

衛生署藥物辦公室
藥物註冊及進出口管制部

香港九龍南昌街 382 號公共衛生檢測中心三樓



DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND
IMPORT/EXPORT CONTROL DIVISION
3/F., Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon, Hong Kong

電話號碼 Tel. No.: 2319 8458
詢問處 Enquiries (852) 2319 8458
傳真號碼 Facsimile No. (852) 2803 4962
本署檔號 OUR REF.: DH DO PRIE/7-30/15

BY FAX

27 July 2012

(*函覆請註明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dr. Raymond LIANG
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)

Dear Dr. LIANG,

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.

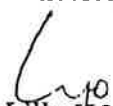
Please refer to Health Canada's website for details:

http://www.hc-sc.gc.ca/dhp-mps/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 encourage your members to 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 sincerely,


(Ms. Lilly HO)
for AD(D)