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2025 Parenteral Nutrition Product Shortage Recommendations: Lipid Injectable Emulsions

ASPEN has developed parenteral nutrition (PN) shortage considerations to assist its members and other clinicians in coping with PN shortages for their patients. These lipid injectable emulsion (ILE) product shortage recommendations were approved by the ASPEN Parenteral Nutrition Committee and the Board of Directors.

Document Contents:

Important Note:
These recommendations do not constitute medical or other professional advice and should not be taken as such. To the extent that the information published herein may be used to assist in the care of patients, the primary component of quality medical care is the result of the professional judgment of the healthcare professionals providing care. The information presented here is not a substitute or replacement for the exercise of professional judgment by healthcare professionals; rather, it is intended to supplement professional training and judgment. Circumstances and patient specifics in clinical settings may require actions different from those recommended in this document; in those cases, the judgment of the treating professionals should prevail. Use of this information does not in any way guarantee any specific benefit in outcome or survival.

These shortage recommendations are intended only for use during product shortages, when adequate product is unavailable. These measures are not ideal for ensuring safe and optimal patient care and should not be considered standard practice. Any deviation from manufacturer-recommended practices should be temporary and reversed once adequate product supply is restored. No single strategy will work for all organizations. Institutions must carefully evaluate each option, weighing potential risks and benefits before implementation. These recommendations are provided with the understanding that they are followed at the institution's own risk, and each organization assumes responsibility for any resulting outcomes.

Questions regarding these recommendations should be directed to clinicalpractice@nutritioncare.org.

Terms and Abbreviations

EFAs	Essential fatty acids
EFAD	Essential fatty acid deficiency
EN	Enteral nutrition
FO-ILE	Fish oil-based ILE
ILE	Lipid injectable emulsion
OO, SO-ILE	Olive oil, soybean oil-based ILE, also known as 2-oil ILE
PN	Parenteral nutrition
SO-ILE	Soybean oil-based ILE
SO, MCT, OO, FO-ILE	Soybean oil, medium chain triglycerides, olive oil, and fish oil-based ILE, also known as 4-oil ILE

Introduction

Four types of lipid injectable emulsion (ILE) products are approved for use in the United States (Table 1).[1-6] These products have different oil sources and may contain a single oil source or a combination of oils. To ensure efficacy and patient safety, clinicians must understand the differences between the ILE products, especially during times of short supply. Several considerations are required, including, but not limited to, indications, dosing, potential for complications (e.g., hypersensitivity), compatibility and stability, and monitoring.[7-9] Data from one ILE product cannot be applied to other ILE products.[8,9]

Table 1. Lipid Injectable Emulsion (ILE) Products, Description, Abbreviations, Indications, and Approval for Use in the United States

Lipid Injectable Emulsion (ILE) Product	Description	Abbreviation	FDA-Approved Indication	FDA Approval for Adult Patients	FDA Approval for Pediatric Patients (including term and preterm neonates)
Intralipid (20% and 30%) (Fresenius Kabi USA, LLC, Uppsala, Sweden)[1,2]	100% SO	SO-ILE	Indicated as a source of calories and essential fatty acids for adult and pediatric patients requiring parenteral nutrition and as a source of essential fatty acids for prevention of EFAD	Yes	Yes
Nutrilipid 20% (B. Braun Medical, Inc., Bethlehem, PA, USA)[3]	100% SO	SO-ILE	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.	Yes	Yes

Clinolipid 20% (Baxter Healthcare Corporation, Deerfield, IL, USA)[4]	80% OO, 20% SO	OO, SO-ILE	Indicated in adults and pediatric patients, including term and preterm neonates, as a source of calories and essential fatty acids for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.	Yes	Yes
SMOFlipid 20% (Fresenius Kabi USA, LLC, Uppsala, Sweden)[5]	30% SO, 30% MCT, 25% OO, 15% FO	SO, MCT, OO, FO-ILE	Indicated in adult and pediatric patients, including term and preterm neonates, as a source of calories and essential fatty acids for parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated.	Yes	Yes
Omegaven 10% (Fresenius Kabi USA, LLC, Graz, Austria)[6]	100% FO	FO-ILE	Indicated as a source of calories and fatty acids in pediatric patients with parenteral nutrition-associated cholestasis.	No	Yes

Key: SO, soybean oil; ILE, EFAD, essential fatty acid deficiency; OO, olive oil; MCT, medium chain triglycerides; FO, fish oil

General Recommendations for Lipid Injectable Emulsion Shortage Management

During an ILE product shortage, ASPEN recommends consideration of the following general measures:

1. **For all patients,** routinely assess and reassess patient-specific indication(s) for nutrition support and requirement for PN; provide nutrition via the oral or enteral route when possible and clinically appropriate.[10,11]
2. **Communicate with all key stakeholders.** (e.g., PN prescribers, pharmacy and nutrition departments, nursing leadership and staff, central supply, home infusion pharmacies). Communication is essential to understanding the current stock, procurement issues, and bedside practice. Establish a process to maintain clear communication across departments. Ensure that this process includes the ability to provide frequent updates to all key stakeholders during transitions of care.
3. **Develop an organizational strategy.** Include PN component and product shortages in the healthcare organization's strategies and procedures for managing medication shortages. These procedures should include processes to:
    a. notify clinicians when a shortage of a PN component or product occurs,
    b. notify clinicians when PN formulations are adjusted due to shortages of PN components and products,

c. identify and monitor patients who are receiving a PN regimen that has been modified due to a product shortage,

d. notify patients receiving long-term (i.e., more than 1 month) PN therapy and their caregivers when their PN formulation has been adjusted for shortages of PN components and products,

e. notify clinicians when a PN component shortage has resolved,

f. **resume standard dosing practices when a PN component shortage has resolved.**

4. **Do not stockpile.** Maintain an ongoing evaluation of current usage, and purchase only as much supply as needed in the interest of fair allocation to all patients. If feasible, in order to provide for maximally efficient utilization of existing stocks, consider sharing supplies between pharmacies.

5. **Ensure understanding of the differences between ILE products.** ILE products differ in oil concentration, oil source(s), fatty acid content, indications, and dosing.

    a. Clinicians should consult product labeling and published ILE guidance for specific formulation characteristics and appropriate dosing. Commercially available ILE products in the US are listed in Table 1. Refer to product labeling for the specific product used in addition to published literature if off-label dosing is considered.[1-6] **Compatibility and stability data from one ILE formulation should not be applied to another** (e.g., compatibility and stability data for one ILE formulation must not be extrapolated to other ILE products)[8,9]

        i. For example, a total nutrient admixture containing SO-ILE has different limits for safe amounts of macro- and micronutrients than a similar PN admixture containing SO, MCT, OO, FO-ILE.
        ii. Contact manufacturers for product-specific information.

    b. During prolonged shortages, the FDA may temporarily approve importing alternative products from outside the United States. These products may differ in oil concentration, oil source(s), fatty acid content, indications, dosing, packaging, and labeling from products in the United States.

        i. The “Dear Healthcare Professional” letter accompanying imported products must be carefully reviewed before implementing clinical use. Members of the healthcare team should be educated on any differences between imported products and products approved for use in the United States.

6. **Maintain or incorporate the following sterile compounding practices:**

    a. **Facilities must continue to observe and comply with the product labeling (e.g., package insert), USP General Chapter <797> Pharmaceutical Compounding-Sterile Preparations and associated USP chapters, and state Boards of Pharmacy and federal rules and regulations.**[12]

    b. Compound PN in a single, central location (either in a centralized pharmacy or as outsourced preparation) and consider consolidating ILE compounding to specific days of the week (i.e. intermittent ILE dosing schedule) to decrease inventory waste. For example, a facility may choose to provide ILE on Monday, Wednesday, and Friday only to conserve supply. Consider a supply outreach to other facilities in your geographic location.

    c. Repackaging ILE into syringes or intravenous (IV) bags to infuse the ILE separately from the dextrose/amino acids PN admixture is not recommended due to increased risk of microbial contamination.[13,14] However, this approach is commonly used in neonatal and pediatric populations, and strategies to optimize the safety of this practice have been described.[8,14,15] If this approach is utilized during an ILE shortage to minimize waste or reduce administration errors using the manufacturer’s original container, the infusion duration of the transferred product should be limited to 12 hours. For prolonged infusions (i.e., greater than 12 hours), the

daily dose should be divided into multiple doses, with a new container for each 12-hour period.[8,14,15]

7. **Report shortages and errors.**
    a. Report significant drug product shortage information to the of FDA CDER Drug Shortage Program and the ASHP Drug Shortage Team.
    b. Report any patient adverse events or medication hazards related to shortages to the ISMP Medication Errors Reporting Program (MERP), and FDA MedWatch.

Specific Recommendations for Hospitalized Neonatal and Pediatric Patients

1. Efforts to prioritize ILEs for the neonatal and pediatric population should be made to minimize the risk of adverse effects associated with essential fatty acid deficiency (EFAD).
2. Neonatal and pediatric patients should continue to receive daily doses based on their targeted estimated needs to promote appropriate growth and development.[8]
3. ILE dosing to meet energy and essential fatty acid (EFA) needs for neonatal and pediatric patients differs among the available ILE products. Refer to product-specific labeling for the specific ILE product used, in addition to published literature, if off-label use is considered.

Considerations for ILE Product Substitutions:
Note: The dosage of ILE may need to be adjusted when switching between products with different oil compositions, because the percentage of EFAs and dosing recommendations vary among products.

During a shortage of:	Consider using another ILE product, such as:
SO-ILE	A different brand of SO-ILE; OO, SO-ILE; or SO, MCT, OO, FO-ILE
OO, SO-ILE	SO-ILE or SO, MCT, OO, FO-ILE
SO, MCT, OO, FO-ILE	SO-ILE or OO, SO-ILE
SO-ILE; **SO, MCT, OO, FO-ILE**; and **OO, SO-ILE**	FO-ILE *Note: FO-ILE is FDA-approved as a source of energy and fatty acids in pediatric patients with parenteral nutrition-associated cholestasis.[6] It should be prioritized for use in this population.*
FO-ILE	SO, MCT, OO, FO-ILE. If a FO-containing ILE is unavailable, consider using OO, SO-ILE or SO-ILE. *Note: If SO-ILE is being used, dose at 1 g/kg/day for patients with a history of intestinal failure-associated liver disease (IFALD). Do not reduce dosing of SO, MCT, OO, FO-ILE or OO, SO-ILE as it increases the risk of developing EFAD.[8]*

Specific Recommendations for Hospitalized and Alternate Site Adult Patients

1. During a shortage of one or more ILE products, consider the use of a different brand of the same oil source (i.e., for SO-ILE products) or another ILE product with a different oil composition. The use of a lipid-containing multi-chamber bag PN may also be a consideration for some patients.
2. The dose of ILE may need to be adjusted when switching between products with different oil compositions, because the percentage of EFAs and dosing recommendations vary among products.
3. Efforts to prioritize ILEs for the neonatal and pediatric population should be made to minimize the risk of adverse effects associated with EFAD.
4. Considerations for specific adult populations**:**
    a. **Patients without malnutrition receiving PN for less than 2 weeks:**
        i. ILE may be withheld during a shortage unless it is considered essential per the judgment of the healthcare professional.
    b. **Mild-to-moderately malnourished patients receiving PN for 2 weeks or longer:**
        i. ILE should be provided at doses targeted for EFAD prevention (Monitoring for EFAD). Refer to Table 2 for signs and symptoms of EFAD and refer to Table 3 for the average daily ILE dosing in adult patients to prevent EFAD.
        ii. Monitor patients for the development of EFAD (Table 2).
    c. **Pregnant patients, those at risk of refeeding syndrome, those with poor glycemic control, or severely malnourished patients who require PN:**
        i. ILE should be provided as a component of daily energy intake based on current practice recommendations and continued at the same dosage as prior to the shortage.
    d. **Critically ill patients who require PN:**
        i. Lipid intake from all other sources (e.g., dietary fat, EN, or other medications such as propofol or clevidipine) should be considered when determining the appropriate ILE dose.
        ii. Patients receiving medications containing ILE may not require additional ILE for EFAD prevention since the amount of SO-ILE in the medication may meet EFA needs (Table 3). Routinely monitor changes in intake received from other sources.
    e. For patients who are appropriate for an ILE dose reduction, ensure the dose of dextrose and/or amino acids is also adjusted to account for the decrease in calorie provision from ILE, and continue meeting estimated energy requirements for patients during this time.
        i. Ensure any modifications to individual doses of macronutrients continue to align with:
            1. patient-specific dosing recommendations;
            2. product-specific dosing recommendations; and
            3. product-specific considerations for maintaining PN compatibility and stability.

Considerations for ILE Product Substitutions:
Note: The dosage of ILE may need to be adjusted when switching between products with different oil compositions, because the percentage of EFAs and dosing recommendations vary among products.

During a shortage of:	Consider using another ILE product, such as:
SO-ILE	A different brand of SO-ILE; OO, SO-ILE; or SO, MCT, OO, FO-ILE
OO, SO-ILE	SO-ILE or SO, MCT, OO, FO-ILE
SO, MCT, OO, FO-ILE	SO-ILE or OO, SO-ILE

Specific Recommendations for Neonatal, Pediatric, and Adult Patients in the Home Setting

1. Efforts to prioritize ILEs for the neonatal and pediatric population should be made to minimize the risk of adverse effects associated with EFAD.
2. Neonatal and pediatric patients should continue to receive daily doses based on their targeted estimated needs to promote appropriate growth and development.[8]
3. Some adult patients on home/long-term PN should continue to receive ILE as a daily component of their PN regimen without a reduction in ILE dosage (e.g., patients with poor glycemic control, severe malnutrition, risk for refeeding syndrome, and pregnancy).
4. If clinically feasible, ILE provision (dose and/or frequency) should be decreased for adult patients. The minimum ILE dose provided to patients who rely on PN as their only nutrition source should meet their EFA requirements to prevent the development of EFAD (See Monitoring for EFAD). Barring concerns for intestinal malabsorption, patients transitioning from PN to EN or an oral diet should have fat intake from other sources considered when determining the appropriateness of withholding or decreasing ILE in the PN formula.
    a. For patients who are appropriate for an ILE dose reduction, ensure the dose of dextrose and/or amino acids is also adjusted to account for the decrease in calorie provision from ILE, and continue meeting estimated energy requirements for patients during this time.
        i. Ensure any modifications to individual doses of macronutrients continue to align with:
            1. patient-specific dosing recommendations;
            2. product-specific dosing recommendations; and
            3. product-specific considerations for maintaining PN compatibility and stability.

5. The use of a lipid-containing multi-chamber bag PN may also be a consideration for some adult patients.

Considerations for ILE Product Substitutions:
Note: The dosage of ILE may need to be adjusted when switching between products with different oil compositions, because the percentage of EFAs and dosing recommendations vary among products.

During a shortage of:	Consider using another ILE product, such as:
SO-ILE	A different brand of SO-ILE; OO, SO-ILE; or SO, MCT, OO, FO-ILE
OO, SO-ILE	SO-ILE or SO, MCT, OO, FO-ILE
SO, MCT, OO, FO-ILE	SO-ILE or OO, SO-ILE
SO-ILE; **OO, SO-ILE**; and **SO, MCT, OO, FO-ILE**	FO-ILE (pediatric patients only) *Note: FO-ILE is FDA-approved as a source of energy and fatty acids in pediatric patients with parenteral nutrition-associated cholestasis.[5] It should be prioritized for use in this population.*
During a shortage of **FO-ILE**	SO, MCT, OO, FO-ILE. If a FO-containing ILE is unavailable, consider using OO, SO-ILE or SO-ILE. *Note: If SO-ILE is being used, dose at 1 g/kg/day for patients with a history of IFALD. Do not reduce dosing of SO, MCT, OO, FO-ILE or OO, SO-ILE as it increases the risk of developing EFAD.[8]*

Monitoring for Essential Fatty Acid Deficiency (EFAD)

EFAD may occur more frequently when patients are receiving reduced doses of ILEs during shortages. Closely monitor patients receiving PN for developing EFAD during ongoing shortages. Increase awareness and assessment for signs and symptoms of EFAD (Table 2).

1. Identify patients receiving PN who are at risk for EFAD and closely monitor for developing EFAD, including EFA profiles to ensure deficiencies do not occur.[16,17] Note that EFA profiles may not be available at all laboratories, and results may be delayed while samples are processed at a remote reference laboratory.
2. Conduct a thorough nutrition assessment upon initiating PN in any patient to evaluate the potential risk for EFAD. When feasible, a review of the patient's prior PN formulation should be included in this assessment for patients receiving PN before admission to your institution, including patients who are transferred from an outside institution and those on home/long-term PN.
3. Refer to product-specific information and/or directly communicate with manufacturers to confirm that the minimum doses of EFAs are provided to help prevent EFAD (Table 3).

Table 2. Clinical Signs, Symptoms, and Biochemical Evidence of Essential Fatty Acid Deficiency (EFAD)

Category	Findings	Notes
Clinical Signs and Symptoms	• Diffuse dry, scaly rash • Alopecia • Hair depigmentation • Growth restriction in children • Increased susceptibility to infection • Impaired wound healing • Elevated liver function tests • Hyperlipidemia • Altered platelet aggregation • Anemia • Thrombocytopenia	List is not all-inclusive.[16]
Biochemical Evidence	• Triene-to-Tetraene ratio > 0.2 has historically been diagnostic of EFAD • Reference ranges vary based on the fatty acid assay used by the laboratory	Biochemical changes may manifest before clinical signs[8,9,17] Because fatty acid profile interpretation is complex, evaluation of EFA should go beyond the Triene-to-Tetraene ratio. Clinicians should refer to: Gramlich et al. 2019.[17]

Table 3. Minimum Daily ILE Dosing Requirements to Prevent Essential Fatty Acid Deficiency in Adult Patients

Estimated Daily Caloric Requirements (kcal)	**Minimum Daily** ILE Dose to Prevent EFAD* (see note below re: stability) Minimum doses represent average daily amounts needed to meet EFA requirements and can be provided daily or via an intermittent schedule (e.g., three times/week)		
	SO-ILE 20%	OO, SO-ILE 20%	SO, MCT, OO, FO-ILE 20%
1000	4.1 g	12.3 g	12.6 g
1500	6.1 g	18.4 g	18.9 g
2000	8.2 g	24.6 g	25.1 g

Adapted from Mirtallo 2020[9]; based on 20% products only

***Total nutrient admixtures (3-in-1) with very low ILE concentrations (i.e., less than 2% or otherwise specified by the product manufacturer) are unlikely to be stable.[14] In most cases, higher ILE doses need to be administered intermittently versus daily, or the ILE may need to be infused separately if a stable total nutrient admixture cannot be prepared.** Clinicians should refer to the ILE product manufacturer for stability information.

The values in Table 3 **do not represent routine (e.g., outside of a shortage) practice standards for daily ILE requirements** and should **only be used during periods of limited ILE supply when conservation strategies are necessary**. They indicate the minimum ILE amounts needed to prevent EFAD for adult patients only. In times of adequate ILE supply, these doses should not be used as target daily doses. If ILE doses must be reduced to conserve supply, adjust the PN formulation to provide sufficient dextrose and amino acids to meet the patient's nutritional needs and maintain admixture stability.

Note: Neonatal and pediatric patients should continue to receive daily doses based on their targeted estimated needs to promote appropriate growth and development.[8]

Example: A 50 kg adult patient receiving PN has an estimated total caloric need of 1500 kcal per day. Their PN regimen is a total nutrient admixture (e.g., 3-in-1) that includes protein 65 g (supplied as amino acid 15% brand), dextrose 215 g, and ILE 50 g (supplied as 20% SO-ILE) in a total volume of 1560 mL infused over 24 hours daily. There is currently a shortage of multiple ILE products, and alternative ILE formulations are unavailable. Therefore, an ILE dose reduction strategy must be implemented to conserve the current supply, and this PN regimen will be modified to provide the minimum dose of SO-ILE to meet EFA requirements.

1. **What is the minimum dose of SO-ILE that should be provided in this PN regimen to prevent EFAD?**
    a. As described in Table 3, an average of 6.1 g daily of a 20% SO-ILE is needed to prevent EFAD with estimated caloric needs of 1500 kcal per day.
        i. Convert the ILE dose from Table 3 from daily to weekly requirements because a SO-ILE dose of 6.1 g would not be stable in the PN admixture described in the example.
            1. 6.1 g/day x 7 days/week = 42.7 g/week
2. **This is the <u>minimum</u> dose of SO-ILE that should be provided each week to prevent EFAD. What modifications to SO-ILE dosing in this PN regimen would be appropriate?**
    a. A dose of 45 g SO-ILE once weekly in a total nutrient admixture (3-in-1) provides the minimum dose necessary to prevent EFAD and maintains a stable admixture (i.e., greater than or equal to 2%). This dose remains within product-specific dosing recommendations and does not exceed the maximum ILE infusion rate for a 50 kg adult patient.
3. **What other changes to the macronutrient doses in this PN regimen are necessary with the modified ILE dosing?**
    a. Increase the dose of dextrose and amino acids as appropriate to meet the patient's nutritional needs and maintain admixture stability. Doses of amino acids and dextrose should remain within appropriate ranges for individual patient needs.

Summary of Key Considerations

- ✓ Neonatal and pediatric patients should continue to receive daily doses based on their targeted estimated needs to promote appropriate growth and development.
- ✓ For adult patients appropriate for an ILE dose reduction, provide at least the minimum dose necessary to prevent EFAD.
    - Adjust the dose of dextrose and amino acids as appropriate to meet the patient's nutritional needs and maintain admixture stability.
        - Ensure any modifications to individual doses of macronutrients continue to align with:
            - patient-specific dosing recommendations;
            - product-specific dosing recommendations; and
            - product-specific considerations for maintaining PN compatibility and stability.
    - Resume appropriate dosing when the shortage resolves.
- ✓ Consider stability and compatibility differences to the total nutrient admixture (3-in-1) with any change in ILE dose or product. Data from one ILE product cannot be applied to other ILE products. Contact manufacturers for product-specific information.
- ✓ The decision to provide a total nutrient admixture (3-in-1) versus a 2-in-1 with separate ILE infusion should be based on the following:
    - Stability of the ILE dose in a total nutrient admixture.
    - Compatibility of the ILE product with other PN components in the admixture (e.g., amino acid product/concentration).
    - Minimization of ILE waste (consider manufacturer package sizes).
- ✓ The frequency of ILE dosing (daily versus an intermittent schedule [e.g., three times per week]) should be based on the following:
    - Stability of the ILE dose in a total nutrient admixture.
    - The product-specific maximum infusion rate (g/kg/hr.) or daily dose (gram per kilogram) of the ILE product.
    - Minimization of ILE waste (consider manufacturer package sizes)

ASPEN Resources

PN/EN Indications:

- When Is Parenteral Nutrition Appropriate?
- When is Enteral Nutrition Indicated?

PN Dosing and Safe Practices:

- Appropriate Dosing for Parenteral Nutrition: ASPEN Recommendations
- ASPEN Clinical Guidelines: Parenteral Nutrition Ordering, Order Review, Compounding, Labeling, and Dispensing
- ASPEN Parenteral Nutrition Safety Consensus Recommendations

PN Compatibility and Stability:

- Parenteral Nutrition Compatibility and Stability: A Comprehensive Review
- Parenteral Nutrition Compatibility and Stability: Practical Considerations

Multi-Chamber Bag Parenteral Nutrition (MCB-PN):

- ISMP/ASPEN Multi-Chamber Bag Parenteral Nutrition Consensus Statements

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About ASPEN

The American Society for Parenteral and Enteral Nutrition (ASPEN) is dedicated to improving patient care by advancing the science and practice of nutrition support therapy and metabolism. Founded in 1976, ASPEN is an interdisciplinary organization whose members are involved in the provision of clinical nutrition therapies, including parenteral and enteral nutrition. With members from around the world, ASPEN is a community of dietitians, nurses, nurse practitioners, pharmacists, physicians, PAs, researchers, scientists, and students from every facet of nutrition support clinical practice, research, and education. For more information about ASPEN, please visit www.nutritioncare.org.