GlaxoSmithKline Notification of Recall
VENTOLIN (salbutamol sulphate) DISKUS Lot 786G

2018/02/16

Audience
Health care professionals and patients who prescribe or use VENTOLIN DISKUS.

Key messages

- **GSK has initiated a voluntary recall of one lot (786G) of VENTOLIN DISKUS devices from wholesalers, pharmacies and patients in Canada**
- **A small number of VENTOLIN DISKUS devices may not deliver the full number of doses in the device**
- **If a patient believes their VENTOLIN DISKUS is not effective at relieving their symptoms, they should seek medical treatment.**
- **Metered dose inhalers ("VENTOLIN HFA") are *not* affected by this issue.**

What is the issue?
A small number of VENTOLIN DISKUS devices from one lot (Lot 786G) may not deliver the full number of doses in the device. GSK is recalling Lot 786G of VENTOLIN DISKUS from wholesalers, pharmacies and patients in Canada.

Products affected
- VENTOLIN DISKUS, salbutamol sulfate dry powder for inhalation
- Strength: 200 mcg salbutamol/blister (60 Dose)
- Lot: 786G
- Expiry Date: May 2019
- DIN: 02243115

No other lots of VENTOLIN DISKUS are affected. No other VENTOLIN products or DISKUS products are impacted.

Background information

GSK identified an issue on one assembly line at the manufacturing site that may

result in a mark or tear in the foil strip in a small number of DISKUS devices. A torn strip could mean the device is not delivering the full number of doses.

VENTOLIN DISKUS is commonly used as a rescue medication. A defect in a rescue device could lead to a serious health risk, such as an increased risk of asthma exacerbation.

Information for consumers

Patients should examine their VENTOLIN DISKUS to check the lot number. The recalled lot number is 786G. The lot number (LOT: 786G) is shown on the bottom of your VENTOLIN DISKUS cardboard package and in the centre of your DISKUS (see pictures below).

VENTOLIN DISKUS with lot 786G should be returned to the patient's local pharmacy. Patients should contact their healthcare professional for more information.

Metered dose inhalers, commonly referred to as 'puffers' ("VENTOLIN HFA"), and other DISKUS products are ***not*** affected by this issue, and patients can continue to use as prescribed by their healthcare professional.

Information for health care professionals

If a patient believes their VENTOLIN DISKUS device is not effective at relieving their symptoms, they should seek medical treatment. The issue should also be reported to GSK (see **Report Health or Safety Concerns**, below).

Patients are asked to return their VENTOLIN DISKUS devices (Lot 786G) to their local pharmacy. Wholesalers and Pharmacies have been instructed to remove the affected lots from sale.

Report health or safety concerns

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any device issue or lack of efficacy, or other serious or unexpected side effects in patients receiving VENTOLIN DISKUS should be reported to GlaxoSmithKline Inc. or Health Canada.

GlaxoSmithKline Inc.
7333 Mississauga Road
Mississauga, Ontario
L5N 6L4
Tel: 1-800-387-7374

To correct your mailing address or fax number, contact GlaxoSmithKline Inc.

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax.

For more information, please contact GlaxoSmithKline Inc. Medical Information at 1-800-387-7374.

Sincerely,

Original signed by

Dr. Susie Barnes MRCGP FFPM
Vice President and Country Medical Director
GlaxoSmithKline Inc.

VENTOLIN DISKUS. Note arrows showing LOT: 786G EXP: 05/2019.