Institute for Safe Medication Practices Canada
REPORT MEDICATION INCIDENTS
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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

Volume 16 • Issue 3 • April 21, 2016

Safety Considerations with Newer Inhalation Devices

Over the past few years, several new devices for the administration of inhaled medications have been introduced in Canada. Some of these devices are used to administer newly marketed medications, whereas others contain previously available drugs in a different administration format. A reported concern about one of these devices prompted a review of all new inhalers from a safety perspective. This bulletin provides proactive consideration of the potential safety issues related to these devices for discussion during patient counselling, with the goal of preventing medication incidents.

Reported Concern

A concern about the inadvertent aspiration of a capsule when using the Seebri Breezhaler was reported to ISMP Canada. Administering a dose with the Seebri Breezhaler entails removing the capsule from its foil packaging, placing it in the inhaler chamber, and piercing the capsule by pressing the buttons on either side of the device so the powdered contents of the capsule can be then inhaled through the mouthpiece. First-time users may incorrectly place the capsule into the inhaler mouthpiece instead of the chamber that is designed to hold the capsule. When the capsule is placed in the mouthpiece the patient may swallow or aspirate the capsule in its entirety, resulting in erroneous route of administration or, more critically, creating a choking hazard.

Background

Inhaled medications are the cornerstone of managing asthma and chronic obstructive pulmonary disease (COPD). Typically, patients self-administer these medications using either metered-dose inhalers (MDIs; e.g., salbutamol inhaler) or dry powder inhalers (DPIs).[1] Some DPIs are available preloaded with the medication already inside the device (e.g., Symbicort Turbuhaler), whereas others are supplied empty with a requirement for loading or insertion of the medication before each dose is inhaled (e.g., Spiriva Handihaler). With the introduction of several new formats of DPIs (i.e., Breezhaler, Ellipta, Genuair), along with a soft mist inhaler (SMI; e.g., Respimat), healthcare providers must familiarize themselves with the safe and effective use of all of these inhaler devices so that they can impart key information to patients and their caregivers.

Device Design Enhancements to Promote Safety

It has been reported that up to 94% of patients demonstrate incorrect inhaler technique, which can lead to underdosing and poor disease control.[2] The new devices incorporate different design concepts intended to improve patients' ability to use their devices correctly and safely:

- Presence of a dose counter: allows the patient to see when the supply of medication is low. This feature

was previously available on some DPIs, however not on MDIs.
- Longer duration of aerosol generation and low aerosol velocity: reducing dependence on the patient's coordination and inspiratory flow (Respimat SMI).[3]
- Inability to activate the device when all of the medication has been used: once the last preloaded dose has been taken and the device is empty, the mechanism to prepare another dose is locked, and the patient is prevented from administering "empty" doses.

Strategies to Support Optimal Use of Inhalation Devices

Prescribers

- Ensure that prescriptions for inhaled medications include the medication name and strength, the device name, and the desired dose, particularly if the medication is available in more than one device format.
- When prescribing any inhalation device, consider pertinent patient characteristics, such as inspiratory flow, cognition, and manual dexterity.
- Provide opportunities for patients to access videos on proper inhalation devices while in the office.

Respiratory Educator/Nurse

- Ensure that patient counselling includes a demonstration of how the inhalation device is to be used. The Ontario branch of the Canadian Lung Association has a series of helpful how-to videos: https://www.on.lung.ca/inhalationdevicevideos
- Ask the patient to demonstrate inhaler technique (using a placebo inhaler).
- Provide opportunities for patients to access videos on proper inhalation devices while in the office.

Community Pharmacists

- In addition to providing written instructions, reinforce proper and safe use of the inhalation devices.
- Ask the patient to demonstrate inhaler technique (using a placebo inhaler) both when filling new prescriptions and periodically when refilling existing prescriptions. Such demonstrations can create opportunities to correct improper technique, which may be a contributing factor for patients who continue to experience difficulty with symptoms of asthma or COPD. For devices using capsules, emphasize the need to place the capsule in the piercing chamber.

Healthcare Organizations

- Distribute this bulletin to healthcare providers to support awareness of the new inhalation devices.
- Post the summary chart included as the last page of this bulletin in patient care areas for reference and to help staff and physicians when they are providing instruction to patients. The chart provides an overview of the new inhalation devices, the medications they deliver, and selected safety considerations to be shared with patients. It supplements the information provided by the manufacturers.

Acknowledgements

ISMP Canada gratefully acknowledges the following individuals for their expert review of this bulletin (in alphabetical order):

Ann Bartlett RN MSc BScN CRE - Certified Respiratory Educator; Karen Brooks RN BScN CRE CTE, Certified Respiratory Educator/Certified Tobacco Educator, TEACH Certified Smoking Cessation Counsellor, CDM Patient Educator, Picton Doctors Group/Prince Edward Family Health Team, Picton, ON; Wendy Li, BScPhm, Pharmacist, Sobeys Pharmacy, Toronto, ON; Olivia Ng RPh BScPhm PharmD, Clinical Pharmacist, Thoracics/Respirology, University Health Network.

The pictures in the summary chart are provided courtesy of (in the order in which they appear in the chart): Novartis Pharmaceuticals Canada Inc. (Breezhaler), AstraZeneca Canada Inc. (Genuair), and Boehringer Ingelheim (Canada) Ltd. (Respimat).

Safe Use of Newer Inhalation Devices

Breezhaler (dry powder inhalers)

Usual Dose: Contents of 1 capsule inhaled daily[4-6]

Onbrez Breezhaler
indacaterol 75 mcg
per capsule

Seebri Breezhaler
glycopyrronium 50 mcg
per capsule

Ultibro Breezhaler
indacaterol 110 mcg /
glycopyrronium 50 mcg
per capsule

Safety Considerations and Counselling Tips:

- Capsules are for inhalation only; they must not be swallowed.[4-6] Capsules can mistakenly be placed into the inhaler mouthpiece, resulting in inadvertent swallowing and/or aspiration of the entire capsule.
- If swallowed by accident, skip the dose.
- Capsules are packaged separately from the inhaler and must be inserted into the capsule chamber.[4-6] The mouthpiece must be opened to prompt capsule placement inside the capsule chamber.
- If the chamber is not immediately emptied after use, pieces of the capsule can remain inside and impede the free flow of product for the next dose.
- Discard the capsule directly into the garbage without touching. Wash hands.

Ellipta (dry powder inhalers)

Usual Dose: 1 inhalation daily[7-10]

Anoro Ellipta
umeclidinium
62.5 mcg / vilanterol
25 mcg per actuation

Arnuity Ellipta
fluticasone 100 or
200 mcg per actuation

Breo Ellipta
Fluticasone 100 or
200 mcg / vilanterol
25 mcg per actuation

Incruse Ellipta
umeclidinium 62.5 mcg
per actuation

Safety Considerations and Counselling Tips:

- The foil packaging and desiccant must be discarded immediately after opening.[7-10]
- The coloured cap should be opened before inhaling the dose. There is an audible "click" when the dose is ready to be inhaled.[7-10]
- If the device cover is opened and then closed without inhalation of the loaded dose, that dose will be lost.[7-10] If a dose is lost, another dose can be loaded by opening the device cover again; double-dosing will not occur.
- If the device is tipped past horizontal, medication can fall out of the mouthpiece.
- When there are less than 10 doses remaining, the left half of the counter shows red.

Genuair (dry powder inhalers)

Usual Dose: 1 inhalation twice daily[11,12]

Duaklir Genuair
aclidinium 400 mcg /
formoterol 12 mcg per actuation

Tudorza Genuair
aclidinium 400 mcg per actuation

Safety Considerations and Counselling Tips:

- To prepare for inhalation, the coloured button should be pressed and then released. The coloured control window will change from red to green when the dose is ready to be inhaled. Do not hold down the button while inhaling.[11,12]
- During dose inhalation, there is an audible "click". Upon proper inhalation of the dose the coloured control window will change back to red. Keep breathing in even after the "click" to ensure delivery of the full dose.[11,12]
- When a red striped band appears in the dose window, obtain a new inhaler. The device will "lock" when the last dose has been loaded.[11,12]
- Some patients experience an unpleasant taste - rinse mouth and swallow water.

Respimat (soft mist inhalers)

Combivent Respimat
ipratropium 20 mcg /
salbutamol 100 mcg per actuation
Usual Dose: 1 inhalation 4 times daily[13]

Inspiolto Respimat
tiotropium 2.5 mcg /
olodaterol 2.5 mcg per actuation
Usual Dose: 2 inhalations daily[14]

Spiriva Respimat
tiotropium 2.5 mcg per actuation
Usual Dose: 2 inhalations daily[15]

Safety Considerations and Counselling Tips:

- Insertion of the cartridge before first use may require more force than expected; cartridges should be preloaded by the pharmacy before dispensing. Priming is required before first use.[13-15]
- Before initiating the dose, the lips should be tightly closed over the mouthpiece without covering the air vents (on the sides of the mouthpiece).[13-15]
- When approximately a 7-day supply of medication remains in the device, the red pointer will enter the red zone of the dose counter on the base.[13-15]
- Spiriva is also available in a DPI format (Handihaler) that delivers a different dose.[16]

Safe Use of Newer Inhalation Devices - REFERENCE POSTER

Download the Safe Use of Newer Inhalation Devices Reference Poster.

- printable poster (8.5″ x 14″)
- http://ismp-canada.org/download/InhalationDevices-ReferencePoster.pdf

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Call for Medication Incidents Involving Delayed First Doses

To better understand why first doses of prescribed medication are sometimes delayed, ISMP Canada will be conducting a multi-incident analysis on this type of medication error. To enrich the existing pool of data, you are invited to submit details about incidents involving delay of the first dose to ISMP Canada's Individual Practitioner Reporting Program at https://www.ismp-canada.org/err_ipr.htm. The deadline is May 12, 2016. If you require assistance, please contact info@ismp-canada.org.

Thanks to everyone who has already shared an incident and to those who will be submitting information in the coming weeks. Sharing and learning from incidents that have already occurred is one way that Canadian healthcare practitioners can collaborate to help prevent this type of situation from recurring.

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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 the Canadian Patient Safety Institute (CPSI). 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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