

Meningitis and Stroke Associated with Potentially Contaminated Product

Voluntary recall of all Ameridose medical products
Contamination identified in more products from New England Compounding Center

To: Healthcare Providers, Hospitals, Pharmacies, and Ambulatory Care Centers
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Ameridose Recall: Summary

The Food & Drug Administration (FDA) has announced that Ameridose is voluntarily recalling all of its unexpired medical products that are in circulation. Ameridose is based in Westborough, MA, and is managed by some of the same people as the New England Compounding Center (NECC). FDA is not aware of any recent reports of infections associated with the recalled Ameridose products. However, the preliminary results of FDA's ongoing inspection of Ameridose have raised concerns about a lack of sterility assurance for products produced and distributed by this facility.

Drug Shortage Considerations: FDA has identified some Ameridose products that are currently on the critical drug shortage list, including Sodium Bicarbonate Injection, Succinylcholine Injection, Atropine Sulfate Injection, Bupivacaine Hydrochloride Injection, Lidocaine Hydrochloride Injection, and Furosemide Injection. These products were in shortage before this recall, but supplies may be further affected. Hospitals and clinics may feel the impact. FDA is taking a number of actions to maintain supplies.

More information is available on the FDA's Drug Shortage website:
<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>.

FDA encourages health care providers and facilities to use only FDA-approved drugs if possible. If you believe there is a drug that is entering shortage, notify FDA's Drug Shortage staff at drugshortages@fda.hhs.gov.

Requested Actions:

- Stop use of all Ameridose products and isolate for return to Ameridose. Contact Ameridose at 1-888-820-0622 for instructions on how to return products. Products can be identified by name or its company logo. A complete list is available at: www.ameridose.com
- At this time CDC and FDA do not urge direct patient follow-up for Ameridose products.

- Stay alert to the possibility of infections associated with the use of these products, and report any infection or adverse events in a patient known to have received a product from Ameridose to the Health Department 24/7 at 802-863-7240 – and to FDA’s MedWatch program by fax at 1-800-332-0178 or on the Medwatch website at www.fda.gov/medwatch.

Contamination Identified in More Medical Products from NECC: Summary

As part of the ongoing investigation of the multistate outbreak of fungal meningitis and other infections, CDC and FDA continue to test medical products from the New England Compounding Center (NECC). CDC and FDA are reporting that product testing has identified bacterial contamination with several *Bacillus* species and closely related bacterial organisms in unopened vials of betamethosone and cardioplegia solution that were distributed and later recalled by NECC on October 6, 2012. These bacteria are commonly found in the environment and have been rarely reported as a cause of human disease. It is not known how product contamination with these species might affect patients. Although clinical infection is possible, CDC has not received reports of laboratory-confirmed cases of infection due to these organisms linked to these products.

Betamethosone and cardioplegia solutions produced by NECC were not distributed in Vermont.

Requested Actions:

- Healthcare professionals have previously been advised to cease use of any product produced by NECC. Clinicians were also advised to follow-up with patients who received any injectable NECC product, including betamethasone or cardioplegia solution purchased from or distributed by NECC after May 21, 2012. Clinicians were also asked to report any suspected adverse events.
- Report any symptomatic patients undergoing evaluation for adverse events related to any of these recalled products to the Health Department 24/7 at 802-863-7247 – and to the FDA’s MedWatch program www.fda.gov/medwatch.

Previous advisories on this topic:

October 5, 2012

http://healthvermont.gov/advisory/documents/100512_fungal_meningitis.pdf

October 9, 2012

http://healthvermont.gov/advisory/2012/documents/100912_fungal_meningitis_update1.pdf

October 16, 2012

http://healthvermont.gov/advisory/2012/documents/101612_fungal_meningitis_update2.pdf