衞生署藥物辦公室
藥物註冊及進出口管制部

香港九龍南昌街 382 號公共衞生檢測中心三樓

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

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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

BY FAX

4 September 2012

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

Dear Dr. LIANG,

Ambroxol Injection: the risk of severe hypersensitivity reactions

Your attention is drawn to that the China State Food and Drug Administration (SFDA) reminded healthcare professionals of safety information regarding reports of severe hypersensitivity reactions in patients treated with ambroxol injection, which is used in the treatment of acute and chronic respiratory disorders, neonatal respiratory distress syndrome and prevention of postoperative pulmonary complications.

The National Center for Adverse Drug Reaction (ADR) Monitoring database received 2,973 ADR reports associated with the use of ambroxol injection for the year of 2011. Among these, 169 were severe cases with the reports of hypersensitivity reactions, difficulty in breathing and anaphylactic shock. It was found that there were cases of improper use of the drug, especially in children and of overdose.

SFDA advised healthcare professionals that particular attention should be paid to the dosage regime of ambroxol including the dose adjustment in individual patients and avoid unapproved indications when prescribing ambroxol injection. And ambroxol injection should be used in caution in patients with history of hypersensitivity and allergy, such as bronchial asthmatics. Besides, ambroxol injection should not be co-administrated with any medicines and the concomitant use with alkaline liquids, cephalosporins or Chinese medicines should be avoided.

Please refer to SFDA's website for details:

http://www.sda.gov.cn/WS01/CL0051/74649.html

In Hong Kong, there are 2 injectable pharmaceutical products containing ambroxol, namely Nadoxol Inj 15mg/2ml (HK-50296) and Huons Ambroxol Hcl Inj 15mg/2ml (HK-57625). They are indicated for the treatment of respiratory diseases caused by respiratory mucosa-secretion disturbance. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

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. Christine CHEUNG)
for AD(D)

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