

Fatal Gastrointestinal Mucormycosis in an Infant Following Use of Contaminated ABC Dophilus From Solgar Company



DATE:	11/21/2014
TO:	Health Alert Network
FROM:	Michael Wolf, Secretary of Health
SUBJECT:	Fatal Gastrointestinal Mucormycosis in an Infant Following Use of Contaminated ABC Dophilus From Solgar Company
DISTRIBUTION:	Statewide
LOCATION:	Statewide
STREET ADDRESS:	Statewide
COUNTY:	Statewide
MUNICIPALITY:	Statewide
ZIP CODE:	Statewide

This transmission is a “Health Alert”: conveys the highest level of importance; warrants immediate action or attention.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, INFECTION CONTROL, NURSING, AND LABORATORY STAFF IN YOUR HOSPITAL

EMS COUNCILS: PLEASE DISTRIBUTE AS APPROPRIATE

FQHCs: PLEASE DISTRIBUTE AS APPROPRIATE

LOCAL HEALTH JURISDICTIONS: PLEASE DISTRIBUTE AS APPROPRIATE

PROFESSIONAL ORGANIZATIONS: PLEASE DISTRIBUTE TO YOUR MEMBERSHIP

Purpose:

The Pennsylvania Department of Health is notifying all health care entities of an ongoing investigation of the October 2014 death of a premature infant in Connecticut with GI mucormycosis after the use of Solgar ABC Dophilus.

Action Items:

1. **Immediately discontinue the use of Solgar ABC Dophilus**, a probiotic product available for both health care and commercial use and sold in retail stores and through online retailers. In neonatal intensive care units, the product has been used to prevent necrotizing enterocolitis (NEC) in premature infants.
2. Notify the Pennsylvania Department of Health or your local health department of:
 - a. Confirmed or suspected cases of infants with gastrointestinal mucormycosis (diagnosed via culture or histopathology) since November 1, 2013, OR
 - b. Unexplained infant deaths within 30 days of receipt of Solgar ABC Dophilus since November 1, 2013

Full Description of Investigation: The CDC and FDA, in collaboration with the Connecticut Department of Public Health, are investigating a fatal case of GI mucormycosis in a premature infant of 29 weeks gestation. The infant received Solgar ABC Dophilus lot #074 024 01R1 and subsequently developed signs and symptoms consistent with necrotizing enterocolitis (NEC). Surgical exploration of the infant's GI tract revealed necrotic bowel which was resected; histopathology results from the resected bowel revealed a heavy fungal burden with angioinvasion, consistent with a Mucormycete.

Sequencing of fungal DNA recovered from the infant's tissue block identified the fungus as *Rhizopus oryzae*, a pathogenic Mucormycete. *R. oryzae* was also recovered from 2 unopened bottles of Solgar ABC Dophilus, lot #074 024 01R1. Solgar ABC Dophilus is a probiotic product intended to contain *Bifidobacterium lactis* and *Lactobacillus rhamnosus* and has been used to prevent NEC in premature infants. This product is available for purchase in retail stores and online retailers as well as used in healthcare settings.

The investigation into this fatal case of GI mucormycosis and its association with the contaminated Solgar ABC Dophilus is ongoing. As such, Solgar ABC Dophilus should not be used, especially in infants and children who may be more susceptible to infection, until further information regarding the safety of this product is available. State and local health departments are asked to disseminate this advisory to pharmacists, clinical laboratories, clinical pathologists, healthcare workers and other appropriate parties in their respective jurisdictions.

Categories of Health Alert messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of November 21, 2014, but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.