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

28 Nov 2025

Dear Healthcare Professionals,

Braftovi (encorafenib): Assessing the Potential Risk of Severe Cutaneous Adverse Reactions

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

Product
Braftovi (encorafenib)

Potential Safety Issue
Severe cutaneous adverse reactions (SCAR), a group of serious, potentially life-threatening, adverse reactions to drugs that involve the skin

Key Messages
- Health Canada's review found a possible link between the use of Braftovi and the risk of SCAR.
- Health Canada has worked with the manufacturer to update the product safety information in the Canadian product monograph (CPM) for Braftovi to include the risk of SCAR. Health Canada will also inform healthcare professionals about this update through a Health Product InfoWatch communication.

Overview
Health Canada reviewed the potential risk of SCAR with the use of Braftovi. The safety review was triggered by safety information received from the manufacturer.

Braftovi belongs to a class of prescription drugs called B-Raf serine-threonine kinase (BRAF) inhibitors. Across all BRAF inhibitors marketed in Canada, Braftovi is the only one not labelled for SCAR.

This safety review focused on the following types of SCAR: Stevens-Johnson syndrome (SJS, a severe skin and mucous membrane disorder with peeling), toxic epidermal necrolysis (TEN, a more severe

form of SJS), drug reaction with eosinophilia and systemic symptoms (DRESS, a severe reaction affecting the skin and internal organs), generalized bullous fixed drug eruption (GBFDE, a severe skin disorder with blisters), acute generalized exanthematous pustulosis (AGEP, a severe rash with pustules), and erythema multiforme (EM) major (a severe rash).

Use in Canada

- Braftovi is a prescription drug authorized for sale in Canada for the treatment of:
  - Melanoma (a type of skin cancer), when used in combination with binimetinib. This type of skin cancer must have:
    - a mutation (change) in the BRAF gene, and
    - spread to other parts of the body or cannot be removed by surgery.
  - Metastatic (has spread to other parts of the body) colorectal cancer (a type of large intestine cancer), when used in combination with cetuximab. This type of intestine cancer must have:
    - a mutation in the BRAF gene, and
    - spread to other parts of the body and has already been treated with other cancer drugs.
- Since the completion of this review, Braftovi has also been authorized with conditions for the treatment of metastatic colorectal cancer with a mutation in the BRAF gene, when used in combination with cetuximab and mFOLFOX6 (chemotherapy). The risk of SCAR was not reviewed for this treatment indication.
- Braftovi has been marketed in Canada since 2021. It is currently available as 75 mg capsules.
- Since 2021, approximately 5,200 prescriptions for Braftovi have been dispensed by Canadian retail pharmacies. Overall, there has been a steady increase in prescriptions for Braftovi during this time.

Safety Review Findings

- Health Canada reviewed the available information provided by the manufacturer, as well as from searches of the Canada Vigilance database and the scientific literature.
- At the time of the review, Health Canada had received 1 Canadian report of SCAR in a patient taking Braftovi. However, this case did not meet the criteria for further assessment to determine if there was a link due to incomplete information about when or how long the drug was taken relative to the adverse reaction.
- Health Canada reviewed 7 international cases of SCAR in patients taking Braftovi. Of the 7 cases, SJS and AGEP were reported in 1 case each in patients with colorectal cancer, and 1 case reported TEN, 3 reported DRESS, and 1 reported AGEP in patients with melanoma. All 7 cases were found to be possibly linked to the use of Braftovi and no deaths were reported. Most cases involved the combined use of Braftovi with another medication known to be linked to severe skin reactions.

Conclusions and Actions

- Health Canada's review found a possible link between the use of Braftovi and the risk of SCAR.
- Health Canada has worked with the manufacturer to update the CPM for Braftovi to include the risk of SCAR.

- 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 Braftovi, 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/SSR1760464254070

In Hong Kong, Braftovi Capsules 50mg (HK-67515) and Braftovi Capsules 75mg (HK-67516) are pharmaceutical products containing encorafenib registered by Pierre Fabre Dermo-Cosmetique Hong-Kong Limited. Both products are prescription-only medicines. So far, the Department of Health (DH) has received one case of adverse drug reaction with regard to encorafenib, but the case was not related to severe cutaneous adverse reaction. 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)