

**PUBLIC COMMUNICATION**  
**Health Canada Endorsed Important Safety Information on**  
**PULMICORT® TURBUHALER® (budesonide) powder for oral inhalation, 200 µg per**  
**metered dose**



2012/07/23

**Subject: Potential device failure related to PULMICORT® TURBUHALER® (budesonide) powder for oral inhalation, 200 µg per metered dose (200 doses; DIN 00851752)**

AstraZeneca Canada Inc., in consultation with Health Canada, would like to inform you of important information regarding complaints related to the asthma medication, PULMICORT® TURBUHALER® (budesonide) powder for oral inhalation, 200 µg per metered dose (200 doses). AstraZeneca Canada has received a small number of product complaints for PULMICORT TURBUHALER, 200 µg per metered dose (200 doses) related to the delivery device not working properly. Patients are advised that if they do not hear the ‘click’ sound when the ‘turn grip’ is rotated, the device is not working properly and they will not receive the dose of medication.

- Complaints for PULMICORT TURBUHALER, 200 µg per metered dose (200 doses) have been received about the delivery device not working properly. Patients are advised that if they do not hear the "click" sound, the device is not working properly and they will not receive the dose of medication.
- If a patient believes that their PULMICORT TURBUHALER is not working properly, they should contact their dispensing pharmacist or other health care professional. Additionally, they may contact AstraZeneca Medical Information at 1-800-668-6000 (English) and/or 1-800-461-3787 (French).
- It is important for patients to understand the proper use of PULMICORT TURBUHALER (TURN, CLICK, INHALE), as described in the Consumer Information Leaflet.
- In the Consumer Information Leaflet, patients are instructed to listen for the ‘click’ sound, as an indication that the inhaler has been loaded and is ready to use. A copy of the Consumer Information Leaflet can be found at: <http://www.astrazeneca.ca/en/Our-Medicines/en-Products-AZ>.

PULMICORT TURBUHALER is the brand name for the inhaled form of a drug called budesonide. Budesonide belongs to a group of medicines called corticosteroids which are used to reduce airway inflammation in patients with asthma. TURBUHALER is the brand name for a multiple-dose, dry powder inhaler. AstraZeneca is working to further investigate

the complaints. This issue is specific to PULMICORT TURBUHALER, 200 µg per metered dose (200 doses).

Managing marketed health product-related adverse reactions depends on health care professionals and patients reporting them to the company or Health Canada. Therefore, the number of adverse reactions reported is generally believed to be less than those that actually occur. Any case of adverse reactions in patients receiving PULMICORT TURBUHALER should be reported to AstraZeneca Canada or Health Canada at the following addresses:

**AstraZeneca Canada Inc.**

1004 Middlegate Road  
Mississauga, Ontario  
Canada L4Y 1M4  
Tel: 1-877-404-8277

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701E  
Ottawa, Ontario K1A 0K9

The Reporting Forms, postage paid labels, and Guidelines can be found on the MedEffect™ Canada Web site in the [Adverse Reaction Reporting](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) section (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>). The Reporting Form is also in the *Canadian Compendium of Pharmaceuticals and Specialties*.

For other health product inquiries related to this communication, please contact Health Canada at:

Lead Directorate: Health Products and Food Branch Inspectorate (HPFBI)  
E-mail: [DCVIU\\_UVECM@hc-sc.gc.ca](mailto:DCVIU_UVECM@hc-sc.gc.ca)  
Telephone: 1-800-267-9675  
Fax: 1-613-946-5636

Should you have any medical questions about PULMICORT TURBUHALER, feel free to contact AstraZeneca Medical Information at 1-800-668-6000 (English) and/or 1-800-461-3787 (French).

**original signed by**

Dr. Neil Maresky, M.B., B.Ch.  
Vice President, Scientific Affairs  
AstraZeneca Canada Inc.

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