The CDC issued a health advisory on November 25; *Fatal Gastrointestinal Mucormycosis in an Infant Following Ingestion of Contaminated Dietary Supplement – Connecticut, 2014*. The CDC highlights and full communication are below.

Solgar ABC Dophilus® Powder is distributed in California and many other states and is distributed through pharmacies, retail stores, wholesalers, and online retailers

LAC DPH requests that any confirmed or suspected cases of infants with gastrointestinal mucormycosis (diagnosed via culture or histopathology) or unexplained infant deaths within 30 days after ingesting Solgar ABC Dophilus® Powder by reported to the Acute Communicable Disease Control Program (ACDC) at (213) 240-7941 during normal business hours.

CDC Highlights

- CDC currently recommends that Solgar ABC Dophilus Powder, a dietary supplement, **should not be used.**
- CDC, FDA, and state health departments are investigating a fatal case of gastrointestinal mucormycosis caused by *Rhizopus oryzae* in a premature infant in October 2014. Infection followed the use of ABC Dophilus Powder, a dietary supplement purchased from Solgar, Inc., Leonia, NJ.
- Testing of the same lot of unopened Solgar ABC Dophilus revealed contamination with *Rhizopus oryzae*. The source of contamination is still under investigation.
- Solgar has voluntarily recalled lots 074024-01R1, 074024-01, 074024-02 (expiration date 7/31/15).
- The investigation is ongoing, and new information will be provided when available.

This is an official

CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
November 25, 13:45 EST (1:45 PM EST)
CDCHAN-00373

Fatal Gastrointestinal Mucormycosis in an Infant Following Ingestion of Contaminated Dietary Supplement – Connecticut, 2014

Summary

The Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and Connecticut Departments of Public Health and Consumer Protection are investigating a fatal case of gastrointestinal (GI) mucormycosis caused by Rhizopus oryzae *in a premature infant. The infant received ABC Dophilus® Powder, a dietary supplement product containing viable microbial ingredients purchased from Solgar, Inc., Leonia, New Jersey. The product claimed to have "probiotic" properties and is marketed for infants and children. Subsequent testing of the same lot of unopened Solgar ABC Dophilus®*

Powder revealed contamination with Rhizopus oryzae*. The purpose of this HAN advisory is to provide awareness about this fatal case of GI mucormycosis following ingestion of a contaminated dietary supplement and to provide guidance to state health departments and health care providers. Please disseminate this information to healthcare workers in neonatal intensive care units, hospital pharmacies, pediatricians, and primary care providers, as well as to microbiology and pathology laboratories.*

Background

Mucormycosis is a rare infection caused by mold in the order Mucorales, including *Rhizopus* spp. GI mucormycosis is a very rare manifestation of this disease and occurs when mucormycosis involves the GI tract causing signs and symptoms such as:

- Abdominal pain
- Abdominal distension
- Nausea
- Vomiting

These symptoms are thought to occur primarily when a susceptible person ingests the fungus, and they usually occur in immunocompromised individuals.

In October 2014, a hospital in Connecticut notified CDC and the Connecticut Department of Public Health of a fatal case of gastrointestinal mucormycosis in a preterm infant of 29 weeks' gestation. The infant received lot 074 024 01R1 of ABC Dophilus® Powder for four days, beginning on day one of life. ABC Dophilus® Powder is a product intended to contain three bacteria, *Bifidobacterium lactis, Streptococcus thermophilus,* and *Lactobacillus rhamnosus.* The product was purchased from Solgar, Inc., Leonia, NJ, and is marketed specifically for infants and children. This product and other dietary supplements thought to have probiotic effects have been used in preterm infants on the basis of a recent Cochrane review supporting their use for prophylaxis against necrotizing enterocolitis (NEC), a possible complication in preterm infants. ABC Dophilus ® Powder is intended for use as a dietary supplement and, as such, is not regulated as a drug by the FDA. FDA has not evaluated the safety of this product for any intended use and has not evaluated the veracity of any claims of probiotic or other health benefits.
(Cochrane review link: http://tinyurl.com/pzftml4)

This infant subsequently developed clinical signs and symptoms of NEC. Surgical exploration of the infant's abdomen revealed complete GI ischemia from esophagus to rectum, a portion of necrotic bowel was resected. Following surgery, the infant developed multiple areas of vascular occlusion, a finding not associated with NEC. Shortly thereafter, the infant died. Histopathologic results from the infant's necrotic bowel showed angioinvasive fungal infection, consistent with mucormycosis. Himmunohistochemical staining of the tissue block performed locally and at CDC was posi
tive when tested with a monoclonal antibody known to react with several mucormycete fungal agents. Sequencing of fungal DNA recovered from the tissue block at CDC identified the fungus as *Rhizopus oryzae,* a known cause of mucormycosis.

The hospital initiated an investigation into the infant's death, including evaluation of the Solgar ABC Dophilus® Powder product. Local testing of unopened bottles of lot 074 024 01R1 Solgar ABC Dophilus® Powder revealed contamination with mold, confirmed to be *Rhizopus oryzae* at CDC. On November 14, 2014, Solgar Inc. issued a voluntary recall (http://www.fda.gov/Safety/Recalls/ucm423219.htm) of ABC Dophilus® Powder lots 074024-01R1, 074024-01, and 074024-02 (all with expiration dates of 7/31/15).

This recall notice includes the instructions that "Consumers who have purchased Solgar ABC Dophilus® Powder are urged *not* to consume the product." This product was distributed to 29 states, Puerto Rico, the United Kingdom, and Israel through pharmacies, retail stores, wholesalers, and online retailers.

Investigation into this fatal case of GI mucormycosis following ingestion of contaminated Solgar ABC Dophilus® Powder is ongoing. National case finding efforts are underway to identify additional cases of GI mucormycosis following ingestion of this contaminated dietary supplement.

Recommendations

- Solgar ABC Dophilus® Powder should not be used, especially in infants who may be especially susceptible to infection.
- In considering the use of any dietary supplement, clinicians should consider that the FDA does not regulate these products as drugs.

Clinical Care

- Clinicians evaluating:
  o Preterm infants for necrotizing enterocolitis **OR**
  o Infants who have signs or symptoms of gastrointestinal mucormycosis such as abdominal pain, abdominal distension, nausea, or vomiting

Should review whether Solgar ABC Dophilus® Powder was used as part of the infants' care.

- If Solgar ABC Dophilus® Powder was consumed by the patient within the previous 30 days, clinicians should consider consultation with an infectious disease physician to assist in an assessment which may include the following:
  o Aggressive evaluation for a source of infection, including surgical exploration.
  o Empiric treatment with antifungals active against mucormycete infections.

Reporting

- Clinicians and public health officials are asked to notify their state or local health departments if they learn of cases or deaths in the following categories that have occurred since November 1, 2013:
  o Confirmed or suspected cases of infants with gastrointestinal mucormycosis (diagnosed via culture or histopathology).

  OR
  o Unexplained infant deaths within 30 days after ingesting Solgar ABC Dophilus® Powder.

For more information:

Please consult the CDC website for this investigation: http://www.cdc.gov/fungal/rhizopus-investigation.html. *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.*

Categories of Health Alert Network messages:

Health Alert Requires immediate action or attention; highest level of importance

Health Advisory May not require immediate action; provides important information for a specific incident or situation
Health Update Unlikely to require immediate action; provides updated information regarding an incident or situation
HAN Info Service Does not require immediate action; provides general public health information
##This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, HAN coordinators, and clinician organizations##