



Public Health

Prevent. Promote. Protect.

Region 4 Public Health

Clark, Cowlitz, Skamania, Wahkiakum counties

**Please deliver a copy of the accompanying message to each
of the medical providers in your organization.**

Thank you

Questions regarding this message may be directed to the office of:

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Health Officer

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Categories of Health Alert messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for specific incident for situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; no immediate action necessary.



Health Alert June 1, 2010

This alert is adopted from an alert issued today by the Centers for Disease Control and Prevention (CDC)

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

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. The 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.

Recommendations

While the 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 the FDA's MedWatch program at 1-800-332-1088 or 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 metronidazole injection \(see <http://www.fda.gov/Safety/Recalls/ucm212302.htm>\)](#). Today's 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 FDA at 1-888-463-6332 or druginfo@fda.hhs.gov

Additional information is available at: www.fda.gov