

NOTICE TO HOSPITALS
Health Canada Endorsed Important Safety Information on
CANCIDAS® (caspofungin acetate for injection) 50 mg/vial



June 11, 2010

To: Hospital Chief of Medical Staff

Please **distribute** to relevant Departments including, Pharmacy, Paediatrics, Infectious Disease, Microbiology, Pneumology, Hematology/Oncology, Nursing, Emergency Medicine, Intensive Care, Internal Medicine, and any other professional staff involved in the dispensing and/or administration of CANCIDAS® and **post this Notice** in your institution.

Subject: Voluntary Product Recall of CANCIDAS® (caspofungin acetate for injection) 50 mg/vial: Lot numbers 0204Y, 1513X and 1734X - Expiry date 30-JUN-2010

Merck Frosst Canada Ltd. has initiated a voluntary recall of CANCIDAS® (caspofungin acetate for injection) 50 mg/vial – Lot numbers 0204Y, 1513X and 1734X. This recall is being conducted as a precautionary measure due to a potential for a limited number of cracked vials to be present in these lots. If a crack should occur in the vial, its integrity and sterility may be compromised. The use of product from a cracked vial may present a risk of infection to patients, if the vial has become contaminated, or result in reduced product efficacy.

Only the listed lots of CANCIDAS® 50 mg/vial mentioned above are subject to this recall in Canada. No other presentation or lot of CANCIDAS® is being recalled in Canada.

- All customers that have purchased CANCIDAS® 50 mg/vial units from lots 0204Y, 1513X and 1734X directly from Merck Frosst Canada Ltd. have received a communication with instructions regarding the segregation and return of the affected lots.
- Institutions that have stock subject to this recall and not directly purchased from Merck Frosst Canada Ltd. should return the product to the point of purchase.

There have been no complaints for a cracked vial received against those lots that have been distributed, nor any adverse experience reports based on a review of reports associated with a lot number.

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CANCIDAS[®] is approved for use in adults and children 12 months and older for empirical therapy for presumed fungal infections in febrile, neutropenic patients; treatment of invasive candidiasis including candidemia, intra-abdominal abscesses, peritonitis and pleural space infections; treatment of esophageal candidiasis, and treatment of invasive aspergillosis in patients who are refractory to or intolerant of other therapies.

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 or unexpected adverse reactions in patients receiving CANCIDAS[®] should be reported to Merck Frosst Canada Ltd. or Health Canada at the following addresses:

Merck Frosst Canada Ltd.
16711 Trans-Canada Hwy.
Kirkland, Quebec H9H 3L1
Telephone: 1-800-567-2594
Fax: 1-877-428-8675

Any suspected adverse reaction can also be reported to:

Canada Vigilance Program
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701E
Ottawa, Ontario, K1A 0K9
Telephone: 613-957-0337 or Fax: 613-957-0335
CanadaVigilance@hc-sc.gc.ca

To report an Adverse Reaction, consumers and health professionals may call toll free:
Telephone: 1-866-234-2345
Fax: 1-866-678-6789

Postage paid labels, the Canada Vigilance Reporting Forms and the Adverse Reaction Reporting Guidelines can be found on the MedEffect[™] Canada Web site in the [Adverse Reaction Reporting](#) section. The Reporting Form is also in the *Canadian Compendium of Pharmaceuticals and Specialties*.

<http://hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>

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

Health Product and Food Branch Inspectorate (HPFBI)
E-mail: DCVIU_UVCEM@hc-sc.gc.ca
Telephone: 1-800-267-9675
Fax: 1-613-946-5636

To change your mailing address or fax number, contact Merck Frosst Canada Ltd.

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Your assistance is appreciated and necessary to prevent inadvertent administration of product from the affected lots. If you have any questions regarding this recall, including medical inquiries, please contact the Customer Information Center at 1-800-567-2594 (8:30 am to 4:30 pm Eastern Standard Time), or Health Canada at the number listed above.

original signed by

A handwritten signature in blue ink that reads "Michel Cimon". The signature is written in a cursive style with a long horizontal stroke at the end.

Michel Cimon, MD, MPH
Medical Executive Director, Medical Affairs