



CANADIAN ASSOCIATION OF GASTROENTEROLOGY
L'ASSOCIATION CANADIENNE DE GASTROENTÉROLOGIE
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July 15, 2009

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Dear Colleagues,

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Over the last week the Centre for Disease Control (CDC) in the United States has been investigating reports of non-respiratory febrile reactions beginning 6-18 hours after gastrointestinal endoscopy procedures. The cases have occurred since 1st April 2009 and initial reports suggest that there have been several clusters of cases reported via the FDA's Adverse Event Reporting System.

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The CDC's investigations have revealed that all affected patients received the anesthetic propofol from 100 mL vials manufactured by Teva Pharmaceutical Industries. FDA testing revealed that two lots of this product used in facilities reporting reactions were positive for elevated levels of endotoxin. The lots are 31305429B and 31305430B. Teva Pharmaceuticals is initiating a voluntary recall for these lots, and clinicians have been advised to immediately stop using these lots of Teva Pharmaceuticals propofol. CDC, FDA, and Teva Pharmaceutical Industries are continuing to investigate this issue.

V-P Finance/V-P Finances

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In Canada, NovoPharm markets propofol produced by Teva Pharmaceuticals. NovoPharm has confirmed to the CAG that **the above two lots of propofol have NOT been distributed in Canada**. However, given the potential for bacterial contamination of propofol preparations it is reasonable for Canadian endoscopists to remain vigilant. Should you note any occurrences or clusters of occurrences of febrile reactions after endoscopy in your unit you are asked to report this to the CAG (Sandra Daniels - sandra@cag-acg.org).

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If you have any questions, please do not hesitate to contact CAG.

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Yours sincerely,

David Armstrong
Chair, CAG Endoscopy Committee

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Canadian Journal of Gastroenterology, Editor

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