Institute for Safe Medication Practices Canada
REPORT MEDICATION INCIDENTS
Online: www.ismp-canada.org/err_index.htm
Phone: 1-866-544-7672

A KEY PARTNER IN
CMIRPS Canadian Medication Incident Reporting and Prevention System
SCDPIM Système canadien de déclaration et de prévention des incidents médicamenteux

ISMP Canada Safety Bulletin

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Mitigating Risk for Medication Errors Involving Paxlovid

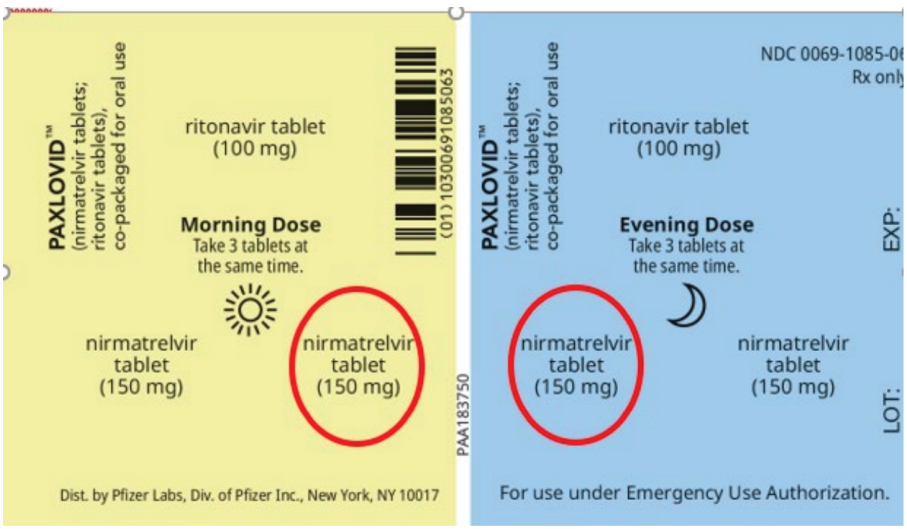
Paxlovid (a co-packaged product containing nirmatrelvir and ritonavir tablets) was recently approved by Health Canada for the treatment of mild to moderate COVID-19 in adults at high risk for progression to severe disease.[1] Several key safety considerations have been identified: (1) the need for product manipulation before it is dispensed for use by patients with moderate renal dysfunction, (2) the display of critical information (e.g., dosing) about the co-packaged product in prescribing and other medication software, and (3) the need for updated drug interaction checking software.

To enable rapid access in Canada, Pfizer is providing the US product labelled for emergency use.[2] Products meeting Canadian label requirements (e.g., bilingual, drug identification number) will be made available as soon as possible. One box of Paxlovid contains 5 blister cards (for a typical 5-day treatment). Each card provides 2 doses to be administered in a single day, with each dose consisting of 2 (pink) nirmatrelvir 150 mg tablets and 1 (white) ritonavir 100 mg tablet.[1]

NEED FOR PRODUCT MANIPULATION FOR PATIENTS WITH MODERATE RENAL IMPAIRMENT

When Paxlovid is dispensed for this patient population, 1 tablet of nirmatrelvir is to be removed from the morning dose and 1 tablet of nirmatrelvir from the evening dose (see red circles in Figure 1). This step is required to dispense the recommended reduced dose of nirmatrelvir 150 mg (i.e., 1 tablet) twice daily.[1-3]

Figure 1.
US Emergency Use Paxlovid blister label currently available in Canada.[3]



ISMP (US) recently described incorrect dispensing of Paxlovid for a patient with moderate renal dysfunction. The dispensed product was missing ritonavir tablets that were needed, whereas nirmatrelvir tablets were present that should have been removed.[4]

To support pharmacists dispensing Paxlovid, a province-wide collaboration in Saskatchewan was undertaken. Additional resources were developed, including a patient information handout describing renal dosing and a template to create stickers for the purpose of communicating package manipulation.[5]

Ensure clear communication with patients if the product has been manipulated to provide a reduced dose.

DISPLAY OF CRITICAL INFORMATION IN MEDICATION SOFTWARE SYSTEMS

A co-packaged medication requiring dose adjustment of one component and not the other present challenges for medication software systems, such as prescriber order entry systems, electronic health or medical records, medical administration records, and pharmacy systems.

Specify the dose for each active ingredient on all prescriptions.[2]

NEED FOR UPDATED DRUG INTERACTION CHECKING SOFTWARE

Ritonavir interacts with many other medications; such interactions can lead to life-threatening situations.[6] Many pharmacies rely upon drug interaction software to identify interactions; however, one hospital reported that their drug interaction software had not yet been updated to detect interactions involving Paxlovid.

Confirm drug interaction software is updated to capture Paxlovid interactions.

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Sharing Matters!
Reported Concern Results in Safer Jardiance Product Labelling

ISMP Canada received a report from HealthPRO Procurement Services Inc. (HealthPRO), a group contracting provider for health care, about a potential patient safety concern with packaging for Jardiance (empagliflozin) tablets. The report described insufficient information on the blister card labels for this drug after a change to the product's package. The blister card did not display the common (generic) name (Figure 1).

The common (generic) name for Jardiance (empagliflozin) was provided on the outer box containing the blister cards. However, given that blister cards are often removed from the outer packaging in both hospital and community care settings, the common name is needed on the blister card as well.

The manufacturers, Boehringer Ingelheim (Canada) Ltd. and Eli Lilly Canada Inc., collaborated with ISMP Canada, HealthPRO, and Health Canada to determine how to optimize the blister card label. The improvements implemented align with recommendations in the Good Label and Package Practices Guide for Prescription Drugs,[1] within the space and software limitations (Figure 2).

Figure 1. Previous blister card label for Jardiance (empagliflozin), without the common (generic) name.

Figure 2. New blister card label for Jardiance (empagliflozin), showing the common (generic) name.

ISMP Canada gratefully acknowledges the commitment from Health Canada, HealthPRO Procurement Services Inc., Boehringer Ingelheim (Canada) Ltd., and Eli Lilly Canada Inc. to model prioritization of product safety

REFERENCE

1. Good label and package practices guide for prescription drugs. Ottawa and Toronto (ON): Health Canada and ISMP Canada; 2019 Jun 21 [cited 2022 Jan 24]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/good-label-package-practices-guide-prescription-drugs-profile/guidance-document.html

Tips for Starting and Stopping Antidepressants Safely

When starting or stopping antidepressants, gradual titration or tapering of the dose, respectively, helps the patient to manage adverse effects from initiation or withdrawal of these medications.

ISMP Canada's consumer reporting program, SafeMedicationUse.ca, received two reports that illustrate the need to better engage with and support patients during the titration or tapering of their antidepressant. One patient, who was beginning therapy with a new antidepressant, inadvertently started with a higher dose than had been prescribed and experienced jitteriness. The other patient abruptly stopped their antidepressant, which resulted in tremors, sweating, and other symptoms of withdrawal.

Tips for Practitioners

- In collaboration with the patient, develop a titration or tapering plan, and create a dosing calendar for the dose adjustment period.
- Review with the patient what they should do if intolerable adverse effects, uncontrolled symptoms of anxiety or depression, or symptoms of medication withdrawal occur. Talk with patients about symptoms that require immediate medical attention, such as suicidal ideation.
- For patients who are stopping antidepressant therapy, encourage them to continue with alternative strategies to manage their anxiety or depression during and after the tapering period.
- Inactivate outdated prescriptions in the pharmacy system to prevent accidental dispensing of incorrect medications or the use of incorrect dosing schedules.

Read the full consumer newsletters here:

Tips for Starting Antidepressants Safely
https://safemedicationuse.ca/newsletter/starting-antidepressants.html

Tips for Stopping Antidepressants Safely
https://safemedicationuse.ca/newsletter/stopping-antidepressants.html

CMIRPS SCDPIM
Canadian Medication Incident Reporting and Prevention System
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The Canadian Medication Incident Reporting and Prevention System (CMIRPS) is a collaborative pan-Canadian program of Health Canada, the Canadian Institute for Health Information (CIHI), the Institute for Safe Medication Practices Canada (ISMP Canada) and Healthcare Excellence Canada (HEC). The goal of CMIRPS is to reduce and prevent harmful medication incidents in Canada.

HIROC

The Healthcare Insurance Reciprocal of Canada (HIROC) provides support for the bulletin and is a member owned expert provider of professional and general liability coverage and risk management support.

ismp CANADA

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit organization committed to the advancement of medication safety in all healthcare settings. ISMP Canada's mandate includes analyzing medication incidents, making recommendations for the prevention of harmful medication incidents, and facilitating quality improvement initiatives.

Report Medication Incidents

(Including near misses)

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ISMP Canada strives to ensure confidentiality and security of information received, and respects the wishes of the reporter as to the level of detail to be included in publications. Medication Safety bulletins contribute to Global Patient Safety Alerts.

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Contact Us

Email: cmirps@ismpcanada.ca
Phone: 1-866-544-7672