

February 3, 2023

IMPORTANT DRUG WARNING- DRUG RECALL

Subject: Serious Risks with Use of ABELCET® (Amphotericin B Lipid Complex) Injection

- **Possible bacterial contamination of the product**
- **Bacteremia associated with intravenous administration of the product**

Dear Health Care Provider:

The purpose of this letter is to inform you of a recall due to an important safety concern for **ABELCET® (Amphotericin B Lipid Complex) Injection, lot 1203A (Exp. 11 May 2024)**. ABELCET® is indicated for the treatment of invasive fungal infections in patients who are refractory to or intolerant of conventional amphotericin B therapy.

Serious Risks with Use of ABELCET®, lot 1203A (Exp. 11 May 2024).

The specific lot of Abelcet, 1203A, was released for commercial distribution on February 10, 2022. We have been informed by the manufacturer of Abelcet that a number of vials from a media fill performed after the manufacture of Abelcet Lot 1203A have been detected with turbidity. A subsequent investigation determined that this turbidity was due to *Cupriavidus pauculus*. This finding raises the concern of a breach of sterility and impacts Lot 1203A. There is a risk that administration of a vial of Abelcet from this lot would introduce bacteria into the bloodstream of the recipient along with the product.

Prescriber Action:

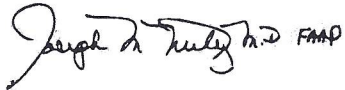
Please notify your pharmacy that provides Abelcet and identify all remaining vials of the product from Abelcet lot 1203A. Do not prescribe Abelcet to any patient with product from this lot. The pharmacy will receive instructions from Lediant or their Abelcet supplier regarding return of the product. Do not use the product from this lot and do not destroy it.

Reporting Adverse Events

Health care providers are encouraged to report adverse events in patients who received Abelcet from Lot 1203A to Lediant Biosciences, Inc at 1-888-393-4584 or drugsafety@lediant.com. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

You may also contact our medical information department at 1-866-634-2765 or
Leadiant@tmacmail.com if you have any questions about the information contained in this letter.

Sincerely,

A handwritten signature in black ink that reads "Joseph M. Wiley MD FAAP". The signature is written in a cursive style with a large initial "J" and "W".

Joseph M. Wiley MD, FAAP
Vice President, Medical Affairs, Drug Safety and Pharmacovigilance
Leadiant Biosciences, Inc.