-based user format

TPN MANAGER CLINICAL DECISION SUPPORT SOFTWARE

TPN Manager is the connective tissue of PN360's in-house system. It's a browser-based software that allows you to bring APEX and PINNACLE online to optimize and integrate all aspects of in-house TPN compounding:

- Streamlines the ordering process
- Automates complex calculations for accuracy
- Delivers protection with Trissel's™ Ca/P Check Safety Software



TPN COMPLETE™ THERAPY

B. Braun and Omnicell have teamed up to help reduce workflow redundancies. We're integrating B. Braun's APEX and Omnicell's I.V. SOFT® semi-automated IV compounding technology to streamline the TPN compounding process, provide checks and documentation, and support remote pharmacist verification.

PN360 is committed to helping your facility deliver safe and accurate parenteral nutrition for the best patient care. To learn more, contact your B. Braun Sales Representative, or call Customer Service at 1-800-227-2862.



PARENTERAL NUTRITION SOLUTIONS

TRUSTED PARENTERAL NUTRITION SOLUTIONS
FOR INDIVIDUAL PATIENT NEEDS



DELIVERING QUALITY AND CONFIDENCE

PARENTERAL NUTRITION FOR BOTH BASIC AND SPECIALTY NUTRITION

B. Braun has a legacy of developing unique formulations to enhance care and improve patient outcomes. This commitment to the continued development of new products has led to a valued and trusted line of parenteral nutrition solutions.

As one of the leading providers of neonatal and pediatric parenteral nutrition solutions, we make sure that every solution we deliver has been thoroughly tested to ensure top-level safety. So, whether you're looking to outsource or compound in-house, you can trust our parenteral nutrition solutions as the building blocks for critical, high-quality nutrition.

THE FULL PARENTERAL NUTRITION SOLUTIONS LINE

Amino Acid Solutions

- Plenamine™ (15% Amino Acid Injection)
- FreAmine® (10% Amino Acid Injection)
- NephrAmine® (5.4% Amino Acid Injection)
- TrophAmine® (6% Amino Acid Injection)
- TrophAmine (10% Amino Acid Injection)
- FreAmine HBC® (6.9% Amino Acid Injection)
- HepatAmine® (8% Amino Acid Injection)

Pre-mixed Peripheral Parenteral Nutrition

- ProcalAmine® (3% Amino Acid & 3% Glycerin Injection with Electrolytes)

Intravenous Fat Emulsions

- Nutrilipid® (20% IV Fat Emulsion)*
250mL / 500mL / 1000mL

Electrolytes

- Concentrated Potassium Chloride Injection USP (KCL)
- Hyperlyte® CR Multi-Electrolyte Concentrate

Dextrose Injections

- 70% Dextrose Injection USP 2000mL bag

Sterile Water Injections

- Sterile Water for Injection USP 2000mL / 3000mL bag



Available Pharmacy Bulk Packs:

- Plenamine (15% Amino Acid Injection)
- Nutrilipid (20% IV Fat Emulsion)* 1000mL
- 70% Dextrose Injection USP 2000mL bag
- Sterile Water for Injection USP 2000mL / 3000mL bag
- FreAmine (10% Amino Acid Injection)

PN360 is committed to developing and delivering high-quality solutions so your facility can continue providing the best possible patient care. To learn more, contact your B. Braun Sales Representative, or call Customer Service at 1-800-227-2862.

* Please see prescribing information included in this packet.
Flexible containers not made with natural rubber latex, PVC, or DEHP.

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 osmolality, 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.



OUTSOURCED COMPOUNDING

THE HIGHEST QUALITY PARENTERAL NUTRITION SOLUTIONS
DELIVERED RIGHT TO YOU BY CAPS®



CAPS® OUTSOURCING

DELIVERING MORE THAN JUST CUSTOMIZED SOLUTIONS

PN360's outsourcing program is administered by Central Admixture Pharmacy Services, Inc. (CAPS®) and delivers safety, confidence, and the highest quality parenteral nutrition solutions. CAPS is a market leader in the outsourcing of customized parenteral nutrition, so your patients and your facility can rely on consistent, on-time deliveries of accurate and safe solutions.

THE HIGHEST QUALITY OF COMPOUNDING

CAPS not only follows regulations, we help create them. For years, CAPS has been a leader for safe compounding in 503A and 503B facilities. Today, we remain at the forefront of complying with and implementing new quality control:

- Meeting industry standards in safety and quality assurance reporting
- Proven track record of delivering customized solutions for more than 25 years
- 100% cGMP release testing for products compounded in our 503B facilities

OPTIMIZED ORDERING

CAPSLink™ Software is designed to make parenteral nutrition order entry secure, safe, and convenient while assuring accuracy throughout the compounding process:

- Online software allows ordering from anywhere in your facility where Internet access is available
- Built-in safety checks throughout, including an additional check by a CAPS pharmacist
- Same day delivery of custom-compounded parenteral nutrition
- Interface capability with your CPOE vendor designed for improved pharmacy efficiency

PN360 outsourcing delivers the highest quality of parenteral nutrition solutions so your facility can continue delivering the best patient care. To learn more, contact your B. Braun Sales Representative, or call Customer Service at 1-800-227-2862.



YOUR PARTNER IN PARENTERAL NUTRITION

Through CAPS ConsultingSM, our experts will work with your facility to help train your team, optimize efficiency, and navigate the evolving regulatory environment:

- Customized staff education and training in parenteral nutrition and compliance
- Expertise in USP <797>, USP <800>, the Drug Quality and Security Act, and more
- On-site analysis with ReadyCheckSM Quality Assurance Program