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(來函請敘明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

27 Mar 2026

Dear Healthcare Professionals,

Bortezomib: Assessing the Potential Risk of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)

Your attention is drawn to the following Health Canada's announcement.

Product

Bortezomib-containing products

Potential Safety Issue

Drug reaction with eosinophilia and systemic symptoms (DRESS), a type of allergic drug reaction with rash, fever, increased white blood cell count, and injury to 1 or more organs

Key Messages

- Health Canada's safety review found a possible link between the use of bortezomib and the risk of DRESS.
- Health Canada will work with the manufacturers to update the product safety information in the Canadian product monograph (CPM) for all bortezomib-containing products to include the risk of DRESS. Health Canada will also inform healthcare professionals about this update through a Health Product InfoWatch communication.

Overview

Health Canada reviewed the potential risk of DRESS with the use of bortezomib. The safety review was triggered by a notification of foreign action received from a manufacturer.

Use in Canada

- Bortezomib is a prescription drug authorized for sale in Canada to treat adults with multiple myeloma (cancer that forms in a type of white blood cell called a plasma cell) and mantle cell

lymphoma (an aggressive type of non-Hodgkin lymphoma, a cancer that affects a type of white blood cells called B lymphocytes, which are part of the immune system).

- Bortezomib has been marketed in Canada since 2005, under the brand name Velcade. It is currently available as a lyophilized (freeze-dried) powder or liquid. Generic versions are also available.

Safety Review Findings

- Health Canada reviewed the available information provided by a manufacturer, as well as from searches of the Canada Vigilance database and the scientific literature.
- At the time of the review, Health Canada had not received any Canadian reports of DRESS in patients treated with bortezomib.
- Health Canada reviewed 29 international cases of DRESS in patients treated with bortezomib. Although the use of other medications was a confounder (other factor that may have been responsible for the occurrence of DRESS) in all 29 cases, 27 of those cases were found to be possibly linked to the use of bortezomib. Two of the 29 cases were unlikely to be linked. One death was reported among the 29 cases reviewed, which was possibly linked to the use of bortezomib.
- Health Canada also reviewed 1 article published in the scientific literature. Due to important limitations regarding the design and analysis of the study, the evidence did not strongly support a link between the use of bortezomib and the risk of DRESS.

Conclusions and Actions

- Health Canada's review found a possible link between the use of bortezomib and the risk of DRESS.
- Health Canada will work with the manufacturers to update the CPM for all bortezomib-containing products to include the risk of DRESS.
- Health Canada will also inform healthcare professionals about this update through a Health Product InfoWatch communication.
- Health Canada will continue to monitor safety information involving bortezomib, as it does for all health products on the Canadian market, to identify and assess potential harms. Health Canada will take appropriate and timely action should new health risks be identified.

Please refer to the following website in Health Canada for details:

<https://dhpp.hpfb-dgpsa.ca/review-documents/resource/SSR1770998522580>

In Hong Kong, there are 13 registered pharmaceutical products containing bortezomib. All products are prescription-only medicines. So far, the Department of Health (DH) has received 20 cases of adverse drug reaction report with regard to bortezomib, but these cases were not related to DRESS. In light of the above Health Canada's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Clinical Trials and Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": <http://www.drugoffice.gov.hk/adr.html>. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,



(Clive CHAN)

for Assistant Director (Drug)