

Alerts and Recalls

Generic Name (Trade Name—Company)

August 3, 2018

Azithromycin

(Zithromax, Zmax—Pfizer, others)

Increased risk of cancer relapse with long-term use of azithromycin after donor stem cell transplant

Uses/Notes

FDA is [warning](#) that the antibiotic azithromycin should not be given long term to prevent an inflammatory lung condition known as bronchiolitis obliterans syndrome in patients with cancers of the blood or lymph nodes who undergo a donor stem cell transplant. Results of a clinical trial found an increased rate of relapse in cancers affecting the blood and lymph nodes, including death, in these patients.

Bronchiolitis obliterans syndrome is caused by inflammation and scarring in the airways of the lungs, resulting in severe shortness of breath and dry cough. Patients with cancer who undergo stem cell transplants from donors are at risk for bronchiolitis obliterans syndrome. There are no known effective antibiotic treatments that prevent the syndrome, and azithromycin is not approved for this use. It is an FDA-approved antibiotic used to treat many types of infections affecting the lungs, sinuses, skin, and other parts of the body.

The drug, which has been used for more than 26 years, is sold under the brand names Zithromax and Zmax and as generics by many different drug companies. Pfizer, the manufacturer of brand name azithromycin, is providing a [Dear Healthcare Provider letter](#) on this safety issue to health professionals who care for patients undergoing donor stem cell transplants.

FDA is reviewing additional data and will communicate its conclusions and recommendations when the review is complete. Patients who have had a stem cell transplant should not stop taking azithromycin without first consulting with their health care provider.

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<http://aphanet.org/alerts-and-recalls/increased-risk-cancer-relapse-long-term-use-azithromycin-after-donor-stem-cell>

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