

Azithromycin – Safety Update

- On August 3, 2018, the [FDA announced](#) that azithromycin ([Zithromax](#)[®], [Zmax](#)[®]) should not be given long-term to prevent bronchiolitis obliterans syndrome in patients with cancers of the blood or lymph nodes who undergo a donor stem cell transplant.
 - Azithromycin is not approved for preventing bronchiolitis obliterans syndrome.
 - Azithromycin is indicated for the treatment of certain mild to moderate infections caused by susceptible isolates of certain microorganisms. Refer to the drug labels for further indication information.
- Bronchiolitis obliterans syndrome is a serious lung condition caused by inflammation and scarring in the airways of the lungs, resulting in severe shortness of breath and dry cough. Cancer patients who undergo stem cell transplants from donors are at risk for bronchiolitis obliterans syndrome.
- Results of a clinical trial found an increased rate of relapse in cancers affecting the blood and lymph nodes, including death, in these patients taking long-term azithromycin.
- Pfizer, the manufacturer of brand Zithromax, is providing a [Dear Healthcare Provider letter](#) on this safety issue to healthcare professionals who care for patients undergoing donor stem cell transplants.
- There are no known effective antibiotic treatments for prophylaxis of bronchiolitis obliterans syndrome. Healthcare professionals should not prescribe long-term azithromycin for prophylaxis of bronchiolitis obliterans syndrome to patients who undergo donor stem cell transplants because of the increased potential for cancer relapse and death.
- Patients who have had a stem cell transplant should not stop taking azithromycin without first consulting with their healthcare professional. Doing so could be harmful without their healthcare provider's direct supervision.
- The safety update is based on data from the [ALLOZITHRO](#) trial which was stopped approximately 13 months after the study completed enrollment of 480 patients. There was an unexpected increase in the rate of both cancer relapses and death in patients taking azithromycin.
 - Cancer relapse was observed in 77 patients (32.9%) with azithromycin treatment vs. 48 patients (20.8%) with placebo.
 - Ninety-five patients died in the azithromycin treatment group vs. 66 patients in the placebo group; thus, the 2-year survival rate was 56.6% in azithromycin-treated patients vs. 70.1% with placebo.
 - At the start of the trial, the death rate was about equal between the groups; however, an imbalance occurred and continued until the 2-year time point.
 - The trial could not determine why the rates of cancer relapse and death were higher with azithromycin.
- The FDA is continuing to review additional data and will communicate their conclusions and recommendations when complete.