

This is an official **CDC HEALTH UPDATE**

Distributed via Health Alert Network
Friday, March 26, 2004, 17:55 EDT (5:55 PM EDT)
CDCHAN-00193-2004-03-26-UPD-N

Manufacturer's Recall of Nasal Spray Contaminated with *Burkholderia cepacia* Complex

Clinicians should be aware that the Centers for Disease Control and Prevention (CDC) has been notified that additional lots of over-the-counter oxymetazoline HCL 0.05% nasal spray has been recalled because of intrinsic contamination with *B. cepacia* complex. Some of the recalled lots have been found to be contaminated and could cause serious or potentially life-threatening infections in patients with compromised immune systems, particularly individuals with cystic fibrosis. The product being recalled is an over-the-counter drug product labeled "Major Soothing Twice-A-Day 12 Hour Nasal Spray Decongestant Regular Oxymetazoline Hydrochloride 0.05%. Distributed by Major Pharmaceuticals, Livonia, MI". The lot number can be found on the bottom of the carton and on the back of the bottle label. The lot numbers being recalled are E4410, F4433, H4464, K4496, L4529, L4535, M4536, A4558, A4588, and B4597. CDC is assisting the state of Missouri, investigating several cases of *B. cepacia* that have been identified in one hospital, to examine the impact of the recalled product on patient safety and the potential spread of *B. cepacia* within the healthcare setting.

Disease symptoms and characteristics

B. cepacia is a multidrug-resistant organism and management of patients with these bacteria should be in accordance with hospital policy for infection control and isolation precautions. *B. cepacia* poses very little medical risks to healthy people; however, people whose health is otherwise compromised may be more susceptible. If individuals have used this product and are concerned they should contact their healthcare provider.

B. cepacia consists of several species, or a complex, of bacteria, that are found in the natural environment. Some of these species threaten the health of individuals with cystic fibrosis (CF). It is important to note that in general, the species that colonize the lungs of people with CF differ from most of those found in the natural environment. However, all species of *B. cepacia* have been recovered from the sputum of people with CF; these bacteria were only first reported in people with CF in the 1970s.

B. cepacia bacteria are able to survive in the environment or in the lungs of a person with CF. They are resistant to most common cleaning disinfectants and to many antibiotics, which makes them difficult to treat once they infect the lungs. However, some species may be successfully treated with combinations of antibiotics. Standard health precautions greatly reduce the risk of infection.

Cases of *B. cepacia* complex infection or colonization associated with use of this product should be reported to the local or state health department and CDC at (800) 893-0485.

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national and international organizations.

DEPARTMENT OF HEALTH AND HUMAN SERVICES