



FDA Issues Immediately in Effect Guidance for Compounding of Amoxicillin to Alleviate Shortages

Amoxicillin oral powder for suspension was recently added to the FDA drug shortage list due to increased demand. FDA is working with drug manufacturers to address amoxicillin oral suspension shortages. The agency has also received requests for clarification about preparation of compounded versions of those products from FDA-approved tablets and capsules.

Recently, the agency issued an [immediately in effect guidance](#) on the preparation of beta-lactam oral antibiotic suspension products that appear on FDA's drug shortage list by a licensed pharmacist in a state-licensed pharmacy or federal facility. The guidance describes steps to reduce the risk of cross-contamination between these and other products. Amoxicillin is a beta-lactam drug, and compounding this drug in an environment without appropriate safety measures could lead to cross-contamination of other drug products. Beta-lactam drugs can cause life-threatening allergic reactions in some patients.

Amoxicillin is widely used for the treatment of bacterial infections in children, among other uses. Antibiotics like amoxicillin treat many different infections caused by bacteria, but they are not effective against viral infections like the common cold, most sore throats, and the flu.

Click here to view the full guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compounding-certain-beta-lactam-products-shortage-under-section-503a-federal-food-drug-and-cosmetic?utm_medium=email&utm_source=govdelivery

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