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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.)

30 Jan 2026

Dear Healthcare Professionals,

Dimethyl Fumarate: Assessing the Potential Risk of Gastrointestinal Events of Perforation, Ulceration, Hemorrhage and Obstruction

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

Product

Dimethyl fumarate-containing products

Potential Safety Issue

Gastrointestinal events of perforation (hole in the wall of the gastrointestinal tract), ulceration (open sore on the lining of the gastrointestinal tract), hemorrhage (bleeding in the gastrointestinal tract) and obstruction (blockage of the gastrointestinal tract)

Key Messages

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

Overview

Health Canada reviewed the potential risk of gastrointestinal events of perforation, ulceration, hemorrhage and obstruction with the use of dimethyl fumarate. The safety review was triggered by a labelling update in the United States for all dimethyl fumarate-containing products.

Use in Canada

- Dimethyl fumarate is a prescription drug authorized for sale in Canada for the treatment of adult patients with relapsing remitting multiple sclerosis. Dimethyl fumarate helps to reduce the number of relapses (flare-ups) and delay physical problems due to multiple sclerosis.
- Dimethyl fumarate has been marketed in Canada since 2013. It is currently available as 120 mg and 240 mg delayed-release capsules, under the brand name Tecfidera, and as generics.
- There were 279,470 prescriptions for dimethyl fumarate dispensed by Canadian retail pharmacies between 2019 and January 2025.

Safety Review Findings

- Health Canada reviewed the available information provided by the manufacturer of Tecfidera, as well as from searches of the Canada Vigilance database, international databases and the scientific literature.
- At the time of the review, Health Canada had received 51 Canadian reports of gastrointestinal events of perforation, ulceration, hemorrhage or obstruction, in patients taking dimethyl fumarate. However, these cases did not meet the criteria for further assessment to determine if there was a link. This was due to incomplete information, the reported events not meeting the definition of perforation, ulceration, hemorrhage or obstruction, or the presence of confounders (other factors that may have contributed to the occurrence of gastrointestinal events), such as underlying medical conditions that are known to affect the gastrointestinal tract.
- Health Canada reviewed 22 international cases of gastrointestinal events of perforation, ulceration, hemorrhage or obstruction, in patients taking dimethyl fumarate, including 2 cases from the published literature. Of the 22 cases, 18 cases (11 of hemorrhage unrelated to an ulcer, 4 of hemorrhage and ulcer, 2 of ulceration and 1 of ulcer perforation) were found to be possibly linked, 1 case of obstruction was unlikely to be linked, and 3 cases (2 of hemorrhage and 1 of ulcer perforation) were unassessable due to limited or conflicting clinical information. No deaths were reported.
- Health Canada also reviewed 3 articles published in the scientific literature, which included the 2 cases from the published literature mentioned above. They supported a link between the use of dimethyl fumarate and the risk of gastrointestinal events of perforation, ulceration, hemorrhage and obstruction.

Conclusions and Actions

- Health Canada's review found a possible link between the use of dimethyl fumarate and the risk of gastrointestinal events of perforation, ulceration, hemorrhage and obstruction.
- Health Canada will work with the manufacturers to update the CPM for all dimethyl fumarate-containing products to include the risk of gastrointestinal events of perforation, ulceration, hemorrhage and obstruction.
- 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 dimethyl fumarate, 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/SSR1765554392576>

In Hong Kong, there are 3 registered pharmaceutical products containing dimethyl fumarate. All products are prescription-only medicines. So far, the Department of Health has not received any case of adverse drug reaction report with regard to dimethyl fumarate. 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)