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CDC HEALTH ADVISORY

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Healthcare Professionals Warned Not To Use Certain Intravenous Metronidazole, Ondansetron, and Ciprofloxacin Due To Potential Contamination

Summary

The U.S. Food and Drug Administration (FDA) is alerting healthcare professionals not to use certain intravenous (IV) bags of metronidazole, ondansetron, and ciprofloxacin because of potential contamination. FDA has received reports of floating matter in IV bags manufactured by Claris Lifesciences Limited, in Ahmedabad, India. Microbiological analysis identified the matter in one of the bags as a *Cladosporium* mold. Molds of this type can cause infections in susceptible patients, such as immunocompromised individuals. At this time, FDA is not aware of any reports of injuries due to administration of these products. Affected products include any metronidazole, ondansetron, and ciprofloxacin manufactured by Claris Lifesciences Limited and sold under the following labels: Claris, Sagent Pharmaceuticals, Pfizer, West-Ward Pharmaceuticals.

Background

Metronidazole and ciprofloxacin are antibiotics used to treat a variety of infections. Ondansetron is an antiemetic used to treat nausea and vomiting associated with chemotherapy or surgery. A complaint of white matter in a bag of metronidazole was received, and subsequent microbiological analysis identified the matter as a *Cladosporium* mold. Molds of this type can cause infections in susceptible patients, such as immunocompromised individuals. Another complaint of white matter in a bag of ondansetron was received and that bag is currently under analysis. Foreign matter should not be present in a sterile injectable product.

Recommendations

While FDA is learning more about the situation, healthcare professionals should NOT use and should immediately remove from their pharmacy inventories any metronidazole, ondansetron, and ciprofloxacin intravenous bags sold under the following labels:

- Claris
- Sagent Pharmaceuticals

- Pfizer
- West-Ward Pharmaceuticals

Only metronidazole, ciprofloxacin, and ondansetron in IV bags sold under the Claris, Sagent, Pfizer, and West-Ward Pharmaceuticals labels are affected. Claris is initiating a recall of all lots of these products. These products were all manufactured on the same production line.

For patients who have received any one of these products, clinicians are advised to stop usage immediately and observe patients for any signs of new infection (e.g., fevers or chills). Clinicians are requested to report any suspected adverse events following use of these products to FDA's MedWatch program at 1-800-332-1088 or http://www.fda.gov/medwatch. On May 17, 2010, FDA posted an announcement that Sagent Pharmaceuticals, Inc. had announced a voluntary recall of specific lots of metronidozole injection (see http://www.fda.gov/Safety/Recalls/ucm212302.htm). Today's HAN Advisory announces a recall initiated by Claris covering all lots of the three affected products (metronidazole, ciprofloxacin, and ondansetron) manufactured by Claris and sold under the labels Claris, Sagent, West-Ward, and Pfizer.

For More Information:

- FDA intends to provide new information when it becomes available. Clinicians with additional questions may contact the FDA at 1-888-463-6332 or druginfo@fda.hhs.gov
- Additional information is available at: http://www.fda.gov