

NOTICE TO HOSPITALS

Health Canada Important Safety Information on Certain Drug Products Imported into Canada from Ben Venue Laboratories Inc.

August 17, 2011

Dear Chief of Medical Staff,

Please distribute to relevant Departments [Surgery, Oncology, Emergency Medicine, Pharmacy, Cardiology, Neurology, Radiology, Paediatrics, Anaesthesia, Geriatrics, Internal Medicine, Infectious Diseases, Nursing, Dentistry, Intensive Care, Long Term Care, and other Departments], other groups associated with your institution, and other involved professional staff and **post this Notice** in your institution.

Subject: Potential supply shortage of certain injectable and inhalational sterile drugs imported from the contract manufacturer Ben Venue Laboratories Inc. located in Bedford, Ohio, US

Health Canada is advising Healthcare Professionals of a potential supply shortage of certain drugs currently available in Canada. The drugs affected are imported into Canada by a small number of companies from the contract manufacturer Ben Venue Laboratories Inc. (BVL) located in Bedford, Ohio, United States. BVL is a large contract manufacturer of injectable and inhalational sterile drug products. A recent assessment by Health Canada has identified deficiencies in the area of Good Manufacturing Practices (GMP) at the BVL manufacturing site. In light of these deficiencies, Health Canada is allowing only the importation of drugs deemed medically necessary (see definition below) from the BVL site. These deficiencies may have an impact on product quality and have led to manufacturing capacity limitations which could affect the supply of medically necessary drugs imported into Canada.

- Healthcare Professionals should refer to the attached list of affected drugs (see Annex A). The importation and sale of drugs deemed medically necessary will continue to be allowed at this time. **“Medically necessary drug” refers to a market authorized drug which is used to prevent or treat a serious or life-threatening disease or medical condition, for which there is no other available source with sufficient supply of that drug or alternative drug available.** Healthcare professionals need to be aware that the supply of these drugs may be affected.
- The list of affected drugs (Annex A) will be updated periodically as new information is received by Health Canada. Please replace with the updated notice as needed in your institution.
http://hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2011/index-eng.php#aug
- Healthcare professionals should be aware that the company name “Ben Venue Laboratories Inc” may not appear on the product label as this company is a contract manufacturer for other pharmaceutical companies named on the label as the manufacturer/market authorization holder.

The identified GMP deficiencies have raised concern with product quality and although a specific risk to health from the use of the affected drugs has not been identified at this time, Health Canada has put in place controls which include the increased oversight of the site/products through collaboration with the Canadian importers and Health Canada’s international regulatory partners. Should a specific risk to health be identified, Health Canada will take the appropriate action to mitigate the risk. Furthermore, BVL has committed to carrying out improvements to its

facility in order to rectify the identified quality deficiencies. Health Canada will continue to monitor closely the activities of BVL and the products being imported from this site, in an effort to minimize risk to the health of Canadians while at the same time allowing to the extent possible uninterrupted access to these medically necessary drugs in Canada.

Healthcare Professionals should contact the Canadian importers for information on the availability of specific drugs and for information on alternate suppliers if available. Refer to Annex A for the importers' contact information.

Managing marketed health product-related adverse reactions is dependent on Healthcare Professionals and Consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of serious or unexpected adverse reactions in patients receiving any of the drugs listed the attached table (see Annex A) should be reported to the respective market authorization holder or to Health Canada's Canada Vigilance Program.

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.health.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario K1A 0K9

The Reporting Forms, postage paid labels, and Guidelines can be found on the MedEffect™ Canada Web site in the [Adverse Reaction Reporting](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) section (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>). The Reporting Form is also in the *Canadian Compendium of Pharmaceuticals and Specialties*.

For other health product inquiries related to this communication, please contact Health Canada at:
Health Products and Food Branch Inspectorate
E-mail: GMP_Questions_BPF@hc-sc.gc.ca
Telephone: 613-957-1492
Fax: 613-957-6709

Sincerely,

Original signed by

Diana Dowthwaite
Director General
Health Products and Food Branch Inspectorate

Annex A – List of medically necessary drugs imported from the contract manufacturer Ben Venue Laboratories Inc. located in Bedford, Ohio, US
http://hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2011/index-eng.php#aug
(This list is updated periodically as new information is received)

Last update: August 15, 2011

<u>Drug Name (active ingredient) / Nom du médicament (ingrédient actif)</u>	<u>Drug Identification Number (DIN) / Numéro d'identification du médicament (DIN)</u>	<u>Canadian Importer / Importateur canadien</u>
AMEVIVE (ALEFACEPT)	02259052	Astellas Pharma Canada Inc. 675 Cochrane Drive, 500 West Tower Markham, Ontario L3R 0B8 Phone / tél : 1-800-575-1382
ANGIOMAX (BIVALIRUDIN)	02246533	Sepracor Pharmaceuticals Inc. 6790 Century Avenue, Suite 100 Mississauga, Ontario L5N 2V8 Phone / tél : 1-905-814-9145
BICNU (CARMUSTINE)	00297763	Bristol Myers Squibb Canada 2344 Boul. Alfred-Nobel #300 Montréal (Saint-Laurent) (Québec) H4S 0A4 Phone / tél : 1-800-267-1088
CAELYX (DOXORUBICIN HYDROCHLORIDE)	02238389	Janssen Inc. 19 Green Belt Drive Toronto, Ontario M3C 1L9 Phone / tél : 1-800-387-8781
CARDIOLITE (Technetium Tc99m Sestamibi Injection)	N/A (radiopharmaceutical)	Lantheus MI Canada Inc. 1111 Boul. Dr.-Frederik-Philips #100 Montréal (Québec) H4M 2X6 Phone / tél: 1-514-333-1003
COLISTIMETHATE FOR INJECTION U.S.P. (COLISTIN (COLISTIMETHATE SODIUM))	02244849	Sterimax Inc. 2735 Matheson Blvd East, Suite 1 Mississauga, Ontario L4W 4M8 Phone / tél: 1-800-881-3550
DAUNORUBICIN HYDROCHLORIDE FOR INJECTION (DAUNORUBICIN (DAUNORUBICIN HYDROCHLORIDE))	02231420	Teva Canada (Novopharm Limited) 30 Novopharm Court Toronto, Ontario M1B 2K9 Phone / tél : 1-416-291-8888
DEFINITY (PERFLUTREN)	02243173	Lantheus MI Canada Inc. 1111 Boul. Dr.-Frederik-Philips #100 Montréal (Québec) H4M 2X6 Phone / tél : 1-514-333-1003
DOXORUBICIN HYDROCHLORIDE INJECTION (DOXORUBICIN HYDROCHLORIDE)	02230108	Teva Canada (Novopharm Limited) 30 Novopharm Court Toronto, Ontario M1B 2K9 Phone / tél : 1-416-291-8888

MIRALUMA (Technetium Tc99m Sestamibi Injection)	N/A (radiopharmaceutical)	Lantheus MI Canada Inc. 1111 Boul. Dr.-Frederik-Philips #100 Montréal (Québec) H4M 2X6 Phone / tél : 1-514-333-1003
NEUROLITE (Technetium Tc99m Bicisate Injection)	N/A (radiopharmaceutical)	Lantheus MI Canada Inc. 1111 Boul. Dr.-Frederik-Philips #100 Montréal (Québec) H4M 2X6 Phone / tél : 1-514-333-1003
STREPTOMYCIN FOR INJECTION USP (STREPTOMYCIN SULFATE))	02243660	Sterimax Inc. 2735 Matheson Blvd East, Suite 1 Mississauga, Ontario L4W 4M8 Phone / tél : 1-800-881-3550
TOBRAMYCIN FOR INJECTION U.S.P. (TOBRAMYCIN (TOBRAMYCIN SULFATE))	02285150	Sterimax Inc. 2735 Matheson Blvd East, Suite 1 Mississauga, Ontario L4W 4M8 Phone / tél : 1-800-881-3550
TOMUDEX (RALTITREXED (RALTITREXED DISODIUM))	02229566	Hospira Healthcare Corporation 1111 Boul. Dr.-Frederik-Philips #600 Saint-Laurent (Québec) H4M 2X6 Phone / tél : 1-866-488-6088
TORISEL (TEMSIROLIMUS)	02304104	Pfizer Canada Inc. 1025 Boul. Marcel-Laurin Saint-Laurent (Québec) H4R 1J6 Phone / tél : 1-800-361-1336
VELCADE (BORTEZOMIB (BORTEZOMIB MANNITOL BORONIC ESTER))	02262452	Janssen Inc. 19 Green Belt Drive Toronto, Ontario M3C 1L9 Phone / tél : 1-800-387-8781
VIRAZOLE (RIBAVIRIN)	02170140	Valeant Canada LP/Valeant Canada S.E.C. 1956 rue Bourdon Montréal (Québec) H4M 1V1 Phone / tél : 1-514-744-6792