

NOTICE TO HOSPITALS
Health Canada Endorsed Important Safety Information on
BiCNU



29 December 2009

Dear Healthcare Professional:

Please distribute to all Canadian hospitals to the attention of Chiefs of Medical Staff and hospital pharmacies for distribution to relevant departments (eg. Surgery, Oncology, Emergency Medicine, Pharmacy, Pediatrics, Anaesthesia, Geriatrics, Internal Medicine, Nursing, Intensive Care and other Departments as required) and other involved professional staff and post this Notice in your institution.

Subject: Type I risk of infection as a result of a sterility assurance concern regarding BiCNU (carmustine injection)

Bristol-Myers Squibb Canada has initiated a voluntary recall of the BiCNU (carmustine for injection) Combo kit Lot number **8K4218A** (vial Lot number 1486494C) - expiry date Dec 2011. This recall is being conducted as a precautionary measure due to a sterility assurance concern. A vial of BiCNU has been found to be contaminated with the microorganism *Bacillus Circulans*. This was recently identified during a product investigation due to an out-of-specification sterility test result reported during routine in-country release testing in one of the distribution markets.

BiCNU (carmustine for injection) 100 mg vial is indicated as adjuvant therapy to surgery and radiotherapy or in combination therapy with other chemotherapeutic agents in the following: primary brain tumors, malignant lymphomas, multiple myeloma, malignant melanoma (disseminated) and gastrointestinal carcinoma (Product Monograph dated 24 August 2007).

- Use of a contaminated vial of BiCNU could cause a life-threatening infection given the patient population to whom BiCNU is administered.
- Patients undergoing cancer chemotherapy are susceptible to infection because they develop neutropenia. These infections may become disseminated if not treated promptly.
- Signs and symptoms of infection in neutropenic patients are often absent.

Use of a vial of BiCNU contaminated with a microorganism, *Bacillus Circulans*, could cause an infection. The severity of such an infection would depend on the risk factors for the involved patient and the condition being treated. Physicians should remain vigilant to the possibility of infection in patients having received BiCNU.

No reports of adverse events correlating with a loss of sterility of the subject lot of BiCNU have been received.

Given the recall, there are potential shortage concerns regarding BiCNU and Health Canada is working with the sponsor to ensure continued availability of this product.

Bristol-Myers Squibb Canada is requesting your assistance in returning all product from lot 8K4218A. Please review your inventory and segregate any product with the affected lot number and return the affected product

according to the directions below. Though the 3 mL ampoules of sterile diluent lot number 8724CA provided with BiCNU are not impacted by this recall event, they must also be returned.

Should any recalled product be found, please remove it from inventory and return both the vial of carmustine and the 3 mL ampoule of sterile diluent and the completed *Product Recall Return Form* via Purolator, courier collect account no. 1-6088353 to the Bristol-Myers Squibb distribution center LSU Inc. for credit. You can reach Purolator at 1-888-744-7123. For your convenience, Bristol-Myers Squibb Canada has included a shipping address to be cut out of the form for your shipment.

Please fax the completed product recall return form to 1-800-463-6334 even if you do not have any recalled stock on hand. In this case, check the box to this effect on the form. Your response is vital to Bristol-Myers Squibb's ability to monitor the effectiveness of this voluntary recall.

Managing marketed health product-related adverse reactions depends on healthcare 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 infection or other serious or unexpected adverse reactions in patients receiving BiCNU should be reported to Bristol-Myers Squibb or Health Canada at the following addresses:

Bristol-Myers Squibb Canada
2344 Alfred-Nobel, suite 300
Montréal, Québec
H4S 0A4
Tel : 866-463-6267

Any suspected adverse reaction can also be reported to:

Canada Vigilance Program
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
Ottawa, Ontario, K1A 0K9
Tel: 613-957-0337 or Fax: 613-957-0335
To report an Adverse Reaction, consumers and health professionals may call toll free:
Tel: 866-234-2345
Fax: 866-678-6789
CanadaVigilance@hc-sc.gc.ca

The [AR Reporting Form](#) and the [AR Guidelines](#) can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/ar-ei_form_e.html
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei_guide-ldir_e.html

For other 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
Tel: 1-800-267-9675
Fax: 1-613-946-5636

Please be assured that we are working expeditiously to address this issue in future production and we are

aware that this may create supply challenges for your facility. We sincerely apologize for any inconvenience this may cause and appreciate your prompt attention to this matter.

If you have any questions regarding this recall, please contact Customer Services at 1-800-267-0005 (8:30 a.m. to 5:00 p.m. Eastern Standard Time). For medical queries, please call Medical Services at 1-866-463-6267.

A handwritten signature in black ink that reads "Vicky Esposito". The signature is written in a cursive, flowing style.

Vicky Esposito
Vice-President, Regulatory Affairs & Quality Assurance

**PRODUCT RECALL
RETURN FORM**



Bristol-Myers Squibb Canada

BICNU – DIN 00297763

PLEASE COMPLETE THIS FORM AND RETURN IT WITH INVENTORY				
LIST NO.	FORMAT	LOT NO.	EXPIRY DATE	QTY RETURNED
301261	100 mg vial	8K4218A	December 2011	

We do not have any stock of the above on hand

PLEASE COMPLETE THIS FORM AND FAX IT TO 1-800-463-6334

CUSTOMER NAME:		STREET ADDRESS:		
CITY:	PROVINCE:	POSTAL CODE:		

WHOLESALER

We have requested our accounts to return their stock of this merchandise

CREDIT NOTE: Please indicate your active DIRECT Account number with BMS or the Wholesaler you want to use to issue your Credit Note (account number required)

BMS Active Direct Account no.

OR

Wholesaler name

Your account number at wholesaler

PLEASE CUT PORTION BELOW & TAPE TO SHIPPING CONTAINER

DRUG RECALL: BICNU

PRODUCT RETURN

**LSU INC
ATTENTION: BRISTOL-MYERS SQUIBB CANADA
DIRECTOR, QUALITY ASSURANCE
1375 Chemin Newton
BOUCHERVILLE (QUÉBEC) J4B 5H2**