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## *Propofol (Diprivan®) and Teva Recall of Contaminated Lots*

- Propofol (Diprivan®) is an intravenous (IV) sedative agent used in the induction and maintenance of general anesthesia, monitored anesthesia care sedation, procedural sedation, and sedation for mechanical ventilation.[1]
- On July 13, 2009, the Centers for Disease Control (CDC) reported cases of febrile reactions in patients undergoing endoscopy who received propofol from 100 ml vials manufactured by Teva Pharmaceuticals. All patients have fully recovered.[2]
- The Food and Drug Administration (FDA) identified two lots of this product that tested positive for elevated levels of endotoxin used in facilities reporting febrile reactions.[2]
    - The affected lots are**: 31305429B** and **31305430B.** [2]
    - **Teva Pharmaceuticals is initiating a voluntary recall for these lots.** [2]
    - The CDC is advising clinicians to immediately stop using the affected lots of propofol from Teva Pharmaceuticals. [2]
- FDA had previously issued an alert to healthcare professionals in 2007 addressing chills, fever, and body aches in patients shortly after receiving propofol for sedation or general anesthesia.[3]
    - Patients began to experience symptoms 6-18 hours following administration and lasted up to 3 days.[3]
    - Several patients were hospitalized, 1 had seizures, but all fully recovered. [3]
    - Contrary to recent findings, when FDA examined the propofol vials and lots used in these patients in 2007, they did not find contamination with bacteria or endotoxins. [3]
    - Based on those findings, in June 2007, FDA recommended *to minimize the potential for bacterial contamination when using propofol for general anesthesia or procedural sedation* via the following methods[3]*:*
        - *both the vial and prefilled syringe formulations must be used on only one patient;*
        - *administration must commence immediately after the vial or syringe has been opened; and*
        - *administration from a single vial or syringe must be completed within six hours of opening.*
    - FDA also recommended for healthcare staff to carefully follow the handling procedures including the guidelines for aseptic technique that are included in the current prescribing information for propofol. [3]
- FDA, CDC, and Teva Pharmaceuticals continue to investigate this safety issue.

**REFERENCES**

1. Diprivan package insert. Wilmington, DE: AstraZeneca; 2005 Aug.
2. CDC Health Advisory. Clinicians Advised to Halt Use of Propofol from Tainted Lots. Atlanta, GA: Center for Disease Control and Prevention Health Alert Network, July 13, 2009; CDC publication no. HAN-00296-09-07-13-ADV-N.
3. FDA Information for Healthcare Professionals. http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm125817.htm (Accessed July 14, 2009).