

Azithromycin and Cystic Fibrosis: Is it right for you?

Azithromycin is a commonly used antibiotic made by Pfizer Inc. and sold as Zithromax[®]. Many people have taken this drug to treat pneumonia, sore throats, or ear infections. In 1999, the Cystic Fibrosis Foundation recognized that azithromycin might help people with cystic fibrosis (CF) and designed a clinical trial to test that possibility. At the 2002 North American Cystic Fibrosis Conference, your CF care center team was given the results of the clinical trial.

So now you are asking: What does this mean for me? Here is some information that will prepare you for talking to your CF care center team to see if you or your child should add azithromycin to your routine CF care.

What were the results of the trial?

During the clinical trial, lung function (FEV₁), weight, and days spent in the hospital to treat lung infections were watched for changes. The people with CF who were involved in the study were split into two groups. One group took a placebo -- an inactive pill that has no treatment value. The other group took azithromycin. During the trial, neither the patient nor the CF researchers knew who took azithromycin. Over six months, the group that took the azithromycin saw about a six-percent improvement in their lung function, an increase in their weight, and had 47 percent fewer days in the hospital for the treatment of a lung infection.

Were there any side effects?

The side effects that were noted by some people were mild and included nausea, diarrhea, and wheezing. A few people had side effects that made the researchers reduce their dose or the amount of the drug that they took. Only one person had to stop taking azithromycin.

Is azithromycin right for me or my child?

Your CF care team can help answer this question. Knowing who was chosen for the clinical trial might help you decide if azithromycin is right for you or your child. The people with CF in the study were older than six years of age, weighed at least 55 pounds, had mild to moderate lung disease, and had *Pseudomonas aeruginosa* in their sputum for at least one year. If a patient had a sputum culture that contained non-tuberculous mycobacteria, or had liver disease or kidney disease, they were not included in the trial. Your CF care team can provide you with more information and may do some tests (sputum cultures and blood tests) to see if azithromycin is right for you or your child.

Who should not take azithromycin?

Anyone who is allergic to azithromycin, erythromycin, or any macrolide-related antibiotic, should not take azithromycin. People with liver disease, pregnant women, and those with a positive culture for non-tuberculous mycobacteria need to talk with their CF care team before starting azithromycin.

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What are non-tuberculous mycobacteria?

Non-tuberculous mycobacteria are bacteria found in the environment and sometimes cause lung infections in people with CF. Lung infections from this type of bacteria are not passed from one person to another and can be treated with the proper medication. However, if you have non-tuberculous mycobacteria in your sputum, it could affect your physician's decision about whether to start you on azithromycin. Ask your CF care center team for more information.

How would azithromycin be taken?

Azithromycin can be taken with food. In the clinical trial, people with CF took one or two azithromycin pills on Monday, Wednesday, and Friday. As with any medication, you should tell your CF care team what over-the-counter and other CF drugs you or your child are taking.

If azithromycin is added to my or my child's CF care, should I stop taking any drugs?

Azithromycin is one more "tool" in CF care. It may be used as a part of your or your child's regular CF treatment. It is not meant to replace other proven treatments. **Do not stop any therapy before you talk with your CF care team.** It is always a good idea to talk about all of your therapies with your CF care team to make sure that you or your child are getting the proper treatment.

What happened to the bacteria or "bugs" in the sputum?

There was a small drop in the number of *Pseudomonas aeruginosa* bacteria that grew in the sputum of the people who took azithromycin in the clinical trial. It is not known if this is why they had better lung function and weight gain than the people who took the placebo. More studies are planned to figure out exactly how this drug works in CF.

What about resistance?

People can -- and do -- become resistant to antibiotics that are taken over a long period of time. This did not seem to happen in the azithromycin clinical trial. Your CF care team will watch for signs of resistance to azithromycin and any other antibiotics.

What's in the future?

The CF Foundation will work with Pfizer to plan more clinical studies. These studies will answer questions about how azithromycin works, what the long-term benefits are and will watch for signs of resistance in people with CF. The CF patient registry also will be used to help track the use of azithromycin and any resistance that may develop.

What did the CF Foundation do?

The CF Foundation conceived, designed, and initiated this definitive clinical trial to bring azithromycin to people with CF as another therapy. In addition to providing the \$3 million to do the study, the CF Foundation supported the CF Therapeutics Development Network Coordinating Center and the 23 CF Foundation-accredited care centers that participated in this process.

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To find a cure for this disease, the CF Foundation follows the approach of pursuing several different strategies. It has recently invested close to \$131 million in science that uses the latest technology to discover new CF-specific drugs. At the same time the azithromycin study is a part of a “low-hanging fruit” strategy to study the potential of drugs already on the market for other diseases that may have a benefit for CF patients.

Your participation is essential in the process of developing new drugs and making them available sooner for everyone with the CF. The CF Foundation thanks all of the patients and acknowledges the efforts of the physicians, research coordinators, study leaders and Pfizer who made this clinical trial a success.

The mission of the Cystic Fibrosis Foundation is to assure the development of the means to cure and control cystic fibrosis and to improve the quality of life for those with the disease. For more information on cystic fibrosis, call (800) FIGHT CF or visit our Web site at: www.cff.org.

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