Health Advisory: FDA Recall of Ultrasound Gel Due to Bukholderia cepacia complex

Minnesota Department of Health, Thu, Aug 5 14:00 CDT 2021

Action Steps

Local and tribal health department: Please forward to hospitals, clinics, urgent care centers, emergency departments, pharmacies, and convenience clinics in your jurisdiction.
Hospitals, clinics and other facilities: Please forward to infection preventionists, infectious disease physicians, emergency department staff, hospitalists, and primary care clinicians.
Health care providers:

- Immediately stop use and quarantine all lots of ultrasound gels distributed under the multiple brand names listed in the FDA: FDA: Eco-Med Pharmaceutical Issues Voluntary Recall of Eco-Gel 200 https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/eco-med-pharmaceutical-issues-voluntary-recall-eco-gel-200
- Identify the affected products, Eco Gel 200 or MediChoice M500812, by lot number (B029, B030, B031, B032, B040, B041, B048 and B055) and immediately destroy or return products from affected lots to Eco-Med.
- Conduct a look back for non-respiratory cases of Burkholderia cepacia complex (Bcc) since June 1, 2021 and report any cases to MDH.
- Hold clinical isolates at the clinical laboratory until MDH provides further communication.
- Report cases of Bcc associated with these products to FDA MedWatch: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda
- Report all non-respiratory cases of Bcc to MDH, since June 1, 2021, and ongoing at 1-877-676-5414 (toll-free) or 651-201-5414.

Background

The Minnesota Department of Health (MDH) is alerting healthcare facilities of a voluntary recall and quarantine of Eco Gel 200 MediChoice M500812 ultrasound gel because of contamination with Burkholderia cepacia complex (Bcc) bacteria. Cases of Bcc associated with this product have been reported in Minnesota.

MDH is investigating a multi-state cluster of Bcc cases associated with these products, including 8 cases identified to date in Minnesota. MDH is asking health care organizations to do a look back for non-respiratory cases of Bcc since June 1, 2021 and report any cases to MDH. We also request that you continue to report new cases. Available clinical isolates should be held at the clinical laboratory until MDH provides further communication.

Bcc can be transmitted through contaminated medical devices or medications, resulting in healthcare-associated clusters and outbreaks.

For more information regarding B. cepacia in healthcare setting please visit CDC Burkholderia cepacia in Healthcare Settings https://www.cdc.gov/hai/organisms/bcepacia.html

For More Information

- CDC Burkholderia cepacia in Healthcare Settings https://www.cdc.gov/hai/organisms/bcepacia.html
- FDA: Eco-Med Pharmaceutical Issues Voluntary Recall of Eco-Gel 200 https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

A copy of this HAN is available at: MDH Health Alert Network (http://www.health.state.mn.us/han)
The content of this message is intended for public health and health care personnel and response partners who have a need to know the information to perform their duties.