

Notice to Hospitals -
Health Canada Endorsed Important Safety Information on
AmBisome



06/21/2013

Dear Healthcare Professional:

Please distribute to relevant Departments [Surgery, Emergency Medicine, Pharmacy, Paediatrics, Anaesthesia, Geriatrics, Internal Medicine, Nursing, Dentistry, Intensive Care and/or other Departments as required], and other involved professional staff and **post this notice** in your institution.

Subject: Association of AmBisome (liposomal amphotericin B for injection) with risk of bacterial contamination of the medicinal product

Astellas Canada in consultation with Health Canada is advising you that Astellas Canada has initiated a voluntary recall for two lots of AmBisome (liposome amphotericin B for injection); the lot numbers are 042269AA with expiry date 07/2015 and 0422C1AA with expiry date 11/2015. These lots may have been exposed to bacterial contaminant during the manufacturing process.

AmBisome is indicated for the treatment of fungal infections in febrile patients, neutropenic patients and for treatment of cryptococcal meningitis in HIV infected patients. AmBisome is also indicated for the treatment of systemic or disseminated infections due to *Candida*, *Aspergillus* or *Cryptococcus* in patients who are refractory to or intolerant to conventional amphotericin B therapy or renally impaired patients.

Gilead, Inc., the manufacturing partner, notified Astellas Pharma US, Inc. that during a routine simulation of the manufacturing processes and equipment used for the manufacturing of AmBisome, a bacterial contaminant was detected. A subsequent review of batch manufacturing records indicated that two affected lots of AmBisome were distributed in Canada from October 2012 through June 2013.

- Some lots of AmBisome may have been exposed to bacterial contaminant during the manufacturing process.
- Health care professionals should discontinue treatment of patients with product from the affected lots and should switch them over to product from unaffected lots.
- All stock from the affected lots should be quarantined and Customer service should be contacted at the phone number below for additional assistance to return the product.

The manufacturer's investigation has identified the root cause and corrective and preventive actions have been initiated. At this time, we have no evidence that actual bacterial contamination occurred in these lots. This action is initiated as a precautionary measure. Additionally, Astellas has not received any complaints or adverse reaction reports that it believes may be related to this issue. Astellas closely monitors safety reports for any safety findings of concern for its products on an ongoing basis and reports these findings to Health Canada as appropriate.

Only affected lots of AmBisome should be returned. Our Customer Service department (1-800-668-8641) is ready to assist you or answer any questions you may have regarding this action.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-market adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any cases of serious risk of bacterial contamination or other serious or unexpected adverse reactions in patients receiving AmBisome should be reported to Astellas Pharma Canada, Inc. sponsor or Health Canada.

Astellas Pharma Canada Inc.
675 Cochrane Drive, Suite 500, West Tower
Markham, Ontario, Canada, L3R 0B8

To correct your mailing address or fax number, contact Astellas Pharma Canada Inc.

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345, or
- Visiting MedEffect Canada's Web page on [Adverse Reaction Reporting](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax.

For other health product inquiries related to this communication, contact Health Canada at:

Health Products and Food Branch Inspectorate

E-mail: DCVIU_UVECM@hc-sc.gc.ca

Telephone: 1-800-267-9675

Fax: 613-946-5636

Sincerely,



Dr. Fran Paradiso-Hardy, PharmD, MSc
Director of Medical Affairs
Astellas Pharma Canada, Inc.

References:

1. AmBisome Product Monograph, July 29, 2011