Ventolin Diskus: One lot recalled as inhalers may not deliver the intended dose

Report a Concern

Starting date:	February 16, 2018
Type of communication:	Advisory
Subcategory:	Drugs
Source of recall:	Health Canada
Issue:	Important Safety Information
Audience:	General Public
Identification number:	RA-66016

Issue

Health Canada is advising Canadians that GlaxoSmithKline Inc. is voluntarily recalling one lot of Ventolin Diskus inhalers (lot 786G) because the products may not deliver the intended dose. Individuals who do not receive the intended dose may not be aware that the dose was not delivered.

Ventolin Diskus is a prescription drug used in adults and children 4 years or older to relieve and prevent bronchospasm due to asthma, chronic bronchitis and other chronic lung disorders. Bronchospasm is a sudden worsening of shortness of breath and wheezing. Ventolin Diskus is also used to prevent exercise-induced bronchospasm.

If individuals do not receive the therapeutic dose as expected, their symptoms (cough, wheeze, breathlessness or tight chest) may get worse over time and they can suffer serious health consequences, including a potentially life-threatening asthma attack.

Products affected

Ventolin Diskus (200 mcg salbutamol per blister (60 Dose) (DIN 02243115)) Lot 786G, Expiry 05 2019

What you should do

- If you have an inhaler from the affected lot, return it to the pharmacy for a replacement.
- If you have questions or concerns about the recall, contact GlaxoSmithKline Inc. (GSK) via Stericycle (which is managing the recall on GSK's behalf) by calling, toll-free, 1-855-215-5956.
- Individuals who are experiencing continued symptoms after using their Ventolin Diskus should seek medical attention as soon as possible.
- Report adverse events to health products to Health Canada by calling toll-free at 1-866-234-2345, or by reporting online, by mail or by fax.
- Report complaints about health products to Health Canada by calling toll-free at 1-800-267-9675, or complete an online complaint form.

Who is affected

Consumers who use the affected product

Background

GlaxoSmithKline Inc. has advised Health Canada that it is conducting the recall after identifying a manufacturing issue with the affected lot that may result in a small number of devices not delivering the full number of doses.

Media enquiries

Health Canada
(613) 957-2983

Public enquiries

(613) 957-2991
1-866 225-0709

What Health Canada is doing

Health Canada will monitor the company's recall. Should Health Canada become aware of additional safety information, it will take appropriate action and inform Canadians as necessary.

Images

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For more information

Stay connected with Health Canada and receive the latest advisories and product recalls.

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