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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.)

26 Jun 2026

Dear Healthcare Professionals,

Tramadol: Assessing the Potential Risk of Prolonged, Persistent or Recurrent Hiccups

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

Product

Tramadol-containing products

Potential Safety Issue

Prolonged (lasting under 48 hours), persistent (lasting longer than 48 hours but less than 1 month) or recurrent (occurring often or repeatedly) hiccups

Key Messages

- Health Canada's review found a possible link between the use of tramadol and the risk of prolonged, persistent or recurrent hiccups.
- Health Canada will work with the manufacturers to update the product safety information in the Canadian product monograph (CPM) of all tramadol-containing products to include the risk of prolonged, persistent or recurrent hiccups.

Overview

Health Canada reviewed the potential risk of prolonged, persistent or recurrent hiccups with the use of tramadol. The safety review was triggered by Health Canada's identification of published case reports both in Canada and internationally.

Generally, hiccups are not harmful. However, prolonged, persistent or recurrent hiccups can significantly impact an individual's quality of life. Hiccups lasting for hours, days or months can affect an individual's ability to eat, sleep and communicate.

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Use in Canada

- Tramadol is a prescription opioid drug authorized for sale in Canada to manage pain in adults.
- Tramadol has been marketed in Canada since 2005. It is currently available in capsule or tablet form under different brand names and generic versions. It is available as a single ingredient product or in combination with acetaminophen.
- Tramadol is a widely used opioid medication among Canadians for acute or chronic pain.

Safety Review Findings

- Health Canada reviewed the available information from searches of the Canada Vigilance database and the scientific literature.
- Health Canada reviewed 8 cases (2 Canadian and 6 international) of prolonged, persistent or recurrent hiccups in patients taking tramadol, including 2 unique cases from the published literature. Despite the presence of confounders (other factors that may have contributed to the occurrence of prolonged, persistent or recurrent hiccups), such as underlying medical conditions and the use of other prescription drugs, all 8 cases were found to be possibly linked to the use of tramadol.
- Health Canada also reviewed articles published in the scientific literature, which identified a potential biological mechanism that may explain how the use of tramadol could lead to hiccups.

Conclusions and Actions

- Health Canada's review found a possible link between tramadol and the risk of prolonged, persistent or recurrent hiccups.
- Health Canada will work with the manufacturers to update the Canadian product monograph of all tramadol-containing products to include the risk of prolonged, persistent or recurrent hiccups.
- Health Canada will continue to monitor safety information involving tramadol, 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/SSR1777053339707>

In Hong Kong, there are 44 registered pharmaceutical products containing tramadol. All products are prescription-only medicines. So far, the Department of Health (DH) has received 9 cases of adverse drug reaction related to tramadol, but these cases are not related to prolonged, persistent or recurrent hiccups. 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.

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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)