

衛生署藥物辦公室
藥物註冊及進出口管制部

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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

Health Canada: Potential malfunction of the delivery device of Pulmicort Turbuhaler (budesonide)
200 µg per metered dose

Your attention is drawn to the Health Canada's announcement regarding a potential malfunction of the delivery device of Pulmicort Turbuhaler (budesonide) 200 µg per metered dose.

AstraZeneca Canada Inc (AstraZeneca) has received a small number of product complaints for Pulmicort Turbuhaler 200 µg per metered dose regarding the malfunction of the delivery device that results in a failure to dispense the dose of medication.

According to the information from AstraZeneca, the cause of the complaints is related to an issue within the dosing unit and this affects the Pulmicort Turbuhaler 200 µg per metered dose. The patient will not hear the 'click' sound when the 'turn grip' is rotated, and the intended dose of medication will not be loaded into the unit. Patients who do not realize that the dose has not been loaded may go for a period of time without receiving the prescribed treatment. AstraZeneca is investigating the source of the problem.

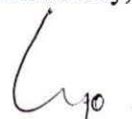
Please refer to Health Canada's website for details:

http://www.hc-sc.gc.ca/dhp-mpps/medeff/advisories-avis/prof/_2012/pulmicort_hpc-cps-eng.php

In Hong Kong, Pulmicort Turbuhaler 200mcg per metered dose (100 doses and 200 doses) (HK-33965) is a prescription drug registered by AstraZeneca Hong Kong Ltd. Pulmicort Turbuhaler contains budesonide which is a glucocorticosteroid for the treatment of bronchial asthma. Healthcare professionals are advised to reinforce the proper use of the Pulmicort Turbuhaler device with patients (TURN, CLICK, INHALE) and remind patients the importance of listening to the 'click' sound.

Please report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": <http://www.drugoffice.gov.hk/adr.html>. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly drug safety digest of drug safety news and information issued by Drug Office.

Yours faithfully,


(Ms. Lilly HO)
for AD(D)