

May 4, 2016

Parenteral Nutrition Amino Acids Product Shortage Considerations

ASPEN has developed shortage recommendations to assist members and other clinicians in coping with parenteral nutrition (PN) shortages for their patients.

For the most up-to-date product shortage information, please see these websites:

- [American Society of Health-System Pharmacists \(ASHP\), Drug Shortages Resource Center](#)
- [U.S. FDA Drug Shortages](#)
- [ASPEN Product Shortage Latest News](#)

Important Notes:

- These recommendations do not constitute medical or professional advice and should not be taken as such. To the extent the information published herein may be used to assist in the care of patients, this is the result of the sole professional judgment of the attending health professional whose judgment is the primary component of quality medical care. The information presented herein is not a substitute for the exercise of such judgment by the health professional.
- Revised by the ASPEN Clinical Practice Committee's Nutrition Product Shortage Subcommittee: Steve Plogsted, PharmD, BCNSP, CNSC (Chair); Stephen C. Adams, MS, RPh, BCNSP; Karen Allen, MD; M. Petrea Cober, PharmD, BCNSP; June Greaves, RD, CNSC, CD-N, LD, LDN; Kris M. Mogensen, MS, RD, LDN, CNSC; Amy Ralph, MS, RD, CNSC, CSO, CDN; Ceressa Ward, PharmD, BCPS, BCNSP; and Joe Ybarra, PharmD, BCNSP.
- Approved by the ASPEN Clinical Practice Committee and the Board of Directors on April 20, 2016. Questions regarding these recommendations should be directed to clinicalpractice@nutritioncare.org.

During the Shortage Period, Consider One or More of the Following Measures:

1. Assess and regularly reassess each patient as to the indication for PN and provide nutrition via the oral or enteral route when possible.
2. Purchase only as much amino acids products supply as needed. In the interest of fair allocation to all patients nationally, please do not stockpile.
3. ONLY use Neonatal/Pediatric-specific amino acids or disease-specific amino acids for the indicated patient populations.
4. Reserve high concentration amino acids products (e.g., greater than 10%) for fluid-restricted patients requiring PN.

5. Consider reviewing the entire portfolio of amino acids products available nationally. There may be a shortage in one concentration but availability in another. Amino acids products along with their compositions and availability can be obtained from manufacturers.
 - Baxter Healthcare International, Inc. Customer Service: 1-800-262-3784
 - B. Braun Medical, Inc. Customer Service: 1-800-227-2862
 - ICU Medical, Inc. Customer Service: 1-800-824-7890
6. Different brands of amino acids products are not always directly substitutable, especially for total nutrient admixture (3-in-1) vs. dextrose/amino acids (2-in-1) PN formulations. They may have different pHs, different calcium-phosphorus solubilities, different amounts of phosphorus, as well as other characteristics that should be considered.
7. Assess your PN patient population to determine if standardized, commercially-available parenteral nutrition products¹ may be appropriate for a portion of your patient population.
8. During prolonged shortages of intravenous amino acids products, the FDA may approve the temporary importation of alternative products. These products may have different electrolytes, ratios (doses), packaging and labeling than United States products. The Dear Healthcare Professional Letter accompanying imported products should be read carefully.
9. Include PN component shortages and outages in the health care organization's strategies and procedures for managing medication shortages and outages. These procedures should include:
 - a process to notify providers when PN formulations are adjusted due to shortages and outages of PN components, and
 - a process to notify patients receiving long-term PN therapy when their PN formulation has been adjusted for shortages and outages of PN components.
10. Compound PN in a single, central location (either in a centralized pharmacy or as outsourced preparation) in order to decrease inventory waste. Consider a supply outreach to other facilities in your geographic location.
11. Facilities and practitioners need to continue to observe and be compliant with the product labeling (e.g., package insert), USP General Chapter <797> Pharmaceutical Compounding-Sterile Preparations, and state Boards of Pharmacy and federal rules and regulations.
12. Report severe drug product shortage information to the FDA Drug Shortage Program (DSP).
13. Report any patient adverse events or medication hazard related to shortages to ISMP Medication Errors Reporting Program (MERP).

References

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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.