Health Canada Endorsed Important Safety Information on VELCADE®*

janssen
PHARMACEUTICAL COMPANIES OF Johnson&Johnson

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Dear Health Care Professional:

Subject: VELCADE® (bortezomib): Fatal if Given Intrathecally

Janssen Inc., in consultation with Health Canada, would like to alert you to the risk of fatal outcome associated with the inadvertent intrathecal administration of the antineoplastic drug VELCADE® (bortezomib).

Since the first global approval of VELCADE® in May 2003, three cases of inadvertent intrathecal administration with fatal outcome have been reported worldwide; these occurred in France and Italy. Each case occurred when an intrathecal oncology chemotherapy was scheduled at the same time as the VELCADE® intravenous administration.

Health Canada has not received any Canadian reports involving inadvertent intrathecal administration of VELCADE®.

- Fatal outcomes have been reported from inadvertent intrathecal administration of VELCADE®.
- VELCADE® should only be administered via the approved intravenous (IV) route; VELCADE® is fatal if given intrathecally.
- Health care professionals are encouraged to administer chemotherapy intended via the intrathecal route at a different time than other parenteral chemotherapy. Different connectors should be used for medicinal products to be administered via the intrathecal or intravenous route.
- Health care professionals are encouraged to clearly label syringes with the name of the medicinal product and route of administration to be used and ensure procedures are in place to enforce a double check of syringe labelling before administration.
- Train and inform healthcare professionals involved in administration and/or management of oncology chemotherapy on dangers of intrathecal administration of VELCADE® and the above risk minimization measures.

VELCADE® (bortezomib) for Injection is indicated as: combination therapy in patients with previously untreated multiple myeloma unsuitable for stem cell transplantation; treatment of progressive multiple myeloma in patients who have received at least 1 prior therapy and have undergone or are unsuitable for stem cell transplantation; treatment of patients with mantle cell lymphoma who have relapsed or were refractory to at least 1 prior therapy.

The reconstituted solution is administered as a 3-5 second bolus intravenous injection through a peripheral or central intravenous catheter followed by a flush with 0.9% Sodium Chloride Injection, USP. Please refer to the **DOSAGE and ADMINISTRATION** section of the Product Monograph, for complete instructions on the reconstitution and administration of VELCADE®.

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-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of medication errors involving incorrect intrathecal route of administration or other serious or unexpected adverse reactions in patients receiving VELCADE® should be reported to Janssen Inc., or Health Canada at the addresses provided below. Medication incidents/errors can also be reported to the Institute for Safe Medication Practices (ISMP) Canada through the Canadian Medication Incident Reporting and Prevention System (http://www.ismp-canada.org/cmirps.htm).

Janssen Inc.
Medical Information Department
19 Green Belt Drive
Toronto, Ontario M3C 1L9
Telephone: 1-800- 567-3331 or 1-800- 387-8781
Fax: (416) 449-5248
MedinfoCanada@joica.jnj.com

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.healthcanada.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 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:
Marketed Health Products Directorate
E-mail: mhpd_dpsc@hc-sc.gc.ca
Telephone: 613-954-6522 Fax: 613-952-7738

To change your mailing address or fax number, contact the Market Authorization Holder (Industry).

Sincerely,
original signed by

Dr. Cathy Lau,
Vice President, Regulatory Affairs and Quality Management

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