Safety Communication: Bacteria Found in Other-Sonic Generic Ultrasound Transmission Gel Poses Risk of Infection

Summary

The FDA received a report from a hospital that 16 patients had developed colonization or infection with the bacteria *Pseudomonas aeruginosa*. Each of these patients were examined with transesophageal ultrasound probes* using Other-Sonic Generic Ultrasound Transmission Gel. Upon investigation, the ultrasound gel was found to be contaminated with the bacteria *Pseudomonas aeruginosa* and *Klebsiella oxytoca.*

The product, Other-Sonic Generic Ultrasound Transmission Gel, is not labeled as sterile. It is **NOT** sterile.

At this time, the FDA is concerned about contamination of Other-Sonic Generic Ultrasound Transmission Gel lot numbers 060111 through 120111. These lots contain both 250 milliliter (mL) bottles and 5 liter (L) dispensing containers of gel. The lot number is printed on each bottle of gel. The lots were manufactured June through December 2011 by Pharmaceutical Innovations. You **cannot** identify contaminated products by looking at the gel.

Not every patient exposed to *Pseudomonas aeruginosa* and *Klebsiella oxytoca* bacteria will develop colonization (the presence of bacteria at a site without any signs of infection) or infection, but the risk remains present.

Background

Pseudomonas aeruginosa is found in water and soil. Patients exposed to the bacteria on the surface of their skin could develop inflammatory dermatitis, even on intact skin. *Pseudomonas aeruginosa* is not usually found in places such as the upper airway, the lower GI tract or the female genital tract—if it is introduced to those places, it could colonize or cause an infection.

Invasive biopsy procedures can carry bacteria into tissues, and could cause an abscess or sepsis. The bacteria can also move from one site to another. For example, if *Pseudomonas aeruginosa* is introduced into the upper airway through a TEE procedure and begins to grow, it may cause no symptoms. However, if it is accidentally inhaled into the lower airway, it could cause pneumonia.

Klebsiella bacteria is often found in the digestive tract where they do not often cause infection; however, when the lungs or other tissues are exposed to *Klebsiella* bacteria, either minor problems or more serious infections such as pneumonia, wound infection, or bloodstream infections could occur.

Recommendations for Health Care Professionals and Facilities Regarding Other-Sonic Generic Ultrasound Transmission Gel

- **Do NOT use** Other-Sonic Generic Ultrasound Transmission Gel from lot numbers 060111 through 120111.
- Identify patients who have been exposed to these lots of Other-Sonic Generic Ultrasound Transmission Gel. Review the procedures they underwent and the outcomes of those procedures to determine if further evaluation is needed.
- To report adverse events associated with use of the contaminated gel, contact Pharmaceutical Innovations Inc. at 973-242-2900 (897 Frelinghuysen Avenue, Newark, NJ 07114). Refer to your facility's infection control or other risk control procedures for appropriate disposal of Other-Sonic Generic Ultrasound Transmission Gel.

**These probes (flexible tubes) are used during diagnostic tests, such as a transesophageal echocardiography (TEE) procedure. During a TEE, doctors guide the probe with a transducer at its tip down a patient's throat into the esophagus. Once in the esophagus, the transducer sends ultrasound waves to make detailed images of the heart chambers, valves, and surrounding areas.*

Recommendations for Health Care Professionals Regarding All Ultrasound Transmission Gels

- **Be aware that only unopened containers of ultrasound gel labeled as sterile should be used for an indication that requires sterile gel.** Ultrasound gel products that are labeled as non-sterile or that are not labeled at all with respect to sterility are NOT sterile.
- Review your policies and clinical practice standards to ensure you are always using sterile ultrasound gel for those procedures that require it.
    - Check the instructions for use, as well as hospital/facility policies, to determine if sterile ultrasound gel is needed for a particular procedure or if non-sterile ultrasound gel is recommended for procedures using ultrasound transducers.
    - Use sterile ultrasound gel as recommended in clinical practice standards for all sterile body site procedures and any invasive procedures using ultrasound-guided biopsy.
    - Use sterile ultrasound gel for procedures with mucosal contact where biopsy is not planned but any possible added bioburden would be undesirable or mucosal trauma is likely (e.g., transesophageal echocardiography (TEE) procedures, transvaginal ultrasound procedures without biopsy, transrectal ultrasound procedures without biopsy).

- **Be aware that once a container of sterile or non-sterile ultrasound gel is opened, it is no longer sterile and contamination during ongoing use is possible.**
    - Use open containers of ultrasound gel only for low risk procedures on intact skin and for low risk patients.
    - Never refill or "top off" containers of ultrasound gel during use. The original container should be used and then discarded.
    - Review clinical policies for the handling of ultrasound gel products, and take these recommendations into account when choosing the ultrasound gel product, size and type.

FDA Activities

The FDA collected and tested unopened bottles of Other-Sonic Generic Ultrasound Transmission Gel at the reporting hospital and at Pharmaceutical Innovations Inc.'s facility. The FDA's testing revealed that the finished product contained significant amounts of *Pseudomonas aeruginosa* and *Klebsiella oxytoca*. This result suggests that contamination occurred during the manufacturing process.

On April 18, 2012, the Food and Drug Administration issued a safety communication and news release notifying the public about the seizure of remaining inventory of Other-Sonic Generic Ultrasound Transmission Gel located at Pharmaceutical Innovations, Inc. Newark, N.J.

Reporting Problems

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect a problem with Other-Sonic Generic Ultrasound Transmission Gel, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program. Healthcare personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities. Device manufacturers must comply with the Medical Device Reporting (MDR) regulations.

To help us learn as much as possible about the adverse events associated with Other-Sonic Generic Ultrasound Transmission Gel, please include the following information in your reports, if available:

- Lot number
- Bottle size
- Date of adverse event
- Type of ultrasound procedure
- Details of the adverse event and medical intervention (if required)

For More Information

If you have questions about this communication, please contact the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV, 800-638-2041 or 301-796-7100.