AvKARE– Recall of atovaquone oral suspension

- On April 1, 2024, AvKARE announced a consumer level recall of one lot of atovaquone oral suspension because of potential *Bacillus cereus* contamination in the product found during stability testing at a 3rd party lab.
- Atovaquone was distributed nationwide between March 18, 2024 and March 21, 2024.

Product Description	NDC#	Lot# (Expiration Date)
Atovaquone oral suspension 750 mg/5 mL	50268-086-12	AW0221A (8/2025)

- Atovaquone is indicated for prevention and treatment of *Pneumocystis jiroveci pneumonia* (PCP) in adults and children 13 years of age and older who cannot tolerate other medicines, such as trimethoprim-sulfamethoxazole.
- In the population most at risk, immunocompromised population, there is a reasonable probability that microbial contamination of atovaquone oral suspension can result in disseminated, life threatening infections such as endocarditis and necrotizing soft tissue infections.
- To date, AvKARE has not received any reports of adverse events related to this recall.
- Anyone with the affected lots on hand should stop distribution and return product. Patients that have bottles from the recalled lots of atovaquone oral suspension should contact their healthcare provider.
- Contact AvKARE by phone at **1-855-361-3993** or by email at **drugsafety@avkare.com** for questions regarding this recall.

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